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Contents

Federal Register

Vol. 83, No. 221

Thursday, November 15, 2018

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:
9822.....57661
9823.....57665
9824.....57667
9825.....57669

12 CFR

Proposed Rules:
Ch. II.....57351
268.....57343

14 CFR

Proposed Rules:
39.....57364

20 CFR

Proposed Rules:
401.....57366
404.....57368
416.....57368

21 CFR

Proposed Rules:
50.....57378
312.....57378
812.....57378

26 CFR
54 (2 documents) 57336, 57592

29 CFR
2590 (2 documents) 57336, 57592
4022.....57307

Proposed Rules:
570.....57386

31 CFR
547.....57308

33 CFR
165 (4 documents) 57318, 57319, 57321, 57322

37 CFR

Proposed Rules:
201.....57386

40 CFR
51.....57324
52.....57324
180.....57333

Proposed Rules:
60.....57387
721.....57634

45 CFR
147 (2 documents) 57336, 57592

49 CFR

Proposed Rules:
192.....57388

50 CFR
622.....57339
635.....57340
679.....57341

Proposed Rules:
648 (2 documents) 57389, 57395

Rules and Regulations

Federal Register
Vol. 83, No. 221
Thursday, November 15, 2018

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in December 2018. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective December 1, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@PBGC.gov*), Attorney, Regulatory Affairs Division, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–326–4400 ext. 6563. (TTY users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400, ext. 6563.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminated single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's website (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in appendix B to part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for December 2018.[1]

The December 2018 interest assumptions under the benefit payments regulation will be 1.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for November 2018, these assumptions represent an increase of 0.25% in the immediate rate and are otherwise unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during December 2018, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 302 is added at the end of the table to read as follows:

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
302	12–1–18	1–1–19	1.50	4.00	4.00	4.00	7	8

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

■ 3. In appendix C to part 4022, Rate Set 302 is added at the end of the table to read as follows:

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
302	12–1–18	1–1–19	1.50	4.00	4.00	4.00	7	8

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2018–24746 Filed 11–14–18; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 547

Democratic Republic of the Congo Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending the Democratic Republic of the Congo Sanctions Regulations to implement Executive Order 13671 of July 8, 2014 (''Taking Additional Steps to Address the National Emergency With Respect to the Conflict in the Democratic Republic of the Congo''). This rule also incorporates other technical and conforming changes.

DATES: *Effective:* November 15, 2018.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel: 202–622–4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available from OFAC's website (*www.treasury.gov/ofac*).

Background

On May 28, 2009, OFAC issued the Democratic Republic of the Congo Sanctions Regulations, 31 CFR part 547 (the ''Regulations'') (74 FR 25439, May 28, 2009) to implement Executive Order 13413 of October 27, 2006 (71 FR 64105, October 31, 2006) (E.O. 13413).

Executive Order 13671

On July 8, 2014, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (IEEPA) and section 5 of the United Nations Participation Act (22 U.S.C. 287c) (UNPA), issued Executive Order 13671 (79 FR 39949, July 10, 2014) (E.O. 13671). In E.O. 13671, the President amended E.O. 13413 to take additional steps to deal with the national emergency with respect to the situation in or in relation to the Democratic Republic of the Congo declared in E.O. 13413, in view of multiple United Nations Security Council Resolutions, including Resolution 2136 of January 30, 2014, and in light of the continuation of activities that threaten the peace, security, or stability of the Democratic Republic of the Congo and the surrounding region, including operations by armed groups, widespread violence and atrocities, human rights abuses, recruitment and use of child soldiers, attacks on peacekeepers, obstruction of humanitarian operations, and exploitation of natural resources to finance persons engaged in these activities.

E.O. 13671 amends several sections of E.O. 13413 but does not amend the Annex to E.O. 13413 as originally issued. Section 1 of E.O. 13671 amends E.O. 13413 by replacing subsection 1(a) of E.O. 13413 in its entirety. New subsection 1(a) of E.O. 13413 as amended by E.O. 13671 (''amended E.O. 13413'')[1] blocks all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person, of: (i) The persons listed in the Annex to amended E.O. 13413; and (ii) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(A) To be a political or military leader of a foreign armed group operating in the Democratic Republic of the Congo that impedes the disarmament, demobilization, voluntary repatriation, resettlement, or reintegration of combatants;

(B) to be a political or military leader of a Congolese armed group that impedes the disarmament, demobilization, voluntary repatriation, resettlement, or reintegration of combatants;

(C) to be responsible for or complicit in, or to have engaged in, directly or indirectly, any of the following in or in relation to the Democratic Republic of the Congo: (1) Actions or policies that threaten the peace, security, or stability of the Democratic Republic of the Congo; (2) actions or policies that undermine democratic processes or institutions in the Democratic Republic of the Congo; (3) the targeting of women, children, or any civilians through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law; (4) the use or recruitment of children by armed groups or armed forces in the context of the conflict in the Democratic Republic of the Congo; (5) the obstruction of the delivery or distribution of, or access to, humanitarian assistance; (6) attacks

[1] For the purposes of this subsection, the term ''amended E.O. 13413'' refers to E.O. 13413 as amended by E.O. 13671. Because E.O. 13671 did not amend the Annex, the term ''Annex to amended E.O. 13413'' refers to the Annex as originally issued to E.O. 13413.

against United Nations missions, international security presences, or other peacekeeping operations; or (7) support to persons, including armed groups, involved in activities that threaten the peace, security, or stability of the Democratic Republic of the Congo or that undermine democratic processes or institutions in the Democratic Republic of the Congo, through the illicit trade in natural resources of the Democratic Republic of the Congo;

(D) except where intended for the authorized support of humanitarian activities or the authorized use by or support of peacekeeping, international, or government forces, to have directly or indirectly supplied, sold, or transferred to the Democratic Republic of the Congo, or been the recipient in the territory of the Democratic Republic of the Congo, of arms and related materiel, including military aircraft and equipment, or advice, training, or assistance, including financing and financial assistance, related to military activities;

(E) to be a leader of (i) an entity, including any armed group, that has, or whose members have, engaged in any of the activities described in paragraphs (A) through (D) above or (ii) an entity whose property and interests in property are blocked pursuant to amended E.O. 13413;

(F) to have materially assisted, sponsored, or provided financial, material, logistical, or technological support for, or goods or services in support of: (i) Any of the activities described in (A) through (D) above; or (ii) any person whose property and interests in property are blocked pursuant to amended E.O. 13413; or

(G) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to amended E.O. 13413.

The property and interests in property of the persons described above may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

Section 2 of E.O. 13671 adds new subsection (d) to section 1 of E.O. 13413. This new subsection provides that the prohibitions in subsection 1(a) of amended E.O. 13413 apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to amended E.O. 13413, and notwithstanding any contract entered into or any license or permit granted prior to the effective date of the order.

Section 3 of E.O. 13671 amends section 2 of E.O. 13413 by adding a prohibition. Section 2 of E.O. 13413 prohibited any transaction by a U.S. person or within the United States that evades or avoids, has the purpose of evading or avoiding, or attempts to violate any of the prohibitions set forth in E.O. 13413, as well as any conspiracy formed to violate such prohibitions. Section 3 of E.O. 13671 adds a prohibition on causing a violation of any prohibitions set forth in amended E.O. 13413 to the existing prohibitions.

Section 4 of E.O. 13671 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA and the UNPA as may be necessary to carry out the purposes of E.O. 13671 and amended E.O. 13413. Section 4 of E.O. 13671 also provides that the Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the U.S. government.

Current Regulatory Action

This rule amends the Regulations to implement the relevant provisions of E.O. 13671, as well as to update certain provisions and to make other technical and conforming changes. OFAC is revising and republishing in its entirety subpart B of the Regulations, which sets forth the prohibitions contained in sections 1 and 2 of amended E.O. 13413. *See, e.g.,* §§ 547.201 and 547.205. In particular, OFAC is revising § 547.201 of subpart B to incorporate the new designation criteria provided for in E.O. 13671. OFAC is also adding § 547.206 to subpart B to clarify which transactions are exempt from the prohibitions in this part.

This rule also amends several sections in subpart C, which defines key terms used throughout the Regulations. New § 547.300 is being added to clarify that the definitions contained in subpart C apply throughout the entire part, and §§ 547.314 and 547.315 are being added to define key terms used in the Regulations. Also, certain existing definitions in subpart C are being updated or revised to take account of new provisions and to provide greater clarity with respect to the terms being used.

This rule also revises and republishes in its entirety subpart D, which contains interpretive sections regarding the Regulations. Section 547.411 of subpart D is being amended to clarify that the property and interests in property of an entity are blocked if the entity is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked, whether or not the entity itself is listed in or designated pursuant to amended E.O. 13413 or incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List). Other sections within subpart D are being amended to reflect current OFAC interpretations.

Transactions otherwise prohibited by the Regulations but found to be consistent with U.S. policy may be authorized by one of the general licenses contained in subpart E of the Regulations or by a specific license issued pursuant to the procedures described in subpart E of 31 CFR part 501. This rule also amends subpart E of the Regulations. In particular, a general license is being added in § 547.508, authorizing payments from outside the United States for the provision of legal services authorized in § 547.507. The general license authorizing certain emergency medical services that was formerly at § 547.508 has been moved to § 547.509 and updated to reflect current licensing policies. Updates to reflect current licensing policies have also been made to several other general licenses. General licenses and statements of licensing policy relating to this part also may be available through the Democratic Republic of the Congo sanctions page on OFAC's website: *www.treasury.gov/ofac.*

This rule revises subpart G of the Regulations and republishes it in its entirety. Subpart G of the Regulations describes the civil and criminal penalties applicable to violations of the Regulations, as well as the procedures governing the potential imposition of a civil monetary penalty or issuance of a Finding of Violation. Subpart G also refers to appendix A of part 501 for a more complete description of these procedures. Finally, this rule updates the delegation of authority by the Secretary of the Treasury in subpart H of the Regulations.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of Executive Order 13771 are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31

CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Part 547

Administrative practice and procedure, Banks, Banking, Blocking of assets, Credit, Democratic Republic of the Congo, Foreign trade, Penalties, Reporting and recordkeeping requirements, Securities, Services.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR part 547 as follows:

PART 547—DEMOCRATIC REPUBLIC OF THE CONGO SANCTIONS REGULATIONS

■ 1. Revise the authority citation for part 547 to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); E.O. 13413, 71 FR 64105, 3 CFR, 2006 Comp., p. 247; E.O. 13671, 79 FR 39949, 3 CFR, 2015 Comp., p. 280.

■ 2. Revise subpart B to read as follows:

Subpart B—Prohibitions

Sec.

§ 547.201 Prohibited transactions involving blocked property.

(a) All property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(1) The persons listed in the Annex to Executive Order 13413 of October 27, 2006; and

(2) Any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) To be a political or military leader of a foreign armed group operating in the Democratic Republic of the Congo that impedes the disarmament, demobilization, voluntary repatriation, resettlement, or reintegration of combatants;

(ii) To be a political or military leader of a Congolese armed group that impedes the disarmament, demobilization, voluntary repatriation, resettlement, or reintegration of combatants;

(iii) To be responsible for or complicit in, or to have engaged in, directly or indirectly, any of the following in or in relation to the Democratic Republic of the Congo:

(A) Actions or policies that threaten the peace, security, or stability of the Democratic Republic of the Congo;

(B) Actions or policies that undermine democratic processes or institutions in the Democratic Republic of the Congo;

(C) The targeting of women, children, or any civilians through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law;

(D) The use or recruitment of children by armed groups or armed forces in the context of the conflict in the Democratic Republic of the Congo;

(E) The obstruction of the delivery or distribution of, or access to, humanitarian assistance;

(F) Attacks against United Nations missions, international security presences, or other peacekeeping operations; or

(G) Support to persons, including armed groups, involved in activities that threaten the peace, security, or stability of the Democratic Republic of the Congo or that undermine democratic processes or institutions in the Democratic Republic of the Congo, through the illicit trade in natural resources of the Democratic Republic of the Congo;

(iv) Except where intended for the authorized support of humanitarian activities or the authorized use by or support of peacekeeping, international, or government forces, to have directly or indirectly supplied, sold, or transferred to the Democratic Republic of the Congo, or been the recipient in the territory of the Democratic Republic of the Congo of, arms and related materiel, including military aircraft and equipment, or advice, training, or assistance, including financing and financial assistance, related to military activities;

(v) To be a leader of:

(A) An entity, including any armed group, that has, or whose members have, engaged in any of the activities described in paragraphs (a)(2)(i) through (iv) of this section; or

(B) An entity whose property and interests in property are blocked pursuant to paragraph (a) of this section;

(vi) To have materially assisted, sponsored, or provided financial, material, logistical, or technological support for, or goods or services in support of any of the activities described in paragraphs (a)(2)(i) through (iv) of this section or any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; or

(vii) To be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to paragraph (a) of this section.

Note 1 to paragraph (a): The names of persons listed in or designated pursuant to Executive Order 13413, both as originally issued and as amended by Executive Order 13671, whose property and interests in property therefore are blocked pursuant to paragraph (a) of this section, are published in the **Federal Register** and incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) with the identifier ''[DRCONGO].'' The SDN List is accessible through the following page on OFAC's website: *www.treasury.gov/sdn.* Additional information pertaining to the SDN List can be found in appendix A to this chapter. See § 547.411 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to paragraph (a) of this section.

Note 2 to paragraph (a): The International Emergency Economic Powers Act (50 U.S.C. 1701–1706), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to paragraph (a) of this section also are published in the **Federal Register** and incorporated into the SDN List with the identifier ''[BPI–DRCONGO].''

Note 3 to paragraph (a): Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, and administrative reconsideration of their status as persons whose property and interests in property are

blocked pursuant to paragraph (a) of this section.

(b) The prohibitions in paragraph (a) of this section include prohibitions on the following transactions:

(1) The making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; and

(2) The receipt of any contribution or provision of funds, goods, or services from any person whose property and interests in property are blocked pursuant to paragraph (a) of this section.

(c) Unless authorized by this part or by a specific license expressly referring to this part, any dealing in securities (or evidence thereof) held within the possession or control of a U.S. person and either registered or inscribed in the name of, or known to be held for the benefit of, or issued by, any person whose property and interests in property are blocked pursuant to paragraph (a) of this section is prohibited. This prohibition includes the transfer (including the transfer on the books of any issuer or agent thereof), disposition, transportation, importation, exportation, or withdrawal of, or the endorsement or guaranty of signatures on, any securities on or after the effective date. This prohibition applies irrespective of the fact that at any time (whether prior to, on, or subsequent to the effective date) the registered or inscribed owner of any such securities may have or might appear to have assigned, transferred, or otherwise disposed of the securities.

(d) The prohibitions in paragraph (a) of this section apply except to the extent provided by regulations, orders, directives, or licenses that may be issued pursuant to this part, and notwithstanding any contract entered into or any license or permit granted prior to the effective date.

§ 547.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 547.201(a), is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or interests in property.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interests in property blocked pursuant to § 547.201(a), unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for the provisions of this part and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other directive or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

Note 1 to paragraph (d): The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(e) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property and interests in property blocked pursuant to § 547.201(a).

§ 547.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 547.201(a) shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally-insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 547.201(a) may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 547.201(a) may continue to be held in the same type of accounts or instruments, provided the funds earn

interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as real or personal property, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, OFAC may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds subject to this section may not be held, invested, or reinvested in a manner that provides immediate financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 547.201(a), nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 547.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of tangible property blocked pursuant to § 547.201(a) shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 547.201(a) may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

§ 547.205 Evasions; attempts; causing violations; conspiracies.

(a) Any transaction on or after the effective date that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Any conspiracy formed to violate the prohibitions set forth in this part is prohibited.

§ 547.206 Exempt transactions.

(a) *United Nations Participation Act.* The exemptions described in this section do not apply to transactions involving property or interests in property of persons whose property and interests in property are blocked pursuant to the authority of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA).

Note 1 to paragraph (a): Persons whose property and interests in property are blocked pursuant to the authority of the UNPA include those listed on *both* OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) and the Consolidated United Nations Security Council Sanctions List (UN List) (see *https://www.un.org*) as well as persons listed on the SDN List for being owned or controlled by, or acting for or on behalf of, persons listed on *both* the SDN List and the UN List.

(b) *Personal communications.* The prohibitions contained in this part do not apply to any postal, telegraphic, telephonic, or other personal communication that does not involve the transfer of anything of value.

(c) *Information or informational materials.* (1) The prohibitions contained in this part do not apply to the importation from any country and the exportation to any country of any information or informational materials, as defined in § 547.314, whether commercial or otherwise, regardless of format or medium of transmission.

(2) This section does not exempt from regulation transactions related to information or informational materials not fully created and in existence at the date of the transactions, or to the substantive or artistic alteration or enhancement of information or informational materials, or to the provision of marketing and business consulting services. Such prohibited transactions include payment of advances for information or informational materials not yet created and completed (with the exception of prepaid subscriptions for widely circulated magazines and other periodical publications); provision of services to market, produce or co-produce, create, or assist in the creation of information or informational materials; and payment of royalties with respect to income received for enhancements or alterations made by U.S. persons to such information or informational materials.

(3) This section does not exempt transactions incident to the exportation of software subject to the Export Administration Regulations, 15 CFR parts 730 through 774, or to the exportation of goods (including software) or technology for use in the transmission of any data, or to the provision, sale, or leasing of capacity on telecommunications transmission facilities (such as satellite or terrestrial network connectivity) for use in the transmission of any data. The exportation of such items or services and the provision, sale, or leasing of such capacity or facilities to a person whose property and interests in property are blocked pursuant to § 547.201(a) are prohibited.

(d) *Travel.* The prohibitions contained in this part do not apply to transactions ordinarily incident to travel to or from any country, including importation or exportation of accompanied baggage for personal use, maintenance within any country including payment of living expenses and acquisition of goods or services for personal use, and arrangement or facilitation of such travel including nonscheduled air, sea, or land voyages.

Subpart C—General Definitions

■ 3. Add § 547.300 to read as follows:

§ 547.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 547.301 [Amended]

■ 4. In the heading and introductory text of § 547.301, remove ''or any'' and add in its place ''and''.

■ 5. Revise § 547.302 to read as follows:

§ 547.302 Blocked account; blocked property.

The terms *blocked account* and *blocked property* shall mean any account or property subject to the prohibitions in § 547.201 held in the name of a person whose property and interests in property are blocked pursuant to § 547.201(a), or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note 1 to § 547.302: See § 547.411 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 547.201(a).

■ 6. Revise § 547.303 to read as follows:

§ 547.303 Effective date.

(a) The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(1) With respect to a person whose property and interests in property are blocked pursuant to § 547.201(a)(1), 12:01 a.m. eastern standard time on October 30, 2006; and

(2) With respect to a person whose property and interests in property are otherwise blocked pursuant to § 547.201(a), the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

(b) For the purposes of this section, *constructive notice* is the date that a notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

■ 7. Revise § 547.306 to read as follows:

§ 547.306 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC's website: *www.treasury.gov/ofac.*

(c) The term *specific license* means any license or authorization issued pursuant to this part, but not set forth in subpart E of this part or made available on OFAC's website: *www.treasury.gov/ofac.*

Note 1 to § 547.306: See § 501.801 of this chapter on licensing procedures.

■ 8. Revise § 547.311 to read as follows:

§ 547.311 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or other extensions of credit, or purchasing or selling foreign exchange, securities, commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, trust companies, securities brokers and dealers, futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

■ 9. Revise § 547.313 to read as follows:

§ 547.313 Financial, material, logistical, or technological support.

The term *financial, material, logistical, or technological support,* as used in § 547.201(a)(2)(vi), means any property, tangible or intangible, including currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods. ''Technologies'' as used in this definition means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

■ 10. Add § 547.314 to read as follows:

§ 547.314 Information or informational materials.

(a)(1) The term *information or informational materials* includes publications, films, posters, phonograph records, photographs, microfilms, microfiche, tapes, compact disks, CD ROMs, artworks, and news wire feeds.

(2) To be considered information or informational materials, artworks must be classified under heading 9701, 9702, or 9703 of the Harmonized Tariff Schedule of the United States.

(b) The term *information or informational materials,* with respect to exports, does not include items:

(1) That were, as of April 30, 1994, or that thereafter become, controlled for export pursuant to section 5 of the Export Administration Act of 1979, 50 U.S.C. App. 2401–2420 (1979) (EAA), or section 6 of the EAA to the extent that such controls promote the nonproliferation or antiterrorism policies of the United States; or

(2) With respect to which acts are prohibited by 18 U.S.C. chapter 37.

■ 11. Add § 547.315 to read as follows:

§ 547.315 OFAC.

The term *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

■ 12. Revise subpart D to read as follows:

Subpart D—Interpretations

Sec.

§ 547.401 Reference to amended sections.

(a) Reference to any section in this part is a reference to the same as currently amended, unless the reference includes a specific date. *See* 44 U.S.C. 1510.

(b) Reference to any ruling, order, instruction, direction, or license issued pursuant to this part is a reference to the same as currently amended unless otherwise so specified.

§ 547.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, instruction, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 547.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 547.201(a), such property shall no longer be deemed to be property blocked pursuant to § 547.201(a), unless there exists in the property another interest that is blocked pursuant to § 547.201(a), the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 547.201(a), such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 547.404 Transactions ordinarily incident to a licensed transaction.

(a) Any transaction ordinarily incident to a licensed transaction and

necessary to give effect thereto is also authorized, except:

(1) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 547.201(a); or

(2) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

(b) For example, a license authorizing a person to complete a securities sale involving Company A, whose property and interests in property are blocked pursuant to § 547.201(a), also authorizes other persons to engage in activities that are ordinarily incident and necessary to complete the sale, including transactions by the buyer, broker, transfer agents, and banks, provided that such other persons are not themselves persons whose property and interests in property are blocked pursuant to § 547.201(a).

§ 547.405 Provision of services.

(a) The prohibitions on transactions contained in § 547.201 apply to services performed in the United States or by U.S. persons, wherever located, including by a foreign branch of an entity located in the United States:

(1) On behalf of or for the benefit of a person whose property and interests in property are blocked pursuant to § 547.201(a); or

(2) With respect to property interests of any person whose property and interests in property are blocked pursuant to § 547.201(a).

(b) For example, U.S. persons may not, except as authorized by or pursuant to this part, provide legal, accounting, financial, brokering, freight forwarding, transportation, public relations, or other services to a person whose property and interests in property are blocked pursuant to § 547.201(a).

Note 1 to § 547.405: See §§ 547.507 and 547.509 on licensing policy with regard to the provision of certain legal and emergency medical services.

§ 547.406 Offshore transactions involving blocked property.

The prohibitions in § 547.201 on transactions or dealings involving blocked property, as defined in § 547.302, apply to transactions by any U.S. person in a location outside the United States.

§ 547.407 Payments from blocked accounts to satisfy obligations prohibited.

Pursuant to § 547.201, no debits may be made to a blocked account to pay obligations to U.S. persons or other persons, except as authorized by or pursuant to this part.

Note 1 to § 547.407: *See also* § 547.502(e), which provides that no license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

§ 547.408 Charitable contributions.

Unless specifically authorized by OFAC pursuant to this part, no charitable contribution of funds, goods, services, or technology, including contributions to relieve human suffering, such as food, clothing, or medicine, may be made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 547.201(a). For the purposes of this part, a contribution is made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 547.201(a) if made by, to, or in the name of, or received from or in the name of, such a person; if made by, to, or in the name of, or received from or in the name of, an entity or individual acting for or on behalf of, or owned or controlled by, such a person; or if made in an attempt to violate, to evade, or to avoid the bar on the provision of contributions by, to, or for the benefit of such a person, or the receipt of contributions from such a person.

§ 547.409 Credit extended and cards issued by financial institutions to a person whose property and interests in property are blocked.

The prohibition in § 547.201 on dealing in property subject to that section prohibits U.S. financial institutions from performing under any existing credit agreements, including charge cards, debit cards, or other credit facilities issued by a financial institution to a person whose property and interests in property are blocked pursuant to § 547.201(a).

§ 547.410 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. bank or other U.S. person, is a prohibited transfer under § 547.201 if effected after the effective date.

§ 547.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 547.201(a) have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 547.201(a), regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 13. Revise § 547.501 to read as follows:

§ 547.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Democratic Republic of the Congo sanctions page on OFAC's website: *www.treasury.gov/ofac.*

■ 14. Revise § 547.502 to read as follows:

§ 547.502 Effect of license or other authorization.

(a) No license or other authorization contained in this part, or otherwise issued by OFAC, authorizes or validates any transaction effected prior to the issuance of such license or other authorization, unless specifically provided in such license or authorization.

(b) No regulation, ruling, instruction, or license authorizes any transaction prohibited under this part unless the regulation, ruling, instruction, or license is issued by OFAC and specifically refers to this part. No regulation, ruling, instruction, or license referring to this part shall be deemed to authorize any transaction prohibited by any other part of this chapter unless the regulation, ruling, instruction, or license specifically refers to such part.

(c) Any regulation, ruling, instruction, or license authorizing any transaction otherwise prohibited under this part has the effect of removing a prohibition contained in this part from the transaction, but only to the extent specifically stated by its terms. Unless the regulation, ruling, instruction, or license otherwise specifies, such an authorization does not create any right,

duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(d) Nothing contained in this part shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain a license or other authorization from another department or agency of the U.S. Government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency. For example, exports of goods, services, or technical data that are not prohibited by this part or that do not require a license by OFAC nevertheless may require authorization by the U.S. Department of Commerce, the U.S. Department of State, or other agencies of the U.S. Government.

(e) No license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

(f) Any payment relating to a transaction authorized in or pursuant to this part that is routed through the U.S. financial system should reference the relevant OFAC general or specific license authorizing the payment to avoid the blocking or rejection of the transfer.

■ 15. Revise § 547.503 to read as follows:

§ 547.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

■ 16. Revise § 547.507 to read as follows:

§ 547.507 Provision of certain legal services.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 547.201(a) or any further Executive orders relating to the national emergency declared in E.O. 13413 of October 27, 2006, is authorized, provided that receipt of payment of professional fees and reimbursement of incurred expenses must be authorized: Pursuant to § 547.508, which authorizes certain payments for legal services from funds originating outside the United States; via specific license; or otherwise pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 547.201(a) or any further Executive orders relating to the national emergency declared in E.O. 13413 of October 27, 2006, not otherwise authorized in this part, requires the issuance of a specific license.

(c) U.S. persons do not need to obtain specific authorization to provide related services, such as making filings and providing other administrative services, that are ordinarily incident to the provision of services authorized by paragraph (a) of this section. Additionally, U.S. persons who provide services authorized by paragraph (a) of this section do not need to obtain specific authorization to contract for related services that are ordinarily incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. See § 510.404.

(d) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 547.201(a) or any further Executive orders relating to the national emergency declared in E.O. 13413 of October 27, 2006, is prohibited unless licensed pursuant to this part.

Note 1 to § 547.507: Pursuant to part 501, subpart E, of this chapter, U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of certain blocked funds for the payment of professional fees and reimbursement of incurred expenses for the provision of such legal services where alternative funding sources are not available. For more information, see OFAC's *Guidance on the Release of Limited Amounts of Blocked Funds for Payment of Legal Fees and Costs Incurred in Challenging the Blocking of U.S. Persons in Administrative or Civil Proceedings,* which is available on OFAC's website at: *www.treasury.gov/ofac.*

§ 547.508 [Redesignated as § 547.509]

■ 17. Redesignate § 547.508 as § 547.509.

■ 18. Add new § 547.508 to read as follows:

§ 547.508 Payments for legal services from funds originating outside the United States.

(a) *Professional fees and incurred expenses.* (1) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 547.507(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 547.201 or any further Executive orders relating to the national emergency declared in E.O. 13413 of October 27, 2006, is authorized from funds originating outside the United States, provided that the funds do not originate from:

(i) A source within the United States;

(ii) Any source, wherever located, within the possession or control of a U.S. person; or

(iii) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 547.507(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order or statute.

(2) Nothing in this paragraph (a) authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 547.201(a), any other part of this chapter, or any Executive order has an interest.

(b) *Reports.* (1) U.S. persons who receive payments pursuant to paragraph (a) of this section must submit annual

reports no later than 30 days following the end of the calendar year during which the payments were received providing information on the funds received. Such reports shall specify:

(i) The individual or entity from whom the funds originated and the amount of funds received; and

(ii) If applicable:

(A) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(B) A general description of the services provided; and

(C) The amount of funds paid in connection with such services.

(2) The reports, which must reference this section, are to be submitted to OFAC using one of the following methods:

(i) *Email:* (preferred method) *OFAC.Regulations.Reports@treasury.gov;* or

(ii) *U.S. mail:* OFAC Regulations Reports, Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Freedman's Bank Building, Washington, DC 20220.

■ 19. Revise newly redesignated § 547.509 to read as follows:

§ 547.509 Emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are otherwise prohibited by this part or any further Executive orders relating to the national emergency declared in Executive Order 13413 of October 27, 2006 are authorized.

■ 20. Revise subpart G to read as follows:

Subpart G—Penalties and Finding of Violation

Sec.

§ 547.701 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) (IEEPA) is applicable to violations of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any license, order, regulation, or prohibition issued under IEEPA.

Note 1 to paragraph (a)(1): IEEPA provides for a maximum civil penalty not to exceed the greater of $295,141 or an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(2) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any license, order, regulation, or prohibition may, upon conviction, be fined not more than $1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b)(1) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(2) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(c) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(d) Section 5 of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA) provides that any person who willfully violates or evades or attempts to violate or evade any order, rule, or regulation issued by the President pursuant to the authority granted in that section, upon conviction, shall be fined not more than $10,000 and, if a natural person, may also be imprisoned for not more than 10 years; and the officer, director, or agent of any corporation who knowingly participates in such violation or evasion shall be punished by a like fine, imprisonment, or both and any property, funds, securities, papers, or other articles or documents, or any vessel, together with her tackle, apparel, furniture, and equipment, or vehicle, or aircraft, concerned in such violation shall be forfeited to the United States.

(e) Violations involving transactions described at section 203(b)(1), (3), and (4) of IEEPA shall be subject only to the penalties set forth in paragraph (d) of this section.

(f) Violations of this part may also be subject to other applicable laws.

§ 547.702 Pre-Penalty Notice; settlement.

(a) *When required.* If OFAC has reason to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) and determines that a civil monetary penalty is warranted, OFAC will issue a Pre-Penalty Notice informing the alleged violator of the agency's intent to impose a monetary penalty. A Pre-Penalty Notice shall be in writing. The Pre-Penalty Notice may be issued whether or not another agency has taken any action with respect to the matter. For a description of the contents of a Pre-Penalty Notice, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to respond to a Pre-Penalty Notice by making a written presentation to OFAC. For a description of the information that should be included in such a response, see appendix A to part 501 of this chapter.

(2) *Deadline for response.* A response to a Pre-Penalty Notice must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a Pre-Penalty Notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier) on or before the 30th day after the postmark date on the envelope in which the Pre-Penalty Notice was mailed. If the Pre-Penalty Notice was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to a Pre-Penalty Notice need

not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof, contain information sufficient to indicate that it is in response to the Pre-Penalty Notice, and include the OFAC identification number listed on the Pre-Penalty Notice. A copy of the written response may be sent by facsimile, but the original also must be sent to OFAC's Office of Compliance and Enforcement by mail or courier and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(c) *Settlement.* Settlement discussion may be initiated by OFAC, the alleged violator, or the alleged violator's authorized representative. For a description of practices with respect to settlement, see appendix A to part 501 of this chapter.

(d) *Guidelines.* Guidelines for the imposition or settlement of civil penalties by OFAC are contained in appendix A to part 501 of this chapter.

(e) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific allegations contained in the Pre-Penalty Notice must be preceded by a written letter of representation, unless the Pre-Penalty Notice was served upon the alleged violator in care of the representative.

§ 547.703 Penalty imposition.

If, after considering any written response to the Pre-Penalty Notice and any relevant facts, OFAC determines that there was a violation by the alleged violator named in the Pre-Penalty Notice and that a civil monetary penalty is appropriate, OFAC may issue a Penalty Notice to the violator containing a determination of the violation and the imposition of the monetary penalty. For additional details concerning issuance of a Penalty Notice, see appendix A to part 501 of this chapter. The issuance of the Penalty Notice shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

§ 547.704 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to OFAC, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a federal district court.

§ 547.705 Finding of Violation

(a) *When issued.* (1) OFAC may issue an initial Finding of Violation that identifies a violation if OFAC:

(i) Determines that there has occurred a violation of any provision of this part, or a violation of the provisions of any license, ruling, regulation, order, directive, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706);

(ii) Considers it important to document the occurrence of a violation; and

(iii) Based on the Guidelines contained in appendix A to part 501 of this chapter, concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial Finding of Violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter. For additional details concerning issuance of a Finding of Violation, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to contest an initial Finding of Violation by providing a written response to OFAC.

(2) *Deadline for response; Default determination.* A response to an initial Finding of Violation must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial Finding of Violation will become final and will constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(i) *Computation of time for response.* A response to an initial Finding of Violation must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier) on or before the 30th day after the postmark date on the envelope in which the initial Finding of Violation was served. If the initial Finding of Violation was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to an initial Finding of Violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof, contain information sufficient to indicate that it is in response to the initial Finding of Violation, and include the OFAC identification number listed on the initial Finding of Violation. A copy of the written response may be sent by facsimile, but the original also must be sent to OFAC by mail or courier and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the regulations did not occur and/or why a Finding of Violation is otherwise unwarranted under the circumstances, with reference to the General Factors Affecting Administrative Action set forth in the Guidelines contained in appendix A to part 501 of this chapter. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted in the response.

(c) *Determination*—(1) *Determination that a Finding of Violation is warranted.* If, after considering the response, OFAC determines that a final Finding of Violation should be issued, OFAC will issue a final Finding of Violation that will inform the violator of its decision. A final Finding of Violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(2) *Determination that a Finding of Violation is not warranted.* If, after considering the response, OFAC determines a Finding of Violation is not warranted, then OFAC will inform the alleged violator of its decision not to issue a final Finding of Violation.

Note to paragraph (c)(2): A determination by OFAC that a final Finding of Violation is not warranted does not preclude OFAC from pursuing other enforcement actions consistent with the Guidelines contained in appendix A to part 501 of this chapter.

(d) *Representation.* A representative of the alleged violator may act on behalf

of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific alleged violations contained in the initial Finding of Violation must be preceded by a written letter of representation, unless the initial Finding of Violation was served upon the alleged violator in care of the representative.

Subpart H—Procedures

■ 21. Revise § 547.802 to read as follows:

§ 547.802 Delegation of certain authorities by the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13413 of October 27, 2006 (E.O. 13413), Executive Order 13671 of July 8, 2014, and any further Executive orders relating to the national emergency declared in E.O. 13413, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Dated: November 7, 2018.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2018–24696 Filed 11–14–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0998]

RIN 1625–AA00

Safety Zone; Columbia River, Cascade Locks, OR

AGENCY: Coast Guard, DHS.

ACTION: Final rule; termination of existing safety zone.

SUMMARY: The Coast Guard is removing the temporary safety zone for navigable waters of the Columbia River between river mile 142 and 143 in vicinity of Cascade Locks, Oregon. The safety zone was necessary to protect personnel, vessels, and the marine environment from potential hazards created by salvage operations of the tug DIANE. The safety zone is no longer needed and the Coast Guard is removing the regulation.

DATES: The rule is effective November 15, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–0998 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Dixon Whitley, Waterways Management Division, Marine Safety Unit Portland, U.S. Coast Guard; telephone 503–240–9319, email *msupdxwwm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this rule to remove a regulation without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to removing the safety zone regulation around the salvage operations for the tug DIANE because to do so would be unnecessary since the salvage operations concluded and the safety zone that is no longer needed.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be unnecessary because this rule removes a safety zone that is no longer needed.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Columbia River (COTP) has determined that potential hazards associated with pile driving, cofferdam installation, diving, and vessel recovery operations are no longer present between Columbia River Mile 142 and 143 in vicinity of Cascade Locks, Oregon.

IV. Discussion of the Rule

On November 2, 2018, the Coast Guard published a temporary final rule ''Safety Zone; Columbia River, Cascade Locks, OR'' in the **Federal Register** (83 FR 55101). The safety zone was necessary to protect personnel, vessels, and the marine environment from potential hazards created by salvage operations of the tug DIANE. The zone covered all navigable waters of the Columbia River between river mile 142 and 143. The salvage operations for the tug DIANE are finished. The safety zone is no longer needed and the Coast Guard is removing the regulation.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the removal of an obsolete safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule

would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. It is categorically excluded from further review under paragraph L60(b) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration is not required for this rule because we are disestablishing a safety zone.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

§ 165.T13–0998 [Removed]

■ 2. Remove § 165.T13–0998.

Dated: November 8, 2018.

J.C. Smith,

Captain, U.S. Coast Guard, Captain of the Port Sector Columbia River.

[FR Doc. 2018–24846 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0948]

RIN 1625–AA00

Safety Zone; Delaware River; Camden, NJ; Fireworks Display

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on a portion of the Delaware River in Camden, NJ. This action is necessary to protect the surrounding public and vessels on these navigable waters adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ, during a fireworks display on November 14, 2018. This regulation prohibits persons and vessels from entering, transiting, or remaining within the safety zone unless authorized by the Captain of the Port Delaware Bay or a designated representative.

DATES: This rule is effective from 8:15 p.m. through 9:15 p.m. on November 14, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0948 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Thomas Welker, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division; telephone 215–271–4814, email *Thomas.j.welker@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On September 14, 2018, Rexel, Inc. notified the Coast Guard that it will be conducting a fireworks display from 8:35 p.m. to 8:55 p.m. on November 14, 2018. The fireworks are to be launched from a barge on the Delaware River adjacent the Battleship New Jersey

Museum and Memorial, Camden, NJ. In response, on October 22, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Delaware River; Camden, NJ; Fireworks Display; 83 FR 53199. There, we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended November 6, 2018, we received one comment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to mitigate the potential safety hazards associated with a fireworks display in this location.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Delaware Bay (COTP) has determined that potential hazards associated with the fireworks display on November 14, 2018, will be a safety concern for anyone within a 600-foot radius of the fireworks barge, which will be anchored in approximate position 39°56′20″ N Latitude, 075°08′08″ W Longitude. This rule is needed to protect persons, vessels and the public near the fireworks barge during the fireworks display.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on our NPRM published October 22, 2018. The comment was generally supportive of the proposed rulemaking. The comment did express concern with public notification of the rule. The comment suggested the Coast Guard notify the public more than once. The Coast Guard agrees that notification to the public of the existence of this rule is a key component to ensuring safety. In addition to publication of the NPRM and final rule in the **Federal Register**, the Coast Guard will provide notification through Broadcast Notice to Mariners and on-scene notice. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a temporary safety zone from approximately 8:15 p.m. through 9:15 p.m. on November 14, 2018, for the navigable waters in the vicinity of the Battleship New Jersey Museum and Memorial, Camden, NJ, during a fireworks display from a barge. The event is scheduled to take place at approximately 8:35 p.m. on November 14, 2018. The safety zone will extend 600 feet around the barge, which will be anchored at approximate position 39°56′20″ N Latitude, 075°08′08″ W Longitude. Persons or vessels will not be permitted to enter, transit through, or remain within the safety zone without obtaining permission from the COTP or a designated representative.

If authorization to enter, transit through, or remain within the safety zone is granted by the COTP or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP or a designated representative. The Coast Guard will provide public notice of the safety zone by Broadcast Notice to Mariners and by on-scene actual notice.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Delaware River for 1 hour during the evening when vessel traffic is normally low. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone, and the rule will allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism

principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 1 hour that will prohibit entry within 600 feet of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0948 to read as follows:

§ 165.T05–0948 Safety Zone; Delaware River; Camden, NJ; Fireworks Display.

(a) *Location.* The following area is a safety zone: All waters of the Delaware River within a 600-foot radius of the fireworks barge, which will be anchored in approximate position 39°56′20″ N Latitude 075°08′08″ W Longitude. All coordinates are based on Datum NAD 1983.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard petty officer, warrant or commissioned officer on board a Coast Guard vessel or on board a federal, state, or local law enforcement vessel assisting the Captain of the Port, Delaware Bay in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part—you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative; and all persons and vessels in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(2) To request permission to enter the safety zone, contact the COTP or the COTP's representative on marine band radio VHF–FM channel 16 (156.8 MHz) or 215–271–4807.

(3) No vessel may take on bunkers or conduct lightering operations within the safety zone during the enforcement period.

(4) This section applies to all vessels except those engaged in law enforcement, aids to navigation servicing, and emergency response operations.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by federal, state, and local agencies.

(e) *Enforcement period.* This zone will be enforced from 8:15 p.m. through 9:15 p.m. on November 14, 2018.

Dated: November 9, 2018.

S.E. Anderson,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2018–24978 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2018–0907]

Safety Zone; Santa Spectacular, Ohio River, Monongahela River, Allegheny River, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Santa Spectacular Fireworks to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River, Monongahela River and Allegheny River during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event in Pittsburgh, PA. During the enforcement period, entry into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1, Line 64 will be enforced from 8 p.m. through 9:30 p.m. on November 16, 2018.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a temporary safety zone for the Santa Spectacular Fireworks Race in 33 CFR 165.801, Table 1, titled ''Sector Ohio Valley Annual and Recurring Safety Zones,'' line 64, from 8 p.m. through 9:30 p.m. on November 16, 2018. This action is being taken to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River, Monongahela River and Allegheny River during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801

specifies the location of the regulated area for the Santa Spectacular Fireworks. Entry into the regulated area is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the regulated area must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of enforcement.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2018–24900 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0849]

RIN 1625–AA00

Safety Zone; The Gut, South Bristol, ME

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters within a 50 yard radius from the center point of The Gut Bridge in South Bristol, ME between Rutherford Island and Bristol Neck. The safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created during bedrock removal operations. When enforced, this regulation prohibits entry of vessels or persons into the safety zone unless authorized by the Captain of the Port Northern New England or a designated representative.

DATES: This rule is effective without actual notice from November 15, 2018 through March 31, 2019. For the purposes of enforcement, actual notice will be used from November 8, 2018 through November 15, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–0849 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Matthew Odom, Waterways Management Division, U.S. Coast Guard Sector Northern New England, telephone 207–347–5015, email *Matthew.T.Odom@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
MEDOT Maine Department of Transportation
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On August 21, 2018, the Maine Department of Transportation (MEDOT) notified the Coast Guard that it will be removing bedrock in the areas between Rutherford Island and Bristol Neck underneath The Gut Bridge. The removal operations include removing bedrock from between the bridge abutments and areas near the navigation channel both upstream and downstream of The Gut Bridge. To remove the bedrock workers will need to utilize the waterway underneath the bridge span and prohibit people and vessels from entering the safety zone at various times. Removal operations are expected to take place between 8 November 2018 and 31 March 2019. However, we only anticipate a continuous 35 day full closure of the waterway. The COTP Northern New England has determined that the potential hazards associated with the removal operations will be a safety concern for anyone transiting within a 50-yard radius of the center point of The Gut Bridge.

In response, on September 27, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zone; The Gut, South Bristol, ME'' (83 FR 48748). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended on October 29, 2018, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with bedrock removal operations near The Gut Bridge which are scheduled to commence on November 8, 2018.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP Northern New England has determined that potential hazards associated with the bedrock removal operations will be a safety concern for anyone transiting within a 50-yard radius of the center point of the bridge. The purpose of this rule is to ensure the safety of vessels and personnel within a 50-yard radius of the center point of The Gut Bridge before, during, and after the bedrock removal operations.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published September 27, 2018. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 12:01 a.m. on November 8, 2018 to 11:59 on March 31, 2019. While the safety zone would be effective throughout this period, it would only be enforced during periods of active bedrock removal operations. The safety zone would include all navigable waters from surface to bottom within a 50 yard radius from the center point of The Gut Bridge between Rutherford Island and Bristol Neck in South Bristol, ME. During times of enforcement, no vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP Northern New England or a designated representative. The Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners via marine Channel 16 (VHF–FM) in advance of any enforcement.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and

Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and selective enforcement of the safety zone. The safety zone impacts only a small designated portion on The Gut waterway for 143 days. This waterway is typically transited by small recreational craft on an infrequent basis after Labor Day Weekend and prior to Memorial Day Weekend. Vessel traffic is able to safely transit around this safety zone with a slight delay (approximately 20–60 minutes) by transiting around Rutherford Island to reach any destination on the other side of The Gut. Additionally, the safety zone will only be enforced during active bedrock removal operations necessitating closure of the waterway or during an emergency. Moreover, the rule allows vessels to seek permission to enter the zone. The Coast Guard will notify the public of enforcement of this rule via appropriate means, such as via Local Notice to Mariners and Broadcast Notice to Mariners via marine Channel 16 (VHF–FM).

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this rule would not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that would prohibit entry within a 50-yard radius of the center point of a bridge. It is categorically excluded from further review under paragraph L60 (a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0849 to read as follows:

§ 165.T01–0849 Safety Zone; The Gut, South Bristol, ME.

(a) *Location.* The following area is a safety zone: All waters of The Gut, a waterway between Rutherford Island and Bristol Neck in South Bristol, ME, from surface to bottom, encompassed by a 50-yard radius from the center point of The Gut Bridge at position 43°51.720′ N, 069°33.480′ W (NAD 83).

(b) *Definitions.* As used in this section:

Designated representative means any Coast Guard commissioned, warrant, petty officer, or designated Patrol Commander of the U.S. Coast Guard who has been designated by the Captain of the Port, Sector Northern New England (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

Official patrol vessels means any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP to enforce this section.

(c) *Enforcement period.* This rule is effective without actual notice from November 15, 2018 through 11:59 p.m. on March 31, 2019. For the purposes of enforcement, actual notice will be used from 12:01 a.m. on November 8, 2018 through November 15, 2018. The rule will only be enforced during active bedrock removal operations or other instances which may cause a hazard to navigation, or when deemed necessary by the Captain of the Port (COTP), Northern New England.

(d) *Regulations.* When this safety zone is enforced, the following regulations, along with those contained in § 165.23 apply:

(1) No person or vessel may enter or remain in the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To obtain permission required by this regulation, individuals may reach the COTP or the COTP's designated representative via Channel 16 (VHF–FM) or (207) 767–0303 (Sector Northern New England Command Center).

(3) During periods of enforcement, any person or vessel permitted to enter the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(e) *Penalties.* Those who violate this section are subject to the penalties set forth in 33 U.S.C. 1232.

(f) *Notification.* Coast Guard Sector Northern New England will give notice through the Local Notice to Mariners and Broadcast Notice to Mariners for the purpose of enforcement of temporary safety zone. Coast Guard Sector Northern New England will also notify the public to the greatest extent possible of any period in which the Coast Guard will suspend enforcement of this safety zone.

Dated: November 8, 2018.

B.J. LeFebvre,

Captain, U.S. Coast Guard, Captain of the Port, Sector Northern New England.

[FR Doc. 2018–24899 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA–HQ–OAR–2003–0064; FRL–9986–47–OAR]

RIN 2060–AP80

Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR): Aggregation; Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action; lifting of administrative stay and announcement of effective date.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is concluding the reconsideration of an earlier action that the EPA published on January 15, 2009, titled ''Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Aggregation and Project Netting.'' The 2009 action—hereafter referred to as ''2009 NSR Aggregation Action''—clarified implementation of the New Source Review (NSR) permitting program under the Clean Air Act (CAA or Act) with respect to treating related physical or operational changes as a single ''modification'' for the purpose of determining NSR applicability at a stationary source. On April 15, 2010, the EPA proposed to revoke the 2009 NSR Aggregation Action. After a review of the public comments received on that proposal, the EPA has now decided to not revoke the 2009 NSR Aggregation Action. The EPA is, therefore, retaining the interpretation set forth in the 2009 NSR Aggregation Action, while not adopting any changes to the relevant rule text. At the same time, the EPA is using this present action to clarify the implications of the 2009 NSR Aggregation Action for EPA-approved permitting programs. This action also lifts the administrative stay and announces the effective date of the 2009 NSR Aggregation Action.

DATES: This action is effective on November 15, 2018.

ADDRESSES: The EPA has established a docket for this action, identified by Docket ID No. EPA–HQ–OAR–2003–0064. All documents in the docket are listed in the *http://www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available electronically in *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For further general information on this action, contact Mr. Dave Svendsgaard, Office of Air Quality Planning and Standards (OAQPS), Air Quality Policy Division, U.S. EPA, Mail Code 504–03, 109 T.W. Alexander Drive, Research Triangle Park, NC 27711; by telephone at (919) 541–2380; or by email at *svendsgaard.dave@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected directly by this action include sources in all industry categories. Entities potentially affected by this action also include state, local and tribal air pollution control agencies (air agencies) responsible for permitting sources pursuant to the NSR program.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this **Federal Register** document will be posted at *https://www.epa.gov/nsr.*

C. How is this document organized?

The information presented in this document is organized as follows:

II. Background

A. What is New Source Review?

The NSR program is a preconstruction permitting program that requires certain stationary sources of air pollution to obtain permits prior to beginning construction. The NSR permitting program applies both to new construction and to modifications of existing sources, regardless of whether the source is in an area where the national ambient air quality standards (NAAQS) have been exceeded (nonattainment area) or if the source is in an area where the NAAQS have not been exceeded (attainment or unclassifiable area). New construction and modifications that emit ''regulated NSR pollutants'' [1] over certain thresholds are subject to major NSR requirements, while smaller emitting sources and modifications may be subject to minor NSR requirements or be excluded from NSR altogether.

Major NSR permits for sources that are located in attainment or unclassifiable areas are referred to as Prevention of Significant Deterioration (PSD) permits. These permits can also cover pollutants for which there are no NAAQS. Major NSR permits for sources located in nonattainment areas and that emit pollutants above the specified thresholds for which the area is in nonattainment are referred to as nonattainment NSR (NNSR) permits. The pollutant(s) at issue and the air quality designation of the area where the facility is located or proposed to be built determine the specific permitting requirements. The CAA requires sources subject to PSD to meet emission limits based on Best Available Control Technology (BACT) as specified by CAA section 165(a)(4), and sources subject to NNSR to meet Lowest Achievable Emissions Rate (LAER) pursuant to CAA section 173(a)(2). Other requirements to obtain a major NSR permit vary depending on whether it is a PSD or NNSR permit.

A new stationary source is subject to major NSR requirements if its potential to emit (PTE) a regulated NSR pollutant exceeds statutory emission thresholds.[2] If it exceeds the applicable threshold, the NSR regulations define it as a ''major stationary source.'' [3] An existing major stationary source triggers major NSR permitting requirements when it undergoes a ''major modification,'' which occurs when a source undertakes a physical change or change in method of operation (*i.e.,* a ''project'') that would result in (1) a significant emissions increase from the project, and (2) a significant net emissions increase from the source (*i.e.,* a source-wide ''netting'' analysis that considers creditable emission increases and decreases occurring at the source as a result of other projects over a 5-year contemporaneous period). *See, e.g.,* 40 CFR 52.21(b)(2)(i) and 40 CFR 52.21(b)(52). For this two-step process, the NSR regulations define what emissions rate constitutes ''significant'' for each NSR pollutant. *See* 40 CFR 51.165(a)(1)(x), 40 CFR 51.166(b)(23), and 40 CFR 52.21(b)(23).

In many cases, these requirements of the major NSR program (or equivalent requirements) are formally adopted by a state or local air agency, and the agency submits a revised state implementation plan (SIP) to the EPA for approval. The EPA's regulations provide for the minimum requirements of these programs. Upon EPA approving the SIP, the air agency becomes the ''permitting authority'' for major NSR permits for sources within its boundaries. When a state or local air agency is not the permitting authority, either the EPA issues the major NSR permits or a state or local air agency issues the major NSR permits on behalf of the EPA by way of a delegation agreement. For sources located in Indian country, the EPA is currently the only permitting authority for major NSR. Currently, state and local air agencies issue the vast majority of major NSR permits each year.

New sources and modifications that do not require a major NSR permit may instead require a minor NSR permit prior to construction. Minor NSR permits are almost exclusively issued by state and local air agencies, although the EPA issues minor NSR permits in some areas of Indian country. Minor NSR requirements are approved into a SIP in order to achieve and maintain the NAAQS. *See* CAA section 110(a)(2)(C). The CAA and EPA's regulations are less prescriptive regarding minimum requirements for minor NSR, so air agencies generally have more flexibility in designing their minor NSR programs.

B. What is project aggregation?

As described in the preceding section, the EPA's implementing regulations for NSR establish a two-step process for determining major NSR applicability for projects at stationary sources. To be subject to major NSR requirements, the project must result in both (1) a significant emissions increase from the project (the determination of which is called ''Step 1'' of the NSR applicability analysis, or ''project emissions accounting''); and (2) a significant *net* emissions increase at the stationary source, taking account of emission increases and emission decreases attributable to other projects undertaken at the stationary source within a specific time frame (called ''Step 2'' of the NSR applicability analysis, or ''contemporaneous netting''). This approach to applicability makes it necessary to accurately define what constitutes the ''project'' under review to ensure that the proper emissions increase resulting from the project is used when comparing it with the applicable NSR significance threshold at Step 1 of the NSR applicability analysis.[4] Otherwise, a source could

[1] 40 CFR 51.165(a)(1)(xxxvii), 40 CFR 51.166(b)(49), 40 CFR 52.21(b)(50).

[2] For PSD, the statute uses the term ''major emitting facility'' which is defined as a stationary source that emits, or has a PTE, at least 100 tons per year (TPY) if the source is in one of 28 listed source categories—or at least 250 TPY if the source is not—of ''any air pollutant.'' CAA 169(1). For NNSR, the emissions threshold for a major stationary source is 100 TPY, although lower thresholds may apply depending on the degree of the nonattainment problem and the pollutant. 40 CFR 51.165(a)(1)(iv)(A).

[3] 40 CFR 51.165(a)(1)(iv), 40 CFR 51.166(b)(1)(i), 40 CFR 52.21(b)(1)(i).

[4] In this notice, we use the terms ''project,'' ''changes,'' and ''activities'' interchangeably in referring to physical or operational changes that occur at a facility. In some cases, particularly in using the term ''activities,'' we are actually referring to ''sub-projects'' that are nominally separate in scope but are nevertheless related to other sub-projects such that they all are part of a larger single project when determining NSR applicability. It is important to note that our use of the term ''activities'' in this notice is not intended to imply that every ''activity'' at a plant is a physical or operational change. The EPA recognizes that there are numerous activities undertaken at a facility, of which only a subset will constitute ''changes'' under the NSR regulations.

conceivably carve up a higher-emitting project into two or more lower-emitting ''projects'' and avoid triggering major NSR requirements.[5] ''Project aggregation,'' therefore, ensures that nominally-separate projects occurring at a source are treated as a single project for NSR applicability purposes where it is unreasonable not to consider them a single project.[6]

As with certain other aspects of the NSR program, determining what constitutes the ''project'' is a case-by-case decision that is both site-specific and fact-driven. There is no pre-determined list of activities that should be aggregated for a given industry or industries. It is, therefore, necessary to establish criteria for determining when nominally-separate activities are considered one project under NSR. The EPA has specifically sought to develop principles for aggregating changes such that a project is appropriately defined by the source, so that the emission increases attributable to the project are accurately quantified for purposes of analyzing NSR applicability. Over the years, the EPA articulated its policy on project aggregation through a series of statutory and regulatory interpretations contained in EPA letters and memoranda, the most commonly cited being a 1993 EPA memorandum regarding NSR applicability for activities that had occurred at a 3M facility in Minnesota.[7]

To date, the EPA's focus in formulating criteria for project aggregation has been to ensure that NSR is not circumvented through some artificial separation of activities at Step 1 of the NSR applicability analysis where it would be unreasonable for the source to consider them to be separate projects. However, in a March 13, 2018, memorandum [8] on the topic of ''project emissions accounting,'' the EPA broached the question of whether it might also somehow be possible for a source to circumvent NSR through some wholly artificial grouping of activities to include decreases in emissions as part of Step 1 of the NSR applicability analysis—*i.e.,* assessing whether a project by itself results in a significant emissions increase before reaching Step 2, where one then determines whether there will be a significant net emissions increase by taking into account all contemporaneous increases and decreases across the source. While we [9] have been mindful of this question in deciding to employ the project aggregation criteria described in this action, we intend to address more fully this scenario in the context of a subsequent rulemaking action on the topic of project emissions accounting.

C. Regulatory History

1. The 2009 NSR Aggregation Action

On January 15, 2009, the EPA published a final action—which we are calling the ''2009 NSR Aggregation Action''—that described the principles of project aggregation that we would apply when determining whether a source had unreasonably segregated a single project into multiple projects, thereby circumventing the NSR permitting requirements.[10] We had initially proposed in 2006 to establish principles for project aggregation through an amendment to the NSR regulations.[11] However, because of the difficulty of creating a bright line to determine when activities should be aggregated, we ultimately decided not to adopt the proposed changes to the regulations and elected instead to pursue a less prescriptive approach by describing, in the 2009 action, the EPA's interpretation of the existing regulations and a policy for applying that interpretation going forward.

The 2009 NSR Aggregation Action called for sources and reviewing authorities to aggregate emissions from nominally-separate activities when they are ''substantially related'' for the purpose of determining whether they are a single modification resulting in a significant emissions increase under NSR at Step 1.[12] This ''substantially related'' criterion is based on an interpretation of the term ''project'' contained in the major NSR regulations.[13] The action also included a statement that the EPA would, as a matter of policy, establish a rebuttable presumption that activities that occurred more than three years apart are not ''substantially related'' and therefore, generally, should not be aggregated for purposes of determining whether they are a single modification at Step 1.

The 2009 NSR Aggregation Action retained the existing rule text defining the term ''project''—*i.e.,* ''a physical change in, or change in method of operation of, an existing major stationary source''—and interpreted this rule text to mean that sources and permitting authorities should combine emissions only when nominally-separate changes are ''substantially related.'' While acknowledging the case-specific nature of a project aggregation determination, the 2009 NSR Aggregation Action described the factors that should be considered when evaluating whether changes are substantially related, including technical or economic dependence. It also offered examples of what it means to be substantially related, and it referenced examples provided in EPA's 2006 proposed rule on project aggregation to further amplify EPA's meaning of the term. Thus, in many respects, the ''substantially related'' interpretation in the 2009 NSR Aggregation Action was intended to encompass principles for aggregating projects that were similar to those that the EPA had proposed in 2006, but ultimately concluded should not be prescriptively defined in a regulation because of the difficulty of developing a bright line for determining when activities should be aggregated.

The 2009 NSR Aggregation Action specifically addressed the timing element of project aggregation decisions in multiple ways. It affirmed that timing alone should not be a basis for aggregating projects because the appropriate basis for aggregation is whether there is a substantial technical or economic relationship. It further explained that activities that occur simultaneously should not be presumed to be substantially related, although it is reasonable to presume that activities

[5] Emission changes from separate projects (not included under Step 1 as falling within the project under review) are considered at Step 2 if they are ''contemporaneous'' and ''otherwise creditable'' under the NSR regulations. *See* 40 CFR 52.21(b)(3).

[6] It is not permissible to seek to circumvent NSR by securing several minor NSR permits for individual projects with the effect of avoiding major NSR requirements for what is actually a single project.

[7] Memorandum from John B. Rasnic, Director, Stationary Source Compliance Division, OAQPS, to George T. Czerniak, Chief, Air Enforcement Branch, EPA Region 5, titled, ''Applicability of New Source Review Circumvention Guidance to 3M—Maplewood, Minnesota'' (June 17, 1993) (hereinafter ''3M Memorandum'').

[8] Memorandum from E. Scott Pruitt, Administrator, to Regional Administrators, titled, ''Project Emissions Accounting Under the New Source Review Preconstruction Permitting Program'' (March 13, 2018) (hereinafter ''Project Emissions Accounting Memorandum'').

[9] In this preamble, the terms ''we'', ''our'' and ''us'' refer to the EPA.

[10] Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Aggregation and Project Netting (74 FR 2376; January 15, 2009).

[11] Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Debottlenecking, Aggregation, and Project Netting (71 FR 54235; September 14, 2006).

[12] *See* 74 FR 2378 (''When there is no technical or economic relationship between activities *or where the relationship is not substantial,* their emissions need not be aggregated for NSR purposes.'' (emphasis added)). That is, mere relatedness is not sufficient to upend the source's definition of its project, but sources cannot circumvent NSR by artificially separating a series of emissions-increasing projects into separate projects that fall below the significance thresholds.

[13] *See, e.g.,* 40 CFR 52.21(b)(52).

closer in time are more likely to be substantially related than activities separated by larger time frames. Thus, it affirmed that the timing between activities remains important from a standpoint of framing the analysis of whether a substantial technical or economic relationship exists.

The 2009 NSR Aggregation Action also expressed that the farther apart projects are timed, the less likely they are to be substantially related, since the activities would likely be part of distinct planning and capital-funding cycles. It stated ''the passage of time provides a fairly objective indicator of nonrelatedness between physical or operational changes. Specifically, the greater the time period between activities, the less likely that a deliberate decision was made by the source to split an otherwise 'significant' activity into two or more smaller, non-major activities.'' 74 FR 2380.

To this end, the 2009 NSR Aggregation Action affirmed that timing could be a basis to not aggregate separate projects, and it established a policy of applying a rebuttable presumption against aggregating projects that occur 3 or more years apart. The EPA justified its selection of 3 years as the presumptive timeframe in part by reasoning that it ''is long enough to ensure a reasonable likelihood that the presumption of independence will be valid, but is short enough to maintain a useful separation between relevant construction cycles, consistent with industry practice. For example, in the case of electric utilities, a commenter explained that companies plan and schedule major turbine outages every four to five years.'' *Id.* However, the EPA did note that this presumptive timeframe may be rebutted in certain circumstances. For instance, the 2009 NSR Aggregation Action noted that where there is ''evidence that a company intends to undertake a phased capital improvement project'' where the activities ''have a substantial economic relationship,'' this would likely overcome the presumption that those activities should not be aggregated. *Id.*

With regard to implementing the 3-year presumption, the EPA stated ''the time period separating physical or operational changes should be calculated based on time of approval (*i.e.,* minor NSR permit issuance). If a permit has not been, or will not be, issued for the physical or operational changes, the time period should be based on when construction commences on the changes.'' 74 FR 2381.

The EPA also explained that a statement within the 3M Memorandum was potentially vulnerable to misapplication and did not properly reflect the ''substantially related'' criterion. The 3M Memorandum stated the following:

> Some minimum level of research activity and commensurate emissions, source-wide, perhaps could be expected from year to year, as would be expected to keep the 3M plant productive or operable. These emissions and thereby modifications cannot be presumed to be independent given the plant's *overall basic purpose* to support a variety of research and development activities. Therefore, even though each research project may have been individually conceived and separately funded, it is appropriate to look at the overall expected research activity in assessing NSR applicability and enforcement. 3M Memorandum at 5 (emphasis added).

In the 2009 NSR Aggregation Action, the EPA expressed concern with this statement from the 3M Memorandum, saying ''it could be interpreted to imply that almost any activity is related to any other activity at that source simply because they are both capital investments and support the company's goal to make a profit.'' 74 FR 2376, 2379. The suggestion that all changes consistent with the ''overall basic purpose'' of the plant can and should be aggregated is inconsistent with the interpretation of ''project'' to include only those changes that have a substantial relationship. While the EPA did not, in the 2009 NSR Aggregation Action, find such a broad approach to project aggregation was often applied after the 3M determination, we nevertheless had concerns that it did not represent an appropriate criterion for aggregating projects for NSR purposes and could be misapplied. Thus, in the 2009 NSR Aggregation Action, we maintained that two nominally separate projects are not substantially related if they are only related to the extent that they both support the source's ''overall basic purpose.''

In summarizing what it means for projects to be substantially related, the 2009 NSR Aggregation Action provided that ''in most cases, activities occurring in unrelated portions of a major stationary source (*e.g.,* a plant that makes two separate products and has no equipment shared among the two processing lines) will not be substantially related. The test of a substantial relationship centers around the interrelationship and interdependence of the activities, such that substantially related activities are likely to be jointly planned (*i.e.,* part of the same capital improvement project or engineering study), and occur close in time and at components that are functionally interconnected.'' 74 FR 2378. The 2009 NSR Aggregation Action added, ''[t]o be 'substantially related,' there should be an apparent interconnection—either technically or economically—between the physical and/or operational changes, or a complementary relationship whereby a change at a plant may exist and operate independently, however its benefit is significantly reduced without the other activity. We note that these factors are not necessarily determinative of a substantial relationship, but are merely indicators that may suggest that two or more activities are likely to be substantially related and, therefore, candidates for aggregation.'' *Id.*

2. Reconsideration and Administrative Stay

On January 30, 2009, the Natural Resources Defense Council (NRDC) submitted a petition for reconsideration of the 2009 NSR Aggregation Action (the ''NRDC Petition''). In response to the NRDC Petition, on February 13, 2009, the EPA convened a proceeding for reconsideration as provided for under the CAA section 307(d)(7)(B), finding that the petitioner had raised objections to the action that arose after the comment period and that were of central relevance to the action.

To allow time to complete the reconsideration prior to the 2009 NSR Aggregation Action becoming effective, the EPA announced a 90-day administrative stay of the action. *See* 74 FR 7284 (February 13, 2009). The EPA subsequently completed an action to further delay the effective date until May 18, 2010. *See* 74 FR 22693 (May 14, 2009). On May 18, 2010, the EPA invoked APA section 705 to stay the action indefinitely pending the proceedings for judicial review or the completion of reconsideration. These stays were intended to allow the EPA the time to take comment on issues that were in question and complete any revisions of the action that became necessary as a result of the reconsideration process.

As part of the reconsideration proceeding, on April 15, 2010, the EPA published a proposed reconsideration of the 2009 NSR Aggregation Action (the ''2010 Reconsideration Proposal'').[14] 75 FR 19567. At the time, the EPA considered whether some of the points

[14] In the 2010 Reconsideration Proposal, the EPA described the 2009 action as the ''NSR Aggregation Amendments.'' However, since this action did not ''amend'' the NSR regulations, but rather laid out an interpretation of our current regulations and described a policy on timing for aggregation, the 2009 action is more appropriately described, as it is described herein, as the 2009 NSR Aggregation Action.

raised by the NRDC petition might demonstrate potential flaws in the process and with fundamental aspects of the 2009 NSR Aggregation Action, including the legal basis, state adoption and implementation, and the clarity of the ''substantially related'' criterion. In the 2010 Reconsideration Proposal, we expressed agreement with the petitioner on a number of fronts, invited comment on all issues raised in the NRDC petition, and proposed a preferred option to revoke the 2009 NSR Aggregation Action. The 2010 Reconsideration Proposal also referenced a number of the past determinations on project aggregation. *See* 75 FR 19570–1.

The EPA received a total of 27 comments on our 2010 Reconsideration Proposal. Of those commenters, 20 represented industry parties, three represented state and local air agencies, one represented a tribal government agency, one represented a federal agency, one represented an environmental advocacy group, and one was a private citizen.

3. Characterizing the 2009 NSR Aggregation Action

In the history of actions that the EPA has taken regarding its project aggregation policy since 2006, the EPA has variously described the 2009 NSR Aggregation Action as a ''rule,'' ''interpretation,'' and ''policy.'' However, we are now mindful that these terms may be used to refer to three distinct types of agency action that have varying degrees of legal effect and can be changed through different types of procedures. *National Mining Association* v. *McCarthy,* 758 F.3d 243, 251–52 (D.C. Cir. 2014). As is explained below, the distinction between the proper procedures for changing rules, interpretations, and policies were not as clear to the agency in 2009 and 2010 as they are today. Recent court decisions have provided more clarity regarding the distinction between these types of actions and the means through which an agency can change them. In order to clarify how state and local permitting authorities may apply the principles for project aggregation that the EPA articulated in 2009, in this final action we seek to address any confusion regarding the nature of that 2009 action.

We begin by defining what we understand each of these terms to mean when they are used in the discussion that follows. We use the term ''rule'' to describe a ''legislative rule,'' which is ''[a]n agency action that purports to impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements.'' *National Mining,* 758 F.3d at 251–52. We use the term ''interpretation'' to describe ''an agency action that merely interprets a prior statute or regulation, and does not itself purport to impose new obligations or prohibitions or requirements on regulated parties.'' *Id.* Following the language in the APA, courts have used the term ''interpretive rule'' to describe this type of action. *Id.* Here, however, we use the term ''interpretation'' to more clearly distinguish such an action from a *legislative* rule. Finally, a ''policy'' or ''statement of policy'' is ''an agency action that merely explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule.'' *Id.*

In 2006, we proposed a rule (meaning a *legislative* rule) that would have changed the text in the Code of Federal Regulations. We included in the preamble an explanation of what we intended that proposed regulatory text to mean. 71 FR 54235 (September 14, 2006). In that **Federal Register** document, we referred to the action as a ''proposed rule.'' *Id.; see also* 71 FR at 54245 (''We are proposing to add our aggregation policy to our NSR regulations . . .'').

In 2009, we took ''final action'' in the matter. That is, we completed the action begun in 2006, while not changing the regulatory text itself. 74 FR 2376. In retaining the existing regulatory text defining the term ''project,'' we said that the action we were taking ''interprets that rule text.'' *Id.* The interpretation offered in the 2009 NSR Aggregation Action was that a ''project,'' which the regulatory text defines to mean ''*a* physical change in, or change in the method of operation of, an existing major stationary source,'' 40 CFR 52.21(b)(53) (emphasis added), includes those activities that are ''substantially related.'' 74 FR 2377. This portion of the 2009 NSR Aggregation Action was an interpretation.[15] Although we had proposed to adopt a legislative rule in 2006 and to reflect that in amended regulatory text, we made a final decision in 2009 not to adopt any legislative rule or to amend the text of the NSR regulations. Instead, we chose to announce an interpretation of the *existing* regulations that drew from EPA's prior experience on the topic of project aggregation, but which to some degree altered the aggregation policy that the EPA had previously articulated in past guidance memoranda and letters.

In 2009, we also discussed our intention to apply a rebuttable presumption that activities separated by more than 3 years would not be considered substantially related. This section of the action is best understood as a statement of policy, as we were describing how we intended to exercise our discretion under the NSR regulations, as we interpreted them. We justified the 3-year presumption as a commonsense approach, in that we believed that in practice once 3 years had passed, ''it is difficult to argue that th[e activities] are *substantially* related and constitute a single project.'' 74 FR 2380. But recognizing that there may be situations that would warrant an exception to this approach, we indicated that the 3-year presumption would be rebuttable. We indicated our view that it would be allowable and appropriate for other permitting authorities to ''also adopt this presumptive timeframe as guidance for their sources.'' 74 FR 2381.

The 2009 action, thus, contained both an interpretation of the existing regulations and a statement of policy on how we intended to implement that interpretation. It is for this reason that we refer to it as the 2009 NSR Aggregation Action. However, when reconsidering that 2009 action, we were not sufficiently clear in the 2010 Reconsideration Proposal regarding the nature of the action we were reconsidering. At times, we described the 2009 action as a ''final rule,'' and called it the ''NSR Aggregation Amendments,'' which could be read to suggest that we considered the 2009 NSR Aggregation Action, despite the lack of regulatory text changes, to somehow be a *legislative* rule, or something that ''amended'' the existing regulations.

Much of the confusion stemmed from the fact that at the time we took these actions, judicial precedent in the United States Court of Appeals for District of Columbia Circuit (D.C. Circuit) provided that, where an agency had given a definitive interpretation to one of its own legislative rules, the agency could not thereafter change that interpretation without providing notice and an opportunity to comment. *Paralyzed Veterans of America* v. *D.C. Arena L.P.,* 117 F.3d 579 (D.C. Cir. 1997). In part because of this precedent, we were persuaded in 2010 that we should provide an opportunity for the public to comment on the 2009 interpretation, which could have been viewed as a

[15] As explained above, courts follow the APA in referring to this type of action as an ''interpretive rule,'' but we refer to it herein simply as an ''interpretation'' to more clearly distinguish such an action from a *legislative* rule.

change from the interpretation that the EPA had articulated in 2006 and earlier. In addition, since we understood the *Paralyzed Veterans* opinion to require a notice-and-comment rulemaking process when an agency wished to change a regulatory interpretation (which, under the APA, would constitute the issuance of an ''interpretive rule,'' or, as we refer to it herein, an ''interpretation''), and because the 2009 NSR Aggregation Action had completed a notice-and-comment rulemaking process that had originally proposed to amend rule text, we chose in the 2010 Reconsideration Proposal to apply the procedures for reconsidering a ''legislative rule.''

The United States Supreme Court has since abrogated the *Paralyzed Veterans* doctrine, ruling that it was inconsistent with the APA, which by its plain terms does not require agencies to go through a notice-and-comment process in issuing an interpretive rule. *Perez* v. *Mortgage Bankers Association,* 135 S. Ct. 1199 (2015). Because the 2009 NSR Aggregation Action did not impose legally binding obligations or prohibitions on regulated entities or state permitting authorities, it was not a legislative rule. Since the 2009 NSR Aggregation Action was a combination of interpretation and policy statement, it could have been issued by the EPA without following notice-and-comment rulemaking procedures. 5 U.S.C. 553(b); 42 U.S.C. 7607(d)(1). Further, to the extent the interpretation reflected therein is a change from a prior interpretation, after the Supreme Court decision in *Mortgage Bankers,* it is now clear that an agency may also change such an interpretation of its regulations without the need to publish notice in the **Federal Register** and solicit public comment. However, because the EPA has been using notice-and-comment rulemaking procedures up to this point, the EPA believes it is prudent, but not required, in order to retain the interpretation of the NSR regulations with regard to project aggregation that we published in 2009, that we publish this document in the **Federal Register**. This procedure also allows us to complete the reconsideration proceeding and lift the indefinite administrative stay of the 2009 NSR Aggregation Action. We also believe that it is prudent to respond to those comments we received during the reconsideration process.

III. This Action

A. Overview

In this action, we are taking final action on reconsideration of the issues for which we asked for comment in the 2010 Reconsideration Proposal. The proposal invited comment on all issues alleged in the petition for reconsideration, including the following: Lack of adequate opportunity for notice and comment on the final action; legal inconsistency with a prior court decision; lack of demonstrated need for a policy change; and lack of clarity over state plan adoption of the action.

This action addresses all of the petitioner's issues. Moreover, to the extent that commenters lacked an adequate notice-and-comment opportunity in the development of the 2009 NSR Aggregation Action, the reconsideration process has addressed this deficiency by inviting comment in 2010 on the issues raised by the petitioner. This action (1) takes final action on the 2010 Reconsideration Proposal and retains the 2009 NSR Aggregation Action without adopting any changes to the rule text or the interpretation and statement of policy contained therein; (2) completes the CAA section 307 reconsideration proceeding on the 2009 NSR Aggregation Action to address any potential notice-and-comment deficiency; and (3) lifts the APA section 705 stay of the 2009 NSR Aggregation Action. The conclusions reached and expressed in this final action are based on careful review of the public comments on the 2010 Reconsideration Proposal.[16]

This final decision on reconsideration of the 2009 NSR Aggregation Action does not finalize the 2010 Reconsideration Proposal's preferred option to revoke the 2009 NSR Aggregation Action's interpretation and policy. Upon reviewing public comments, after further deliberation, and taking account of the Administration's priorities and policy goals, the EPA has concluded that the interpretation and policy in the 2009 NSR Aggregation Action should be retained.[17] We believe the 2009 NSR Aggregation Action articulates a reasonable standard for aggregating related projects and is consistent with the CAA and our regulations.

With regard to the petitioner's concern about how the 2009 NSR Aggregation Action applies to EPA-approved permitting programs, we affirm our decision in 2009 not to revise the current rule text, and instead to conclude that the terms ''project'' and ''a physical change in, or change in method of operation of'' in the existing NSR regulations can be reasonably interpreted as already incorporating the ''substantially related'' test set forth in the 2009 preamble. Because the 2009 NSR Aggregation Action did not amend the rule text, state and local air agencies with approved state implementation plans (SIPs) are not required to amend those plans to adopt this interpretation that projects should be aggregated when ''substantially related.'' If state and local agencies want to adopt this interpretation, we believe that in most cases this interpretation can be applied without formal adoption into their rules. We encourage state and local air agencies to follow this interpretation to ensure greater national consistency in making NSR applicability determinations, though state and local air agencies with approved SIPs can continue to apply their own interpretation of the scope of a ''project.''

Consistent with comments received on the EPA's 2006 proposed rule, commenters on the 2010 Reconsideration Proposal raised concerns with the clarity of our prior policy on project aggregation, which was developed over time through a number of *post hoc* site-specific applicability determinations. We anticipate the 2009 NSR Aggregation Action will reduce any confusion over our past policy and provide sources and regulators with increased clarity when determining whether projects should be aggregated for NSR purposes. The EPA believes the principles outlined in the 2009 NSR Aggregation Action will not only help to achieve greater national consistency in project aggregation determinations but will also streamline NSR permitting by reducing the time needed to assess whether nominally-separate physical and operational changes should be aggregated for NSR applicability purposes.

As this action officially completes our reconsideration proceeding, we are also lifting the APA section 705 stay and announcing the effective date of the 2009 NSR Aggregation.

[16] In the docket for this action, we are making available a document, ''Response to Public Comments for Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Aggregation; Reconsideration'', in which the EPA responds to the public comments received on the 2010 Reconsideration Proposal.

[17] *See* Presidential Memorandum on Streamlining Permitting and Reducing Regulatory burdens for Domestic Manufacturing (82 FR 8667; January 24, 2017); Executive Order 13777 on Enforcing the Regulatory Reform Agenda (82 FR 12285, March 1, 2017).

B. Retaining the 2009 NSR Aggregation Action

1. An Interpretation Is Needed

As explained earlier in this document, the EPA's past position on project aggregation—prior to the 2009 NSR Aggregation Action—was not established through a rule or through a single, comprehensive policy statement. Rather, the policy had been articulated by the EPA through a number of site-specific determinations, many of which were issued after the activities subject to the determination had already occurred. Navigating this collection of EPA statements, capturing their salient points, and determining whether and how to apply their rationale to new determinations with different fact patterns was arguably a challenge for sources and permitting authorities over the years. Such an approach lacked clarity for sources and permitting authorities, making it sometimes difficult to understand the overall policy so they could effectively apply it prospectively.

There is a substantive distinction between making case-by-case determinations after-the-fact and making case-by-case determinations prospectively—*i.e.,* as part of a permitting applicability review—for NSR purposes. Many *post hoc* determinations are made with an eye to determining whether the requirements of NSR were circumvented, whereas prospective determinations are made with the purpose of giving sources an opportunity to evaluate modifications during the planning or preconstruction phase in order to determine whether a planned or proposed modification requires a PSD or NNSR permit, so as *not* to circumvent the NSR process. While the underlying criteria for assessing whether to group multiple activities as a single project should be the same regardless of whether the determination is prospective or *post hoc,* a *post hoc* determination is often very specific to the industry and the individual fact pattern under consideration, and therefore applying the determination's rationale prospectively, while potentially informative, could be misapplied to situations involving different industries or having different fact patterns. The 2009 NSR Aggregation Action also recognized the limitations of having a policy that is based on the specific fact patterns of past determinations: ''the decision to aggregate or disaggregate activities is highly case-dependent, such that letters and memoranda that opine on whether to aggregate a particular set of activities at one facility are not necessarily transferable to a decision to aggregate a similar set of activities but with a slightly different set of circumstances at a different plant.'' 74 FR 2377.

Previous agency statements can be taken out of context or misunderstood when reviewing projects having a different set of facts. For example, while the 3M Memorandum was considered by some as the EPA's guiding policy on project aggregation, parties could certainly misconstrue portions of that statement to suggest that all projects occurring within the same timeframe should be aggregated, or that all projects occurring at a facility should be aggregated as long as they contribute to the source's ''overall basic purpose.'' Such an approach—*i.e.,* to aggregate projects simply because they may occur close in time or may support the same overall purpose of the facility—fails to take proper account of the actual interrelationship of activities. Meanwhile, in other parts of the 3M Memorandum, the EPA's statements clearly indicate that, in order to justify aggregating activities for purposes of major NSR, the reasonable approach is to determine whether those activities are related in some meaningful way: *e.g.,* ''[a]uthorities should scrutinize [permit] applications *that relate to the same process or units* . . .''; ''two or more *related* minor changes over a short time period should be studied for possible circumvention.'' 3M Memorandum at 3 (emphasis added). We consequently do not believe that a broader approach to aggregating activities—*i.e.,* based on their contribution to a plant's overall purpose—is an accurate characterization of the EPA's view at the time of the 3M determination. Furthermore, we do not believe it reflects EPA's view in any other statement made by the agency over the years.

We noted in the 2010 Reconsideration Proposal that ''in reviewing the record for the NSR Aggregation Amendments, we find that the only factual support for the contention that our historic approach caused confusion was anecdotal,'' and that the ''parties supporting a change in policy failed to provide us with any characterization of the overall level of uncertainty or other problems resulting from the existing policy on aggregation.'' 75 FR 19572. However, after further consideration, the EPA finds this to be an insufficient basis for changing or revoking the 2009 NSR Aggregation Action. So-called ''anecdotal'' evidence is nevertheless still evidence of which the agency can properly take account if, in its judgment, it finds it to be meaningful. Indeed, the criticism of relying on ''anecdotes'' suggests that examples of problems offered in public comments should be ignored. The EPA is required to take into account the comments submitted. Furthermore, merely because the overall level of uncertainty demonstrated by public comments cannot be characterized—a given entity would not necessarily know whether others were as uncertain as they were—does not serve to demonstrate that the 2009 NSR Aggregation Action was unwarranted. We believe that the evidence before the EPA in 2009 and the agency's own extensive permitting experience, coupled with statements from public commenters in this reconsideration proceeding, clearly indicates that the EPA's prior policy on project aggregation lacked clarity and promoted confusion. The 2009 NSR Aggregation Action provides a more concise formulation for how to interpret the scope of a project and provides clarity for permitting authorities, regulated entities, and the public.

Finally, the 2010 Reconsideration Proposal states that ''[w]hile the [2009 NSR Aggregation Action] may, in some respects, appear clearer than our previous policy, we are not convinced that it achieved enough additional clarity to improve the process of making aggregation assessments by sources and reviewing authorities. . . .'' 75 FR 19573. After further consideration, we now believe that providing clarity in a single document is a better approach than continuing the previous policy that was based on a host of EPA letters and memoranda, which collectively provided less clarity. We recognize there will continue to be ''gray areas'' that sources and permitting authorities will ultimately have to work through in deciding whether or not to aggregate a set of changes at a facility. But this is attributable to the inherent nature of such decisions, not to some deficiency in the 2009 NSR Aggregation Action. That does not mean that the EPA should abandon the clarity it attempted to provide in that action.

2. ''Substantially Related'' Is an Appropriate Standard

As noted above, the EPA continues to believe that there is a need for *some* criteria for determining when nominally-separate changes should be considered a single ''project'' for purposes of determining NSR applicability. It remains necessary to draw a line between those activities that are to be considered a single ''physical or operational change'' and those that are not. In this action, we are affirming that the 2009 NSR Aggregation Action's

''substantially related'' test is an appropriate standard for project aggregation.

As explained elsewhere in this document, the nature of the project aggregation determination is case-specific, which means it is inherently difficult to establish a bright line standard: Such a standard may be reasonable when conducting an evaluation of project scope in one situation, but could prove to be unreasonable or unworkable when applied in other situations. This case-by-case aspect necessitates that the EPA establish a reasonable general principle to apply, and we believe the ''substantially related'' criterion is an appropriate principle for concluding that claimed separate projects are a single project for NSR applicability purposes. We believe the substantially related criterion is sound from a policy and implementation perspective.

The 2009 NSR Aggregation Action effectively addresses certain past EPA statements in relation to implementing the ''substantially related'' test for future project aggregation determinations. The 2009 NSR Aggregation Action outlined the role of timing—specifically, that timing alone is not determinative of whether activities are substantially related and that, as a policy matter, activities separated in time by three or more years may be presumed to be not substantially related. The 2009 NSR Aggregation Action also rejected the use of an ''overall basic purpose'' criterion for aggregating physical or operational changes, since it could have been read to constitute an open-ended standard, resulting in the unreasonable or improper aggregation of unrelated activities.

Importantly, we do not believe the 2009 NSR Aggregation Action reflects a major shift in policy from EPA's prior policy on project aggregation. To the contrary, we believe that in many ways the 2009 NSR Aggregation Action clarifies and supplements previous statements of policy. For example, in the case of timing, the 3M Memorandum suggested that when minor NSR permit applications occur ''over a short time period (*e.g.,* 1 year or 18 months), the modifications *may* require major new source review.'' 3M Memorandum at 4 (emphasis added). Thus, the 3M Memorandum never said timing was the sole criterion or otherwise conclusive. Rather, timing was a reason to look more closely at the relevant activities' ''intrinsic relationship with each other (physical proximity, stages of production process, etc.) and their impact on economic viability of the plant (scheduling down time in light of production targets, economies of scale, etc.).'' *Id.* Similarly, the 2009 NSR Aggregation Action said that ''whether a physical or operational change is dependent on another for its viability is still a relevant factor in assessing whether the changes should be aggregated,'' and ''substantially related activities are likely to be jointly planned (*i.e.,* part of the same capital improvement project or engineering study), and occur close in time and at components that are functionally interconnected.'' 74 FR 2378.

In addition, the ''substantially related'' criterion is not materially different from the factors the agency has considered in previous project aggregation decisions. Over time, the EPA has used various terms and phrases—*e.g.,* ''intrinsic relationship'' as was used in the 3M Memorandum—to describe the basis for why multiple nominally-separate changes at a source should be treated as a single project for NSR applicability purposes. The term ''substantially related'' is, therefore, little more than a functional synonym for other terms that the EPA has historically used to characterize its project aggregation policy. While sources and permitting authorities making project aggregation determinations may continue to use the EPA's previous terms, and may rely on other terms or phrases going forward, we believe that the terminology used should ultimately express a standard for determining whether the activities are or are not substantially related. Thus, we believe ''substantially related'' works effectively as an umbrella term to include these previous descriptors for analyzing the relationship between projects that warrant aggregation.

Finally, the matter of defining the scope of a project was raised, in a different context, in the Project Emissions Accounting Memorandum issued on March 13, 2018. There, we observed that, as general matter, the source itself is responsible for defining the scope of its own project, subject to the limitation that the source cannot seek to circumvent NSR by characterizing the proposed project in a way that would separate a single project into multiple projects. We further pointed out that, ''[s]ubject to the equivalent understanding that it might be possible [for a source] to circumvent NSR through some wholly artificial *grouping* of activities, the EPA does not interpret its NSR regulations as directing the agency to preclude a source from reasonably defining its proposed project broadly, to reflect multiple activities.'' [18]

In the Project Emissions Accounting Memorandum, we noted that EPA was then evaluating whether to undertake a future notice-and-comment rulemaking to implement, through changes to the regulatory text itself, the interpretation of the NSR applicability provisions set forth in the memorandum. At such time as we proceed with that rulemaking, we will look to provide further guidance with respect to properly accounting for the scope of a project in which a source is seeking to take account of emission decreases at Step 1 of the NSR applicability analysis. Meanwhile, in advance of that rulemaking, we take the opportunity here to clarify that, as a general matter, it is neither necessary nor appropriate to take into consideration such matters as whether emission decreases attributable to a particular activity are ''integral'' to the overall project, as had once been proposed by a petroleum refinery to the EPA.[19] Our current view is that the concerns regarding the real possibility that NSR might be circumvented through some artificial separation of activities where it would be unreasonable to consider them separate projects—*i.e.,* the concerns which the 2009 NSR Aggregation Action is intended to address—are not so obviously presented by the situation where a source itself is choosing to group together, as a single project, activities to which a projected emissions decrease is attributable.[20] In a future rulemaking to clarify, through regulatory text changes, the interpretation set forth in the Project Emissions Accounting Memorandum, the EPA will be taking comment on whether our current view of this issue is reasonable, whether the ''substantially related'' criterion described here may speak to this issue, and other related matters.

3. Legal Basis Is Sound

We believe the 2009 NSR Aggregation Action is legally supportable and makes sense for sometimes difficult case-by-

[18] Project Emissions Accounting Memorandum at 9 (emphasis added).

[19] Letter from Steven C. Riva, U.S. EPA Region 2, to Kathleen Antoine, HOVENSA, LLC, ''Re: Emission Decreases Integral to Projects'' (June 7, 2010) (''EPA, by this letter, is not opining on the merits of HOVENSA's analysis regarding the underlying basis for 'integral to the project' approach.'').

[20] Indeed, the EPA views this latter situation as one where sources could potentially be incentivized to seek out emission reductions that might otherwise be foregone entirely—*e.g.,* because of perceived complexity with contemporaneous netting under Step 2 of the NSR applicability analysis.

case determinations required for assessing whether to aggregate nominally-separate projects. Contrary to the petitioner's argument, the use of the term ''substantially related'' would not create a carve-out from the scope of the statutory definition of ''modification.''

Drawing on arguments made by NRDC in its petition, in 2010 we had postulated, while ''[m]uch of the emphasis'' of *New York* v. *EPA,* 443 F.3d 880 (D.C. Cir. 2006) (*New York II*) and other cases had been on whether the EPA ''could exclude small changes from being considered potential modifications as defined in the Act,'' the court's reasoning in *New York II* also applies to a rule that would split apart one change into separate changes in order to limit the applicability of NSR.'' 75 FR 19571. The D.C. Circuit's *New York II* decision had focused on whether the EPA's amendment to the ''routine maintenance, repair and replacement'' provision of the NSR regulations which provided that a specifically defined category of ''equipment replacement'' projects did not constitute a ''physical change or change in the method of operation,'' was lawful. The court in *New York II* held that it was *not* lawful, opining that the EPA ''must apply NSR whenever a source conducts an emissions-increasing activity that fits within one of the ordinary meanings of physical change.'' 443 F.3d at 885.

In the 2010 Reconsideration Proposal, we said we then read the D.C. Circuit's opinion as ''requir[ing] EPA to aggregate any group of small changes'' that were ''sufficiently related to 'fit[] within one of the ordinary meanings of 'physical change.' '' 75 FR 19571. In this regard, we said that we ''agree[d] with [NRDC's] contention that, to the extent that our 'substantially related' interpretation,'' as set forth in the 2009 NSR Aggregation Action, would ''exclude meanings that fit within a reasonable understanding of the ordinary meaning of 'any physical change,' '' that interpretation would ''impermissibly narrow the scope of CAA section 111(a)(4).'' *Id.* We sought comment on this analysis of the statute and *New York II.*

Upon further consideration and after reviewing the public comments on this reconsideration proposal, the agency does not read *New York II* as supportive of the notion that the ''substantially related'' interpretation set forth in the 2009 NSR Aggregation Action is somehow contrary to the language of CAA section 111(a)(4). While we had previously suggested that there might be some weight to NRDC's argument that the '' 'aggregation of nominally separate changes that are *not* substantially related' also may be within an ordinary meaning of physical change,'' 75 FR 19571, *citing* NRDC Petition at 5–6 (emphasis in original), we do not now perceive any merit in NRDC's assertion.

With NRDC's arguments in mind, the agency at one point read *New York II* as suggesting that the CAA ''prohibits EPA from picking and choosing among meanings of the phrase 'any physical change . . . or change in the method of operation' if it would result in omitting a common meaning that would subject an emission increase to review.'' 75 FR 19571. Based on this, we were concerned that, ''[i]f 'substantially related' would omit an ordinary, common meaning of physical change that would bring an emissions-increasing project under review, then the definition would eliminate a type of physical change that Congress intended to cover (*i.e.,* the change that consists of the group of nominally-separate changes that comprise a project but do not qualify as 'substantially related').'' *Id.* Thus, we reasoned at the time ''that, to the extent that [the] 'substantially related' interpretation would exclude meanings that fit within a reasonable understanding of the ordinary meaning of 'any physical change,' '' then the 2009 NSR Aggregation Action ''would impermissibly narrow the scope of CAA § 111(a)(4).'' *Id.*

We now believe that such concerns were unwarranted. Upon further consideration, we do not view *New York II,* properly understood, as providing support for the proposition that a ''common meaning'' of a single ''change'' would include multiple changes, much less multiple, separate changes that are not substantially related, such as changes which are undertaken at a source at different times, or undertaken for different purposes, or which are otherwise unrelated to each other. That is, the EPA's current view is that nothing in *New York II* supports, much less compels, a reading of the CAA under which all ''nominally-separate changes'' are deemed to ''comprise'' a single ''project,'' where those changes are not substantially related. Nevertheless, under the interpretation reflected in the 2009 NSR Aggregation Action, multiple changes that are ''substantially related'' are to be considered to be one project for purposes of determining NSR applicability.

Finally, to the extent that NRDC argues that the aggregation of activities that are not substantially related into one activity that fits within the ordinary meaning of a physical change—and not aggregating those changes to compare to the significance level would violate *New York II*—it has provided no examples where that may be the case and have not followed the reasoning of their argument to its logical conclusion. This argument would require the EPA to prove a negative: That whatever interpretation or policy on aggregation we adopted would not exclude any level of aggregated activities that fit within the ordinary meaning of a physical change. This impossible task would mean that even the EPA aggregation policy prior to the 2009 NSR Aggregation Action was in violation of *New York II* because it allowed a facility to sometimes disaggregate activities when, if aggregated, they would fall within the ordinary meaning of physical change. A better approach to defining the scope of the ordinary meaning of physical change is to provide, as we did in the 2009 NSR Aggregation Action, a principle for source owners or operators to follow, here the ''substantially related'' principle, when defining the scope of ''a physical change in, or change in method of operation of,'' pursuant to 40 CFR 52.21(b)(52), in a particular case.

4. Adoption Is Not Mandatory

We acknowledge that, by not making any changes to the regulatory text, as had been proposed, it may have been somewhat unclear to some whether state and local air agencies have to adopt or implement the elements of the 2009 NSR Aggregation Action, and, if so, how they should do so. In the 2010 Reconsideration Proposal, we expressed our agreement with ''NRDC's assertion that the state and local implementation requirements of the NSR Aggregation Amendments are unclear,'' and that the ''question of whether a SIP amendment is required when the CFR remains unchanged is likely to cause confusion for reviewing authorities and other stakeholders.'' 75 FR 19572. Taking account of this confusion, the agency considered that it ''added support for our preferred position in this notice, which is to revoke'' the 2009 NSR Aggregation Action. *Id.*

We now find such concerns over potential ''confusion'' to have been overstated. In the Response to Comments document for the 2009 NSR Aggregation Action (2009 RTC), the agency had specifically noted that ''[s]ince we are not promulgating the proposed rule regulatory changes, we are not adding NSR minimum program elements that would require states to modify their SIP.'' 2009 RTC at 56. The agency continued that it would ''begin applying the interpretations laid out in the final action to activities that postdate actions after the effective date of the final rulemaking notice.'' *Id.* ''At

that time,'' the EPA explained, states ''may also begin applying EPA's interpretations to the extent they do not conflict with their approved SIPs.'' *Id.* We now believe it is likely that state and local permitting authorities would have understood this straightforward explanation.

Further, as previously discussed, determining whether a source has sought to circumvent NSR by failing to treat nominally-separate activities as a single project is inherently case-specific and fact-dependent. Given this, it is not reasonable to imagine that perfect clarity could ever be achieved. To the extent, however, that the 2009 NSR Aggregation Action, in setting forth both the ''substantially related'' interpretation and the EPA's policy for applying that interpretation, provides some meaningful guidance to sources and to state and local permitting authorities, we fail to understand how revoking the 2009 NSR Aggregation Action would serve to promote clarity.

Indeed, in this regard, we believe in most cases that sources and state and local air agencies already implement a standard that is similar to the substantially related standard. To the extent that a state or local air agency desires to formally adopt the 2009 NSR Aggregation Action, the EPA will provide support to those agencies to process SIP submittals and issue approvals, as warranted. In most cases, however, we do not think changes in state plans would be needed to implement this interpretation.

C. Completing the Reconsideration Proceeding

We believe that this final action addresses the concerns raised by the petitioner with respect to the 2009 NSR Aggregation Action—*e.g.,* adequate notice and logical outgrowth, the legal underpinnings of the action, state adoption, and our need to change or clarify our aggregation policy. Accordingly, this action concludes the reconsideration proceeding of the 2009 NSR Aggregation Action.

D. Lifting the Administrative Stay; Announcement of Effective Date

On May 18, 2010, after a series of temporary administrative stays of the 2009 NSR Aggregation Action, the EPA exercised the provisions of the APA section 705 to postpone the effectiveness of the action ''until judicial review is no longer pending or the EPA completes the reconsideration process.'' 75 FR 27644. Since this action concludes the reconsideration proceeding, and we have affirmed the legal consistency and policy appropriateness of the 2009 NSR Aggregation Action, we are hereby lifting the indefinite administrative stay and announcing the effective date of the action. The effective date of the 2009 NSR Aggregation Action, published in the **Federal Register** on January 15, 2009 (74 FR 2376), and delayed on February 13, 2009 (74 FR 7284), May 14, 2009 (74 FR 22693), and May 18, 2010 (75 FR 27643), begins again on November 15, 2018.

IV. Environmental Justice Considerations

We believe that this action does not have any effect on environmental justice communities. Through this action, the EPA is affirming its interpretation that its current NSR regulations allow for the 2009 NSR Aggregation Action and, as such, no increased burden is expected for source owners, permitting authorities, or environmental justice communities.

V. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

VI. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final agency actions by the EPA under the CAA. This section provides, in part, that petitions for review must be filed in the U.S. Court of Appeals for the District of Columbia Circuit (i) when the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator'' or (ii) when such action is locally or regionally applicable, if ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.''

This action completes the reconsideration proceeding and makes effective the 2009 NSR Aggregation Action. The 2009 NSR Aggregation Action is an interpretation of NSR rule language that applies in every state and territory in the United States where EPA is the permitting authority. Therefore, to the extent that this action is a ''final action,'' it is ''nationally applicable'' within the meaning of CAA section 307(b)(1).

Under section 307(b)(1) of the Act, to the extent that this action is judicially reviewable, petitions for judicial review of this action must be filed in the United States Court of Appeals for the District of Columbia Circuit by January 14, 2019.

VII. Statutory Authority

The statutory authority for this action is provided by section 301(a) of the CAA as amended (42 U.S.C. 7601(a)). This document is also subject to section 307(d) of the CAA (42 U.S.C. 7407(d)).

Dated: November 7, 2018.

Andrew R. Wheeler,

Acting Administrator.

[FR Doc. 2018–24820 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0744; FRL–9985–45]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on beet, sugar, roots and vegetable, root, except sugar beet, subgroup 1B. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 15, 2018. Objections and requests for hearings must be received on or before January 14, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0744, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0744 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 14, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0744, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 6, 2018 (83 FR 9471) (FRL–9973–27), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8590) by Syngenta Crop Protection, LLC, 18300 Greensboro Road, NC. The petition requested that 40 CFR 180.507 be amended by establishing tolerances for residues of the fungicide azoxystrobin, in or on beet, sugar, roots at 5.0 parts per million (ppm) and vegetable, root, subgroup 1B at 0.5 ppm. The petition also requested that the tolerance for vegetable, root, subgroup 1A be removed once these new tolerances are established. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing the tolerance level for vegetable, root, subgroup 1B at 1.0 ppm instead of 0.5 ppm. Additionally, the Agency has revised the commodity name to vegetable, root, except sugar beet, subgroup 1B. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for azoxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with azoxystrobin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

With repeated dosing by the oral route, the liver and bile ducts were consistently affected by azoxystrobin. Liver and biliary effects were seen in rats (increased liver weights, gross and histopathological lesions of the bile duct and liver), and in dogs (increased liver weights, clinical observations including fluid feces and salivation) and clinical chemistry alterations (including increased serum levels of alkaline phosphatase, and gamma-glutamyl transferase; and decreases in serum albumin). The effects seen are indicative of changes to liver/biliary function. Decreased body weight (rats and mice)

and decreased body weight gain (rats and rabbits) were also consistent findings across studies and species. Other effects including decreased food intake/utilization, increased diarrhea and other clinical toxicity observations such as urinary incontinence, salivation, hunched postures and distended abdomens were also seen in various studies (developmental toxicity, reproduction, and 90-day oral toxicity) in rats. Inhalation exposure to a soluble-concentrate (SC) formulation of azoxystrobin resulted in adverse microscopic changes in the nasal cavity and larynx.

No developmental effects were seen in the rabbit and rat developmental toxicity studies and no reproductive or offspring effects were seen in the 2-generation rat reproduction study. In the reproduction study, decreased body weights and increased adjusted liver weights were observed at the same dose in both offspring and parental animals. Therefore, the toxicity data showed no increased susceptibility in the young.

In the acute and subchronic neurotoxicity studies, there were no consistent indications of treatment-related neurotoxicity. There was no evidence of neurotoxicity seen in the acute neurotoxicity study in rats from a single gavage dose up to 2,000 mg/kg. There was also no evidence of neurotoxicity seen in the subchronic neurotoxicity study in rats up to the highest dose tested (201 mg/kg/day). Based on the toxicity profile of azoxystrobin, a developmental neurotoxicity study in rats is not needed.

Although azoxystrobin induced a weak mutagenic response in the mouse lymphoma assay (non-linear, slight but significant increases in the mutation frequency of mouse lymphoma cells), the activity expressed *in vitro* is not expected to be expressed in whole animals. There was no evidence of carcinogenicity in rats and mice at acceptable tested dose levels; therefore, azoxystrobin is classified as ''not likely to be carcinogenic to humans''.

Azoxystrobin has a low order of acute toxicity via oral, dermal and inhalation routes of exposure. Azoxystrobin is not an eye or skin irritant and is not a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by azoxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Azoxystrobin: Human Health Risk Assessment for a New Post-Harvest Use on Sugar Beets and Amend the existing Vegetable, Root, Subgroup 1A to Vegetable, Root, Subgroup 1B (except Sugar Beets) at pages 11–18 in docket ID number EPA–HQ–OPP–2017–0744.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AZOXYSTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	LOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	Acute RfD = 0.67 mg/kg/day. aPAD = 0.67 mg/kg/day	Acute Neurotoxicity—Rat. LOAEL = 200 mg/kg/day based on diarrhea at two-hours post dose at all dose levels tested.
Chronic dietary (All populations)	NOAEL = 18 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.18 mg/kg/day. cPAD = 0.18 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Feeding Study—Rat. LOAEL = 82.4/117 mg/kg/day (M/F) based on reduced body weights in both sexes and bile duct lesions in males.
Episodic granule ingestion (Children 1 to <2 years old).	LOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x	Residential LOC for MOE = 300.	Acute Neurotoxicity—Rat. LOAEL = 200 mg/kg/day based on diarrhea at two-hours post dose at all dose levels tested.
Incidental oral short-term (1–30 days) (Intermediate-term (1–6 months)).	NOAEL = 35 mg/kg/day UF_A= 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	2-generation reproduction study—Rats. LOAEL = 165 mg/kg/day based on decreased pup weights in both males and females (↓8–21%).
Inhalation (All durations)	Inhalation study NOAEL = 3.8 μg/L (inhalation absorption rate = 100%). UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	28-Day inhalation toxicity study in rats on SC formulation+. LOAEL = 12.2 μg/L based on adverse histopathological changes in the larynx (squamous metaplasia) and nasal cavity (metaplasia of the respiratory epithelium). There was an increase in severity with increases in the test concentrations.
Cancer (Oral, dermal, inhalation)	Azoxystrobin is classified as ''not likely to be carcinogenic to humans''.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to azoxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing azoxystrobin tolerances in 40 CFR 180.507. EPA assessed dietary exposures from azoxystrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for azoxystrobin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment is based on 100% of the registered crops treated, and tolerance-level residues for all existing and proposed commodities, except citrus fruits where the highest field trial residue was used as a refinement.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment was partially refined, and used tolerance-level residues for all commodities and average percent crop treated (PCT) estimates when available.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that azoxystrobin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses for the chronic dietary exposure assessment as follows: Almonds, 20%; apricots, 10%; artichokes, 20%; asparagus, <2.5%; barley, <2.5%; green beans, 15%; blueberries, 15%; broccoli, 10%; cabbage, 10%; caneberries, 5%; cantaloupes, 20%; carrots, 10%; cauliflower, <2.5%; celery, 10%; corn, <2.5%; cotton, <2.5%; cotton (seed treatment), 25%; cucumbers, 20%; dry beans/peas, <2.5%; eggplant, 30%; garlic, 70%; grapefruit, 20%; grapes, 5%; hazelnuts, 5%; lemons, <2.5%; lettuce, <2.5%; nectarines, <2.5%; onions, 5%; oranges, 5%; peaches, 5%; peanuts, 20%; peanuts (seed treatment), 30%; green peas, <2.5%; pecans, 5%; peppers, 20%; pistachios, 5%; plums/prunes, <2.5%; potatoes, 40%; potatoes (seed treatment), <1%; pumpkins, 20%; rice, 40%; soybeans, 5%; soybeans (seed treatment), <1%; spinach, 10%; squash, 20%; strawberries, 25%; sugar beets, 10%; sugar beets (seed treatment), <2.5%; sweet corn, 15%; tangelos, 25%; tangerines, 10%; tobacco, 15%; tomatoes, 25%; walnuts, <2.5%; watermelons, 15%; wheat, 5%; wheat seed (seed treatment), <1%. For crops not specified, 100 PCT was used.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which azoxystrobin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment

for azoxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of azoxystrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Surface Water Concentration Calculator (SWCC) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 70.2 parts per billion (ppb) for surface water and 3.1 ppb for ground water. For chronic exposures for non-cancer assessments the EDWCs of azoxystrobin are estimated to be 48.5 ppb for surface water and 3.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 70.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 48.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Azoxystrobin is currently registered for the following uses that could result in residential exposures: Conventional residential use on turf and ornamentals and antimicrobial uses as a materials preservative in paints and plastics. The proposed use will not result in additional residential exposures. Existing residential uses result in (1) short-term handler dermal and inhalation exposures for adults; (2) short-term post-application dermal exposures for adults, youth 11 to 16 years old, children 6 to 11 years old, and children 1 to <2 years old; and (3) short-term incidental oral exposures to children 1 to <2 years old. Since the effects from inhalation exposure differ from effects from oral exposure, the residential handler exposures are not aggregated with dietary exposures. No hazard was identified for dermal exposure. The Agency's assessment of risk aggregates residential exposure from hand-to-mouth incidental oral exposures to children 1 to <2 years old from preserved vinyl flooring.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found azoxystrobin to share a common mechanism of toxicity with any other substances, and azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that azoxystrobin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No developmental effects were seen in the rabbit and rat developmental toxicity studies, and no reproductive or offspring effects were seen in the 2-generation rat reproduction study. In the reproduction study, decreased body weights and increased adjusted liver weights were observed at the same dose in both offspring and parental animals. Therefore, the toxicity data showed no increased susceptibility in the young.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all exposure scenarios except acute exposure and episodic granule ingestion. For assessing acute dietary risk and episodic oral ingestion of granules, EPA is retaining an FQPA factor of 3X to account for the use of a LOAEL from the acute neurotoxicity study to derive an acute reference dose. The Agency believes that a 3X FQPA SF (as opposed to a 10X) will be adequate to extrapolate a NOAEL in assessing acute risk based on the following considerations:

- The LOAEL is based on a transient effect (diarrhea in rats) expected to be relatively insignificant in nature. This effect is also seen in other chemicals of the same class.
- The diarrhea was only seen in studies using gavage dosing in the rat, but not in studies using repeat dosing through dietary administration in rats or mice, and not through gavage dosing in rabbits.
- The very high dose level needed to reach the acute oral lethal dose $(LD)_{50}$ (>5,000 mg/kg), and the overall low toxicity of azoxystrobin.

The decision to reduce the FQPA safety factor to 1X for the assessment of the remaining exposure scenarios is based on the following findings:

i. The toxicity database for azoxystrobin is considered sufficient for selecting toxicity endpoints and PODs for risk assessment.

ii. There is no indication that azoxystrobin is a neurotoxic chemical. There was no evidence of neurotoxicity seen in the acute neurotoxicity study in rats from a single gavage dose up to 2,000 mg/kg. There was also no evidence of neurotoxicity seen in the subchronic neurotoxicity study in rats up to the highest dose tested (201 mg/kg/day). Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that azoxystrobin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. In the reproduction study, the offspring and the parental effects occurred at the same dose level.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary (food) exposure assessments utilized conservative upper-bound inputs including assuming 100% CT and tolerance-level residues for all commodities except citrus fruits where the highest field trial residue was

used as a refinement. The chronic dietary exposure assessment was partially refined, and used tolerance-level residues for all commodities and PCT information for selected crops. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to azoxystrobin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by azoxystrobin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 82% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to azoxystrobin from food and water will utilize 18% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of azoxystrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Azoxystrobin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to azoxystrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 390 for children 1 to <2 years old. Because EPA's level of concern for azoxystrobin is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, azoxystrobin is not expected to pose an intermediate-term risk. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, azoxystrobin is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to azoxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen-phosphorus detector (GC/NPD) method, RAM 243/04) is available to enforce the tolerance expression for residues of azoxystrobin and its *Z*-isomer in crop commodities. This method (designated RAM 243, dated 5/15/98) has been submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM, Volume II).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for azoxystrobin in or on root and tuber vegetables (except potato) at 1.0 ppm. This MRL is the same as the tolerance being established for azoxystrobin in the United States.

C. Response to Comments

EPA received ten comments to the docket EPA–HQ–OPP–2017–0744. However, only three comments were in response to the petition filed by Syngenta Crop Protection. One comment (ID: EPA–HQ–OPP–2017–0744–0007) among the three, is inclusive of the other two comments (ID: EPA–HQ–OPP–2017–0744–0008 and EPA–HQ–OPP–2017–0744–0009), and describes portions of the content of the **Federal Register** notice EPA published on March 6, 2018 (83 FR 9471), and expresses support for tolerances. The remaining seven comments were not germane to this action, therefore no further response from the Agency is required.

D. Revisions to Petitioned-For Tolerances

The Agency recommends increasing the tolerance for vegetable, root, except sugar beet, subgroup 1B from the proposed 0.5 ppm to 1.0 ppm to harmonize with the existing Codex MRL. Additionally, the Agency is revising the significant figure on root vegetables subgroup 1B based on current policy and revising the commodity definition to reflect the common commodity vocabulary currently used by the Agency. The commodity definition was revised from vegetable, root, subgroup 1B to vegetable, root, except sugar beet, subgroup 1B.

V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin, in or on beet, sugar, roots at 5.0 ppm and vegetable, root, except sugar beet, subgroup 1B at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and

Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 1, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.507:

■ a. Remove the entry for ''Vegetable, root, subgroup 1A'' from the table in paragraph (a)(1).

■ b. Add alphabetically ''Beet, sugar, roots''; and ''Vegetable, root, except sugar beet, subgroup 1B'' to the table in paragraph (a)(1).

The additions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Beet, sugar, roots	5.0
* * * * *	
Vegetable, root, except sugar beet, subgroup 1B	1.0
* * * * *	

* * * * *

[FR Doc. 2018–24974 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160906822–7547–02]

RIN 0648–XG618

Snapper-Grouper Fishery of the South Atlantic; 2018 Commercial Closure for Hogfish in the Florida Keys/East Florida Area of the South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the hogfish commercial sector in the exclusive economic zone (EEZ) of the South Atlantic for the Florida Keys/East Florida (FLK/EFL) stock for the 2018 fishing year through this temporary rule. NMFS estimates commercial hogfish landings for the FLK/EFL hogfish stock for the 2018 fishing year will reach the annual catch limit (ACL) on November 16, 2018. Therefore, NMFS closes the commercial sector for the FLK/EFL hogfish stock in the South Atlantic EEZ on November 16, 2018, through the remainder of the 2018 fishing year. This closure is necessary to protect the hogfish resource in the FLK/EFL region of the South Atlantic.

DATES: This rule is effective 12:01 a.m., local time, November 16, 2018, until 12:01 a.m., local time, January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes hogfish and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The final rule for Amendment 37 to the FMP established two stocks of hogfish in Federal waters of the South Atlantic and new stock boundaries under the jurisdiction of the South Atlantic Fishery Management Council (82 FR 34584; July 25, 2017). One stock is the Georgia through North Carolina

(GA/NC) hogfish stock, with a southern boundary extending east from the Florida/Georgia state border to the North Carolina and Virginia state border. The other stock is the FLK/EFL hogfish stock. The FLK/EFL hogfish stock boundary extends from the 25°09′ N latitude line off the west coast of Florida (near Cape Sable, Florida), east around South Florida, to the Florida/Georgia border. The final rule for Amendment 37 set the 2018 ACL for the commercial sector of the FLK/EFL hogfish stock at 4,524 lb (2,052 kg), round weight.

In accordance with regulations at 50 CFR 622.193(u)(2)(i), the commercial AMs for the FLK/EFL hogfish stock include an in-season closure if the commercial ACL is met or is projected to be met. NMFS is required to close the commercial sector for hogfish when the ACL has been met, or is projected to be met, by filing a notification to that effect with the Office of the Federal Register.

NMFS has determined that the 2018 commercial ACL for the EFL/FLK hogfish stock established by Amendment 37 will be met on November 16, 2018. Therefore, this temporary rule implements the AM to close the commercial sector for EFL/FLK hogfish stock in the South Atlantic for the remainder of the 2018 fishing year. Accordingly, the commercial sector for the EFL/FLK hogfish stock in the South Atlantic EEZ will be closed effective 12:01 a.m. local time, November 16, 2018, until January 1, 2019, the start of the next fishing year.

During the commercial closure, all sale or purchase of hogfish in or from the EEZ off the Florida Keys and east coast of Florida, and south of 25°09′ N lat. off the west coast of Florida is prohibited, and harvest or possession of this species is limited to the bag and possession limits. These bag and possession limits apply for this hogfish stock on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, without regard to where such species were harvested, *i.e.,* in state or Federal waters. The commercial sector for the EFL/FLK hogfish stock in the South Atlantic EEZ will reopen on January 1, 2019.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of hogfish in the South Atlantic snapper-grouper fishery and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.193(u)(2)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and public comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds that the need to immediately implement this action to close the commercial sector for this stock constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment on this temporary rule pursuant to 5 U.S.C. 553(b)(B), because such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the AMs established by Amendment 37 (82 FR 34584; July 25, 2017) and located at 50 CFR 622.193(u)(2)(i) have already been subject to notice and public comment. All that remains is to notify the public of the commercial closure for the EFL/FLK hogfish stock in the South Atlantic EEZ for the remainder of the 2018 fishing year. Such procedures are contrary to the public interest because of the need to immediately implement this action to protect the EFL/FLK hogfish stock, since time for notice and public comment will allow for continued commercial harvest and further exceedance of the commercial ACLs.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2018.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–24915 Filed 11–9–18; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XG624

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; General category October–November fishery for 2018; fishery reopening.

SUMMARY: NMFS has determined that a reopening of the Atlantic bluefin tuna (BFT) General category fishery is warranted. This action is intended to provide a reasonable opportunity to harvest the full annual U.S. BFT quota without exceeding it, while maintaining an equitable distribution of fishing opportunities across time periods; help achieve optimum yield in the BFT fishery; and optimize the ability of all permit categories to harvest their full BFT quota allocations. This action applies to Atlantic tunas General category (commercial) permitted vessels and Atlantic Highly Migratory Species (HMS) Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective 12:30 a.m., local time, November 12, 2018, through 11:30 p.m., local time, November 16, 2018.

FOR FURTHER INFORMATION CONTACT: Uriah Forest-Bulley, 978–675–2154, or Larry Redd, 301–427–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014). NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

NMFS recently published a final rule (*i.e.,* the ''quota rule'' (83 FR 51391, October 11, 2018)) that increased the baseline U.S. BFT quota from 1,058.79 mt to 1,247.86 mt and accordingly increased the subquotas for 2018, including an increase in the General category October through November period subquota from 60.7 mt to 70.2

mt, consistent with the annual BFT quota calculation process. On October 4, 2018, NMFS transferred 55 mt to the General category and closed the General category fishery effective October 5, 2018, based on projections that landings would meet or exceed the adjusted October through November subquota of 127.2 mt by that date (83 FR 50857, October 10, 2018). Since October 5, 2018, NMFS has reopened the October through November subquota period two separate times for multiple days in an attempt to allow the available quota to be harvested (83 FR 52169, October 16, 2018, and 83 FR 55108, November 2, 2018).

General Category Reopening

As of November 6, 2018, reports show that the October through November landings are still less than the available subquota of 127.2 mt. Based on landings rates, NMFS has determined that reopening the General category fishery for five days is appropriate.

Therefore, the General category fishery will reopen at 12:30 a.m., November 12, 2018, and close at 11:30 p.m., November 16, 2018. The General category daily retention limit during this reopening is one large medium or giant BFT per vessel per day/trip. This action applies to those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT. Retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the General and HMS Charter/Headboat categories must cease at 11:30 p.m. local time on November 16, 2018.

The General category will reopen automatically on December 1, 2018, for the December 2018 subquota period at the default retention limit of one fish. In December 2017, NMFS adjusted the General category base subquota for the December 2018 period to 10 mt (82 FR 60680, December 22, 2017), although this amount increased to 14.6 mt with finalization of the quota rule. Based on quota availability in the Reserve, NMFS may consider transferring additional quota to the December subquota period, as appropriate.

Fishermen may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *www.nmfs.noaa.gov/sfa/hms/.*

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason actions to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to implement the fishery reopening is impracticable and contrary to the public interest. The General category recently closed, but based on available BFT quotas, recent fishery performance, and the availability of BFT on the fishing grounds, responsive reopening of the fishery is warranted to allow fishermen to take advantage of availability of fish and of quota. NMFS could not have proposed this action earlier, as it needed to consider and respond to updated data and information about fishery conditions and this year's landings. If NMFS was to offer a public comment period now, after having appropriately considered that data, it would preclude fishermen from harvesting BFT that are legally available. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under § 635.27(a)(1), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: November 9, 2018.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–24954 Filed 11–9–18; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG625

Fisheries of the Exclusive Economic Zone off Alaska; Shortraker Rockfish in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of shortraker rockfish in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary because the 2018 total allowable catch of shortraker rockfish in the Central Regulatory Area of the GOA will be reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 9, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North

Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 total allowable catch (TAC) of shortraker rockfish in the Central Regulatory Area of the GOA is 305 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of shortraker rockfish in the Central Regulatory Area of the GOA will be reached. Therefore, NMFS is requiring that shortraker rockfish in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b). This action does not apply to fishing by trawl catcher/processors in the cooperative fishery in the Rockfish Program for the Central GOA.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of shortraker rockfish in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 8, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 9, 2018.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–24914 Filed 11–9–18; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 221
Thursday, November 15, 2018

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL RESERVE SYSTEM

12 CFR Part 268

[Docket No. R–1630]

RIN 7100–AF 23

Rules Regarding Equal Opportunity

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Board of Governors of the Federal Reserve System (the Board) is proposing to revise and expand its equal employment opportunity regulation to adopt recent changes the Equal Employment Opportunity Commission (EEOC) had made to its rules. The Board's proposed rule is intended to provide Board employees, applicants for employment, and others with the same substantive and procedural rights generally guaranteed to others under Title VII of the Civil Rights Act of 1964, the Equal Pay Act, the Age Discrimination in Employment Act, and the Rehabilitation Act and thus to comply with the spirit of those laws. The Board's proposed rule also clarifies provisions related to Board employees' right to bring a claim before the Merit System Protection Board and the Federal Labor Relations Board.

DATES: Comments on the notice of proposed rulemaking must be received on or before December 17, 2018.

ADDRESSES: You may submit comments, identified by Docket No. R–[1630 and RIN 7100–AF 23], by any of the following methods:

- *Agency Website: www.federalreserve.gov.* Follow the instructions for submitting comments at *www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreservegov.* Include the docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Sheila Clark, Program Director, Office of Diversity and Inclusion, Board of Governors of the Federal Reserve System, (202) 452–2883. For the hearing impaired only, Telecommunications Device for the Deaf (TDD) users may contact 202–263–4869.

SUPPLEMENTARY INFORMATION: The terms of Board employment are established by the Federal Reserve Act and rules established by the Board. 12 U.S.C. 244 (Section 244 provides that the ''employment, compensation, leave, and expenses'' of Board employees ''shall be governed solely by the provisions of this chapter and rules and regulations of the Board not inconsistent therewith.'') Although the Board has broad discretion to establish the terms of Board employment and can establish terms that deviate from the rights afforded to other government employees, the Board, as a matter of policy, has long aligned its employment practices with federal laws that provide for equal employment opportunity. Pursuant to this policy, Part 268 was issued by the Board to provide equal opportunity in employment in compliance with the spirit of Title VII of the Civil Rights Act of 1964 (Title VII), the Equal Pay Act, the Age Discrimination in Employment Act, and the Rehabilitation Act. Part 268 has not been updated in several years, and the Board is now proposing to amend it in order to better align its practices with those of the Equal Employment Opportunity Commission's (EEOC's) rules. The proposed revisions to Part 268 would:

1. Amend section 268.101 to prohibit discrimination on the basis of genetic information to ensure compliance with the Genetic Information Nondiscrimination Act of 2008 (GINA) and to make conforming changes throughout to reflect this proposed change.

2. Amend section 268.102(b)(3) to clarify that the Board follows Commission guidance and management directives relating to advice for ensuring compliance with Title VII, the Equal Pay Act, the Age Discrimination in Employment Act, GINA, and the Rehabilitation Act.

3. Amend section 268.1 to remove references to hiring and granting information access since those rules will be incorporated into internal Board policies;

4. Amend section 268.106(a)(5) to adopt the EEOC's rule requiring dismissal of complaints that allege discrimination on the basis of proposed personnel actions or other preliminary steps unless the complainant has alleged that the proposal or preliminary step is retaliatory;

5. Amend section 268.107(e) to require Board staff, EEO investigators, and complainants to comply with the Board's program for the security of Federal Open Market Committee (FOMC) information when investigating and processing complaints that require access to FOMC information;

6. Amend section 268.107(g) to adopt the EEOC's rule on investigating complaints which requires agencies that have not completed an investigation within EEOC's time limits to send a notice to the complainant indicating the investigation is not complete, providing the date by which it will be completed, and explaining that the complainant has the right to request a hearing or file a lawsuit;

7. Amend section 268.201 to reflect updated address information for the EEOC;

8. Amend section 268.203 to more closely reflect the EEOC's approach to designing an affirmative action plan for individuals with disabilities;

9. Amend section 268.204 and section 268.401 to reflect the EEOC's rules for processing class complaints;

10. Remove section 268.205 since its subject is not related to equal employment opportunity rules and since rules for hiring and granting access to information will be incorporated into the Board's internal policies;

11. Remove section 268.302 to eliminate procedures for handling mixed case complaints since mixed case complaints cannot be brought against the Board;

12. Amend section 268.403 to update address information and to incorporate the EEOC's rule that agencies submit appellate records and complaint files to the EEOC in a digital format that is acceptable to the EEOC;

13. Add a new section 268.405(b) to adopt the EEOC's procedures for class complaints which provide that an administrative judge's decision on the merits of a class complaint is a final decision which the Board can fully implement or appeal in its final action and to provide for expedited processing of appeals of decisions to accept or dismiss class complaints;

14. Amend section 268.502(c) to adopt the EEOC's rule which permits agencies up to 120 days to provide the particular relief the EEOC ordered; and

15. Amend section 268.710 to make changes to headings and titles to conform to the EEOC's rules and to the Board's functional titles.

Changes To Align With EEOC Rules

Except as described below, the above changes are necessary to align the Board's employment practices and complaint processing with the EEOC's rules. The proposed revisions to Part 268 are designed to align the Board's practices with changes the EEOC has made to its rules on Federal Sector Equal Employment Opportunity found at 29 CFR part 1614. In addition, the amendment to section 268.102(b)(3) is proposed in order to clarify that the Board follows Commission guidance and management directives relating to advice for ensuring compliance with Title VII, the Equal Pay Act, the Age Discrimination in Employment Act, GINA, and the Rehabilitation Act.

Complying With FOMC Security Requirements

Currently part 268 requires Board staff, EEO investigators, and complainants to protect confidential information of the Board but does not expressly address confidential FOMC information. Because it is conceivable that a complaint could require access to FOMC information, and because FOMC information is not solely Board information, the Board proposes amending section 268.107(e)(2) to expressly require those seeking access to FOMC information to agree to abide by the Program for Security of FOMC Information before being granted access to such information. This will ensure that FOMC information is protected in the same manner as other confidential Board information.

Remove Rules Related to Hiring and Granting Information Access

The revisions also eliminate section 268.205, which discusses the Board's rules for hiring non-citizens and for allowing access to confidential supervisory information (CSI) and FOMC information. The subject matter of this section is not relevant to the Board's equal employment opportunity rules. Thus, the proposed revisions would remove this section from the Board's equal employment opportunity regulation. Going forward, rules relating to the hiring of non-citizens and governing access to CSI and FOMC information will be incorporated in the Board's internal management policies.

Eliminate References to Mixed Case Complaints

The revisions would eliminate section 268.302, which addresses procedures that apply to ''mixed case complaints.'' A mixed case complaint is an employment complaint which raises violations of both EEO laws (over which the EEOC retains jurisdiction) and merit system principles, created by certain civil service laws over which the Merit Systems Protection Board (MSPB) retains jurisdiction. The Board is not subject to the MSPB's jurisdiction in light of its employment authorities under the Federal Reserve Act. Thus, the revisions would remove this provision of the regulation.

Update Titles To Reflect the Board's Organizational Structure

The revisions proposed to Subpart H reflect changes to the Board's organizational structure since the last time the Board updated its EEO Regulation. Subpart H prohibits discrimination on the basis of disability in programs or activities conducted by the Board and describes how to file complaints alleging such discrimination. The complaint process described in Subpart H incorporates references to position titles that are no longer in use at the Board. For example, Subpart H refers to the Equal Employment Opportunity Office, which has since been replaced by the Office of Diversity and Inclusion; to an EEO Program Director, which has since been replaced by the Office of Diversity and Inclusion Program Director; and to a Staff Director for Management, which has been replaced by the Chief Operating Officer. The amendments to Subpart H replace the out-of-date titles with up-to-date information each place the rule refers to such titles.

Regulatory Analysis

A. Paperwork Reduction Act

Certain provisions of the proposed rule contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521). In accordance with the requirements of the PRA, the Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for the Board is 7100–0313. The Board will address the information collection requirements associated with this proposed rule under a separate **Federal Register** notice.

B. Regulatory Flexibility Act: Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* requires a regulatory flexibility analysis only for rules that will have a significant impact on a substantial number of small entities. Because this rulemaking applies exclusively to Board employees and applicants for employment, the Regulatory Flexibility Act does not apply.

C. Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires each federal banking agency to use plain language in all rules published after January 1, 2000. In light of this requirement, the Board believes this rule is presented in a simple and straightforward manner and is consistent with this ''plain language'' directive.

List of Subjects

12 CFR Part 268

Administrative practice and procedure, Aged, Civil rights, Equal employment opportunity, Federal buildings and facilities, Genetic information, Government employees, Individuals with disabilities, Religious discrimination, Sex discrimination, Wages.

Authority and Issuance

For the reasons set forth in the preamble, the Board proposes to amend 12 CFR part 268 as set forth below:

PART 268—RULES REGARDING EQUAL OPPORTUNITY

Subpart A—General Provisions and Administration

■ 1. The authority citation for part 268 continues to read as follows:

Authority: 12 U.S.C. 244 and 248(i), (k) and (l).

■ 2. In § 268.1 revise paragraph (b) to read as follows:

§ 268.1 Authority, purpose and scope.

* * * * *

(b) Purpose and scope. This part sets forth the Board's policy, program and procedures for providing equal opportunity to Board employees and applicants for employment without regard to race, color, religion, sex, national origin, age, disability, or genetic information. It also sets forth the Board's policy, program and procedures for prohibiting discrimination on the basis of disability in programs and activities conducted by the Board.

■ 3. Revise § 268.101 to read as follows:

§ 268.101 General policy for equal opportunity.

(a) It is the policy of the Board to provide equal opportunity in employment for all persons, to prohibit discrimination in employment because of race, color, religion, sex, national origin, age, disability, or genetic information and to promote the full realization of equal opportunity in employment through a continuing affirmative program.

(b) No person shall be subject to retaliation for opposing any practice made unlawful by Title VII of the Civil Rights Act (title VII) (42 U.S.C. 2000e *et seq.*), the Age Discrimination in Employment Act (ADEA) (29 U.S.C. 621 *et seq.*), the Equal Pay Act (29 U.S.C. 206(d)), the Rehabilitation Act (29 U.S.C. 791 *et seq.*), or the Genetic Information Nondiscrimination Act (GINA) (42 U.S.C. 2000ff *et seq.*) or for participating in any stage of administrative or judicial proceedings under those statutes.

■ 4. In § 268.102 revise paragraphs (a)(4), (b)(3) and (4) to read as follows:

§ 268.102 Board program for equal employment opportunity.

(a) * * *

(4) Communicate the Board's equal employment opportunity policy and program and its employment needs to all sources of job candidates without regard to race, color, religion, sex, national origin, age disability, or genetic information, and solicit their recruitment assistance on a continuing basis;

* * * * *

(b) * * *

(3) Appraise its personnel operations at regular intervals to assure their conformity with the Board's program, this part 268 and the instructions contained in the Commission's management directives relating to advice for ensuring compliance with the provisions of title VII, the Equal Pay Act, the Age Discrimination in Employment Act, GINA, and the Rehabilitation Act.

(4) Designate a Director for Equal Employment Opportunity (EEO Programs Director), EEO Officer(s), and such Special Emphasis Program Managers/Coordinators (*e.g.,* People with Disabilities Program, Federal Women's Program and Hispanic Employment Program), clerical and administrative support as may be necessary to carry out the functions described in this part in all organizational units of the Board and at all Board installations. The EEO Programs Director shall be under the immediate supervision of the Chair. The EEO Programs Director may also serve as the Director of the Office of Diversity and Inclusion.

* * * * *

■ 5. In § 268.103 revise paragraph (a) to read as follows:

§ 268.103 Complaints of discrimination covered by this part.

(a) Individual and class complaints of employment discrimination and retaliation prohibited by title VII (discrimination on the basis of race, color, religion, sex and national origin), the ADEA (discrimination on the basis of age when the aggrieved person is at least 40 years of age), the Rehabilitation Act (discrimination on the basis of disability), the Equal Pay Act (sex-based wage discrimination), or GINA (discrimination on the basis of genetic information) shall be processed in accordance with this part. Complaints alleging retaliation prohibited by these statutes are considered to be complaints of discrimination for purposes of this part.

* * * * *

■ 6. In § 268.104 revise intro paragraph (a) and paragraph (d) to read as follows:

§ 268.104 Pre-complaint processing.

(a) Aggrieved persons who believe they have been discriminated against on the basis of race, color, religion, sex, national origin, age disability, or genetic information must consult a Counselor prior to filing a complaint in order to try to informally resolve the matter.

* * *

(d) Unless the aggrieved person agrees to a longer counseling period under paragraph (e) of this section, or the aggrieved person chooses an alternative dispute resolution procedure in accordance with paragraph (b)(2) of this section, the Counselor shall conduct the final interview with the aggrieved person within 30 days of the date the aggrieved person contacted the Board's Office of Diversity and Inclusion to request counseling. If the matter has not been resolved, the aggrieved person shall be informed in writing by the Counselor, not later than the thirtieth day after contacting the Counselor, of the right to file a discrimination complaint with the Board. This notice shall inform the complainant of the right to file a discrimination complaint within 15 days of receipt of the notice, of the appropriate official with whom to file a complaint and of the complainant's duty to assure that the Programs Director is informed immediately if the complainant retains counsel or a representative.

* * * * *

■ 7. In § 268.106 revise paragraphs (a)(4) and (5) to read as follows:

§ 268.106 Dismissals of complaints.

(a) * * *

(4) Reserved.

(5) That is moot or alleges that a proposal to take a personnel action, or other preliminary step to taking a personnel action, is discriminatory, unless the complaint alleges that the proposal or preliminary step is retaliatory;

* * * * *

■ 8. Amend § 268.107 by:

■ a. Adding a sentence at the end of paragraph (e)(2);

■ b. Redesignating paragraph (g) as paragraph (h) and adding new paragraph (g).

The additions and redesignation read as follows.

§ 268.107 Investigation of complaints.

* * * * *

(e) (1) * * *

(2) * * * Confidential supervisory information, as defined in 12 CFR 261.2(c), and other confidential information of the Board may be included in the investigative file by the investigator, the EEO Programs Director, or another appropriate officer of the Board, where such information is relevant to the complaint. Neither the complainant nor the complainant's personal representative may make further disclosure of such information, however, except in compliance with the Board's Rules Regarding Availability of

Information, 12 CFR part 261, and where applicable, the Board's Rules Regarding Access to Personal Information under the Privacy Act of 1974, 12 CFR part 261a. Any party or individual, including an investigator, who requires access to FOMC information must agree to abide by the Program for Security of FOMC Information before being granted access to such information.

* * * * *

(g) If the Board does not send the notice required in paragraph (f) of this section within the applicable time limits, it shall, within those same time limits, issue a written notice to the complainant informing the complainant that it has been unable to complete its investigation within the time limits required by § 268.107(f) and estimating a date by which the investigation will be completed. Further, the notice must explain that if the complainant does not want to wait until the agency completes the investigation, he or she may request a hearing in accordance with paragraph (h) of this section, or file a civil action in an appropriate United States District Court in accordance with § 268.406(b). Such notice shall contain information about the hearing procedures.

■ 8. In § 268.108 revise the subject heading of paragraph (g) to read as follows:

§ 268.108 Hearings.

* * * * *

(g) Summary Judgement. * * *

* * * * *

■ 9. Amend § 268.201 by revising paragraph (a) and introductory text paragraph (c) to read as follows:

§ 268.201 Age Discrimination in Employment Act.

(a) As an alternative to filing a complaint under this part, an aggrieved individual may file a civil action in a United States district court under the ADEA against the agency after giving the Commission not less than 30 days' notice of the intent to file such an action. Such notice must be filed in writing with EEOC, at P.O. Box 77960, Washington, DC 20013, or by personal delivery or facsimile within 180 days of the occurrence of the alleged unlawful practice.

* * *

(c) When an individual has filed an administrative complaint alleging age discrimination, administrative remedies will be considered to be exhausted for purposes of filing a civil action:

* * *

■ 10. Revise § 268.203 to read as follows:

§ 268.203 Rehabilitation Act.

(a) *Definitions.* The following definitions apply for purposes of this section:

(1) The term *ADA* means title I of the Americans with Disabilities Act of 1990, as amended (42 U.S.C. 12101 through 12117), title V of the Americans with Disabilities Act, as amended (42 U.S.C. 12201 through 12213), as it applies to employment, and the regulations of the Equal Employment Opportunity Commission implementing titles I and V of the ADA at 29 CFR part 1630.

(2) The term *disability* means disability as defined under 29 CFR 1630.2(g) through (l).

(3) The term *hiring authority that takes disability into account* means a hiring authority established under written Board policy that permits the Board to consider disability status during the hiring process.

(4) The term *personal assistance service provider* means an employee or independent contractor whose primary job functions include provision of personal assistance services.

(5) The term *personal assistance services* means assistance with performing activities of daily living that an individual would typically perform if he or she did not have a disability, and that is not otherwise required as a reasonable accommodation, including, for example, assistance with removing and putting on clothing, eating, and using the restroom.

(6) The term *Plan* means an affirmative action plan for the hiring, placement, and advancement of individuals with disabilities.

(7) Reserved.

(8) The term *Section 501* means section 501 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 791).

(9) The term *targeted disability* means a disability that is designated as a ''targeted disability or health condition'' on the Office of Personnel Management's Standard Form 256 or that falls under one of the first 12 categories of disability listed in Part A of question 5 of the Equal Employment Opportunity Commission's Demographic Information on Applicants form.

(10) The term *undue hardship* has the meaning set forth in 29 CFR part 1630.

(b) *Nondiscrimination.* The Board shall not discriminate on the basis of disability in regard to the hiring, advancement or discharge of employees, employee compensation, job training, or other terms, conditions, and privileges of employment. The standards used to determine whether Section 501 has been violated in a complaint alleging employment discrimination under this part shall be the standards applied under the ADA.

(c) *Model employer.* The Board shall be a model employer of individuals with disabilities. The Board shall give full consideration to the hiring, advancement, and retention of qualified individuals with disabilities in its workforce. The Board shall also take affirmative action to promote the recruitment, hiring, and advancement of qualified individuals with disabilities, with the goal of eliminating under-representation of individuals with disabilities in the Board's workforce.

(d) *Affirmative action plan.* The Board shall adopt and implement a Plan that provides sufficient assurances, procedures, and commitments to provide adequate hiring, placement, and advancement opportunities for individuals with disabilities at all levels of Board employment. The Board's Plan must meet the following criteria:

(1) *Disability hiring and advancement program*—

(i) *Recruitment.* The Plan shall require the Board to take specific steps to ensure that a broad range of individuals with disabilities, including individuals with targeted disabilities, will be aware of and be encouraged to apply for job vacancies when eligible. Such steps shall include, at a minimum—

(A) Use of programs and resources that identify job applicants with disabilities, including individuals with targeted disabilities, who are eligible to be appointed under a hiring authority that takes disability into account, examples of which could include programs that provide the qualifications necessary for particular positions within the Board to individuals with disabilities, databases of individuals with disabilities who previously applied to the Board but were not hired for the positions they applied for, and training and internship programs that lead directly to employment for individuals with disabilities; and

(B) Establishment and maintenance of contacts (which may include formal agreements) with organizations that specialize in providing assistance to individuals with disabilities, including individuals with targeted disabilities, in securing and maintaining employment, such as American Job Centers, State Vocational Rehabilitation Agencies, the Veterans' Vocational Rehabilitation and Employment Program, Centers for Independent Living, and Employment Network service providers.

(ii) *Application process.* The Plan shall ensure that the Board has designated sufficient staff to handle any disability-related issues that arise during the application and selection

processes, and shall require the Board to provide such individuals with sufficient training, support, and other resources to carry out their responsibilities under this section. Such responsibilities shall include, at a minimum—

(A) Ensuring that disability-related questions from members of the public regarding the agency's application and selection processes are answered promptly and correctly, including questions about reasonable accommodations needed by job applicants during the application and selection processes and questions about how individuals may apply for appointment under hiring authorities that take disability into account;

(B) Processing requests for reasonable accommodations needed by job applicants during the application and placement processes, and ensuring that the Board provides such accommodations when required to do so under the standards set forth in 29 CFR part 1630;

(C) Accepting applications for appointment under hiring authorities that take disability into account, if permitted under written Board policy;

(D) If an individual has applied for appointment to a particular position under a hiring authority that takes disability into account, determining whether the individual is eligible for appointment under such authority, and, if so, forwarding the individual's application to the relevant hiring officials with an explanation of how and when the individual may be appointed, consistent with all applicable laws;

(E) Overseeing any other Board programs designed to increase hiring of individuals with disabilities.

(iii) *Advancement program.* The Plan shall require the Board to take specific steps to ensure that current employees with disabilities have sufficient opportunities for advancement. Such steps may include, for example—

(A) Efforts to ensure that employees with disabilities are informed of and have opportunities to enroll in relevant training, including management training when eligible;

(B) Development or maintenance of a mentoring program for employees with disabilities; and

(C) Administration of exit interviews that include questions on how the Board could improve the recruitment, hiring, inclusion, and advancement of individuals with disabilities.

(2) *Disability anti-harassment policy.* The Plan shall require the Board to state specifically in its anti-harassment policy that harassment based on disability is prohibited, and to include in its training materials examples of the types of conduct that would constitute disability-based harassment.

(3) *Reasonable accommodation*—

(i) *Procedures.* The Plan shall require the Board to adopt, post on its public website, and make available to all job applicants and employees in written and accessible formats, reasonable accommodation procedures that are easy to understand and that, at a minimum—

(A) Explain relevant terms such as ''reasonable accommodation,'' ''disability,'' ''interactive process,'' ''qualified,'' and ''undue hardship,'' consistent with applicable statutory and regulatory definitions, using examples where appropriate;

(B) Explain that reassignment to a vacant position for which an employee is qualified, and not just permission to compete for such position, is a reasonable accommodation, and that the Board must consider providing reassignment to a vacant position as a reasonable accommodation when it determines that no other reasonable accommodation will permit an employee with a disability to perform the essential functions of his or her current position;

(C) Notify supervisors and other relevant Board employees how and where they are to conduct searches for available vacancies when considering reassignment as a reasonable accommodation;

(D) Explain that an individual may request a reasonable accommodation orally or in writing at any time, need not fill out any specific form in order for the interactive process to begin, and need not have a particular accommodation in mind before making a request, and that the request may be made to a supervisor or manager in the individual's chain of command, the office designated by the Board to oversee the reasonable accommodation process, any Board employee connected with the application process, or any other individual designated by the Board to accept such requests;

(E) Include any forms the Board uses in connection with a reasonable accommodation request as attachments, and indicate that such forms are available in alternative formats that are accessible to people with disabilities;

(F) Describe the Board's process for determining whether to provide a reasonable accommodation, including the interactive process, and provide contact information for the individual or program office from whom requesters will receive a final decision;

(G) Provide guidance to supervisors on how to recognize requests for reasonable accommodation;

(H) Require that decision makers communicate, early in the interactive process and periodically throughout the process, with individuals who have requested a reasonable accommodation;

(I) Explain when the Board may require an individual who requests a reasonable accommodation to provide medical information that is sufficient to explain the nature of the individual's disability, his or her need for reasonable accommodation, and how the requested accommodation, if any, will assist the individual to apply for a job, perform the essential functions of a job, or enjoy the benefits and privileges of the workplace;

(J) Explain the Board's right to request relevant supplemental medical information if the information submitted by the requester is insufficient for the purposes specified in paragraph (d)(3)(i)(I) of this section;

(K) Explain the Board's right to have medical information reviewed by a medical expert of the Board's choosing at the Board's expense;

(L) Explain the Board's obligation to keep medical information confidential, in accordance with applicable laws and regulations, and the limited circumstances under which such information may be disclosed;

(M) Designate the maximum amount of time the Board has, absent extenuating circumstances, to either provide a requested accommodation or deny the request, and explain that the time limit begins to run when the accommodation is first requested;

(N) Explain that the Board will not be expected to adhere to its usual timelines if an individual's health professional fails to provide needed documentation in a timely manner;

(O) Explain that, where a particular reasonable accommodation can be provided in less than the maximum amount of time permitted under paragraph (d)(3)(i)(M) of this section, failure to provide the accommodation in a prompt manner may result in a violation of the Rehabilitation Act;

(P) Provide for expedited processing of requests for reasonable accommodations that are needed sooner than the maximum allowable time frame permitted under paragraph (d)(3)(i)(M) of this section;

(Q) Explain that, when all the facts and circumstances known to the Board make it reasonably likely that an individual will be entitled to a reasonable accommodation, but the accommodation cannot be provided immediately, the Board shall provide an interim accommodation that allows the individual to perform some or all of the essential functions of his or her job, if

it is possible to do so without imposing undue hardship on the Board;

(R) Inform applicants and employees how they may track the processing of requests for reasonable accommodation;

(S) Explain that, where there is a delay in either processing a request for or providing a reasonable accommodation, the Board must notify the individual of the reason for the delay, including any extenuating circumstances that justify the delay;

(T) Explain that individuals who have been denied reasonable accommodations have the right to file complaints pursuant to 12 CFR 268.105;

(U) Encourage the use of voluntary informal dispute resolution processes that individuals may use to obtain prompt reconsideration of denied requests for reasonable accommodation;

(V) Provide that the Board shall give the requester a notice consistent with the requirements of paragraph (d)(3)(iii) of this section at the time a request for reasonable accommodation is denied; and

(W) Provide information on how to access additional information regarding reasonable accommodation, including, at a minimum, Commission guidance and technical assistance documents.

(ii) *Cost of accommodations.* The Plan shall require the Board to take specific steps to ensure that requests for reasonable accommodation are not denied for reasons of cost, and that individuals with disabilities are not excluded from employment due to the anticipated cost of a reasonable accommodation, if the resources available to the Board as a whole, excluding those designated by statute for a specific purpose that does not include reasonable accommodation, would enable it to provide an effective reasonable accommodation without undue hardship. Such steps shall be reasonably designed to, at a minimum—

(A) Ensure that anyone who is authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware that, pursuant to the regulations implementing the undue hardship defense at 29 CFR part 1630, all resources available to the agency as a whole, excluding those designated by statute for a specific purpose that does not include reasonable accommodation, are considered when determining whether a denial of reasonable accommodation based on cost is lawful; and

(B) Ensure that anyone authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware of, and knows how to arrange for the use of, Board resources available to provide the accommodation, including any centralized fund the Board may have for that purpose.

(iii) *Notification of basis for denial.* The Plan shall require the Board to provide a job applicant or employee who is denied a reasonable accommodation with a written notice at the time of the denial, in an accessible format when requested, that—

(A) Explains the reasons for the denial and notifies the job applicant or employee of any available internal appeal or informal dispute resolution processes;

(B) Informs the job applicant or employee of the right to challenge the denial by filing a complaint of discrimination under this part;

(C) Provides instructions on how to file such a complaint; and

(D) Explains that, pursuant to 12 CFR 268.105, the right to file a complaint will be lost unless the job applicant or employee initiates contact with an EEO Counselor within 45 days of the denial, regardless of whether the applicant or employee participates in an informal dispute resolution process.

(4) *Accessibility of facilities and technology*—

(i) *Notice of rights.* The Plan shall require the Board to adopt, post on its public website, and make available to all employees in written and accessible formats, a notice that—

(A) Explains their rights under Section 508 of the Rehabilitation Act of 1973, 29 U.S.C. 794d, concerning the accessibility of agency technology, and the Architectural Barriers Act, 42 U.S.C. 4151 through 4157, concerning the accessibility of agency building and facilities;

(B) Provides contact information for a Board employee who is responsible for ensuring the physical accessibility of the Board's facilities under the Architectural Barriers Act of 1968, and a Board employee who is responsible for ensuring that the electronic and information technology purchased, maintained, or used by the agency is readily accessible to, and usable by, individuals with disabilities, as required by Section 508 of the Rehabilitation Act of 1973; and

(C) Provides instructions on how to file complaints alleging violations of the accessibility requirements of the Architectural Barriers Act of 1968 and Section 508 of the Rehabilitation Act of 1973.

(ii) *Assistance with filing complaints at other agencies.* If the Board's investigation of a complaint filed under Section 508 of the Rehabilitation Act of 1973 or the Architectural Barriers Act of 1968 shows that a different entity is responsible for the alleged violation, the Plan shall require the Board to inform the individual who filed the complaint where he or she may file a complaint against the other entity, if possible.

(5) *Personal assistance services allowing employees to participate in the workplace*—

(i) *Obligation to provide personal assistance services.* The Plan shall require the Board to provide an employee with, in addition to professional services required as a reasonable accommodation under the standards set forth in 29 CFR part 1630, personal assistance services during work hours and job-related travel if

(A) The employee requires such services because of a targeted disability;

(B) Provision of such services would, together with any reasonable accommodations required under the standards set forth in 29 CFR part 1630, enable the employee to perform the essential functions of his or her position; and

(C) Provision of such services would not impose undue hardship on the Board.

(ii) *Service providers.* The Plan shall state that personal assistance services required under paragraph (d)(5)(i) of this section must be performed by a personal assistance service provider. The Plan may permit the Board to require personal assistance service providers to provide personal assistance services to more than one individual. The Plan may also permit the Board to require personal assistance service providers to perform tasks unrelated to personal assistance services, but only to the extent that doing so does not result in failure to provide personal assistance services required under paragraph (d)(5)(i) of this section in a timely manner.

(iii) *No adverse action.* The Plan shall prohibit the Board from taking adverse actions against job applicants or employees based on their need for, or perceived need for, personal assistance services.

(iv) *Selection of personal assistance service providers.* The Plan shall require the Board, when selecting someone who will provide personal assistance services to a single individual, to give primary consideration to the individual's preferences to the extent permitted by law.

(v) *Written procedures.* The Plan shall require the Board to adopt, post on its public website, and make available to all job applicants and employees in written and accessible formats, procedures for processing requests for personal assistance services. The Board may satisfy this requirement by stating,

in the procedures required under paragraph (d)(3)(i) of this section, that the process for requesting personal assistance services, the process for determining whether such services are required, and the Board's right to deny such requests when provision of the services would pose an undue hardship, are the same as for reasonable accommodations.

(6) *Utilization analysis*—

(i) *Current utilization.* The Plan shall require the Board to perform a workforce analysis annually to determine the percentage of its employees at each grade and salary level who have disabilities, and the percentage of its employees at each grade and salary level who have targeted disabilities.

(ii) *Source of data.* For purposes of the analysis required under paragraph (d)(6)(i) of this section an employee may be classified as an individual with a disability or an individual with a targeted disability on the basis of—

(A) The individual's self-identification as an individual with a disability or an individual with a targeted disability on a form, including but not limited to the Office of Personnel Management's Standard Form 256, which states that the information collected will be kept confidential and used only for statistical purposes, and that completion of the form is voluntary;

(B) Records relating to the individual's appointment under a hiring authority that takes disability into account, if applicable; and

(C) Records relating to the individual's requests for reasonable accommodation, if any.

(iii) *Data accuracy.* The Plan shall require the Board to take steps to ensure that data collected pursuant to paragraph (d)(6)(i) of this section are accurate.

(7) *Goals*—

(i) *Adoption.* The Plan shall commit the Board to the goal of ensuring that—

(A) No less than 12% of employees who have salaries equal to or greater than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with disabilities;

(B) No less than 12% of employees who have salaries less than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with disabilities;

(C) No less than 2% of employees who have salaries equal to or greater than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with targeted disabilities; and

(D) No less than 2% of employees who have salaries less than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with targeted disabilities.

(ii) *Progression toward goals.* The Plan shall require the Board to take specific steps that are reasonably designed to gradually increase the number of persons with disabilities or targeted disabilities employed at the Board until it meets the goals established pursuant to paragraph (d)(7)(i) of this section. Examples of such steps include, but are not limited to—

(A) Increased use of hiring authorities that take disability into account to hire or promote individuals with disabilities or targeted disabilities, as applicable;

(B) To the extent permitted by applicable laws, consideration of disability or targeted disability status as a positive factor in hiring, promotion, or assignment decisions;

(C) Disability-related training and education campaigns for all employees in the Board;

(D) Additional outreach or recruitment efforts;

(E) Increased efforts to hire and retain individuals who require supported employment because of a disability, who have retained the services of a job coach at their own expense or at the expense of a third party, and who may be given permission to use the job coach during work hours as a reasonable accommodation without imposing undue hardship on the Board; and

(F) Adoption of training, mentoring, or internship programs for individuals with disabilities.

(8) *Recordkeeping.* The Plan shall require the Board to keep records that it may use to determine whether it is complying with the nondiscrimination and affirmative action requirements imposed under Section 501, and to make such records available to the Commission upon the Commission's request, including, at a minimum, records of—

(i) The number of job applications received from individuals with disabilities, and the number of individuals with disabilities who were hired by the Board;

(ii) The number of job applications received from individuals with targeted disabilities, and the number of individuals with targeted disabilities who were hired by the Board;

(iii) All rescissions of conditional job offers, demotions, and terminations taken against applicants or employees as a result of medical examinations or inquiries;

(iv) All Board employees hired under special hiring authority for person with certain disabilities, and each such employee's date of hire, entering grade level, probationary status, and current grade level;

(v) The number of employees appointed under special hiring authority for persons with certain disabilities who successfully completed the Board's Provisional Employment period and the number of such employees who were terminate prior to the end of their Provisional Employment period; and

(vi) Details about each request for reasonable accommodation including, at a minimum—

(A) The specific reasonable accommodation requested, if any;

(B) The job sought by the requesting applicant or held by the requesting employee;

(C) Whether the accommodation was needed to apply for a job, perform the essential functions of a job, or enjoy the benefits and privileges of employment;

(D) Whether the request was granted (which may include an accommodation different from the one requested) or denied;

(E) The identity of the deciding official;

(F) If denied, the basis for such denial; and

(G) The number of days taken to process the request.

(e) *Reporting*—

(1) *Submission to the Commission.* On an annual basis the Board shall submit to the Commission at such time and in such manner as the Commission deems appropriate—

(i) A copy of its current Plan;

(ii) The results of the two most recent workforce analyses performed pursuant to paragraph (d)(6) of this section showing the percentage of employees with disabilities and employees with targeted disabilities in each of the designated pay groups;

(iii) The number of individuals appointed to positions within the Board under special hiring authority for persons with certain disabilities during the previous year, and the total number of employees whose employment at the Board began by appointment under special hiring authority for persons with certain disabilities; and

(iv) A list of changes made to the Plan since the prior submission, if any, and an explanation of why those changes were made.

(2) *Availability to the public.* The Board shall make the information submitted to the Commission pursuant to paragraph (e)(1) of this section available to the public by, at a minimum, posting a copy of the submission on its public website and providing a means by which members of

the public may request copies of the submission in accessible formats.

* * * * *

■ 11. Amend § 268.204 by revising paragraphs (i) through (k); and the third sentence of paragraph (l)(3) to read as follows:

§ 268.204 Class complaints.

* * * * *

(i) *Decisions.* The administrative judge shall transmit to the agency and class agent a decision on the complaint, including findings, systemic relief for the class and any individual relief, where appropriate, with regard to the personnel action or matter that gave rise to the complaint. If the administrative judge finds no class relief appropriate, he or she shall determine if a finding of individual discrimination is warranted and if so, shall order appropriate relief.

(j) *Board final action.* (1) Within 60 days of receipt of the administrative judge's decision on the complaint, the Board shall take final action by issuing a final order. The final order shall notify the class agent whether or not the Board will fully implement the decision of the administrative judge and shall contain notice of the class agent's right to appeal to the Commission, the right to file a civil action in federal district court, the name of the proper defendant in any such lawsuit, and the applicable time limits for appeals and lawsuits. If the final order does not fully implement the decision of the administrative judge, then the Board shall simultaneously file an appeal in accordance with § 268.403 and append a copy of the appeal to the final order. A copy of EEOC Form 573 shall be attached to the final order.

(2) If the Board does not issue a final order within 60 days of receipt of the administrative judge's decision, then the decision of the administrative judge shall become the final action of the Board.

(3) A final order on a class complaint shall, subject to subpart E of this part, be binding on all members of the class and the Board.

(k) *Notification of final action:* The Board shall notify class members of the final action and the relief awarded, if any, through the same media employed to give notice of the existence of the class complaint. The notice, where appropriate, shall include information concerning the rights of class members to seek individual relief, and of the procedures to be followed. Notice shall be given by the Board within 10 days of the transmittal of the final action to the agent.

(l) * * *

(3) * * * The claim must include a specific detailed showing that the claimant is a class member who was affected by the discriminatory policy or practice, and that this discriminatory action took place within the period of time for which class-wide discrimination was found in the final order. * * *

* * * * *

§ 268.205 [Removed and Reserved]

■ 12. Remove and Reserve § 268.205.

§ 268.302 [Removed and Reserved]

■ 13. Remove and Reserve § 268.302.

■ 14. Amend § 268.401 by revising paragraph (c) to read as follows:

§ 268.401 Appeals to the Equal Employment Opportunity Commission.

* * * * *

(c) A class agent or the Board may appeal an administrative judge's decision accepting or dismissing all or part of a class complaint; a class agent may appeal the Board's final action or the Board may appeal an administrative judge's decision on a class complaint; a class member may appeal a final decision on a claim for individual relief under a class complaint; and a class member, a class agent or the Board may appeal a final decision on a petition pursuant to § 268.204(g)(4).

* * * * *

■ 15. In § 268.403, revise paragraph (a) and add new paragraph (g) to read as follows:

§ 268.403 How to appeal.

(a) The complainant, the Board, agent or individual class claimant (hereinafter appellant) must file an appeal with the Director, Office of Federal Operations, Equal Employment Opportunity Commission, at P.O. Box 77960, Washington, DC 20013, or electronically, or by personal delivery or facsimile. The appellant should use EEOC Form 573, Notice of Appeal/Petition, and should indicate what is being appealed.

* * * * *

(g) The Board will submit appeals, complaint files, and other filings to the Commission's Office of Federal Operations in a digital format acceptable to the Commission, absent a showing of good cause why the Board cannot submit digital records. Appellants are encouraged, but not required, to submit digital appeals and supporting documentation to the Commission's Office of Federal Operations in a format acceptable to the Commission.

■ 16. Amend § 268.405 by revising the third sentence to paragraph (a), revising paragraphs (b) and (c), and adding (d).

The addition and revisions read as follows:

§ 268.405 Decisions on appeals.

(a) * * * The Office of Federal Operations, on behalf of the Commission, shall issue a written decision setting forth its reasons for the decision. The Commission shall dismiss appeals in accordance with §§ 268.106, 268.403(c) and 268.408. The decision shall be based on the preponderance of the evidence. The decision on an appeal from the Board's final action shall be based on a de novo review, except that the review of the factual findings in a decision by an administrative judge issued pursuant to § 268.108(i) shall be based on a substantial evidence standard of review. If the decision contains a finding of discrimination, appropriate remedy(ies) shall be included and, where appropriate, the entitlement to interest, attorney's fees or costs shall be indicated. The decision shall reflect the date of its issuance, inform the complainant of his or her civil action rights, and be transmitted to the complainant and the Board by first class mail. * * *

(b) The Office of Federal Operations, on behalf of the Commission, shall issue decisions on appeals of decisions to accept or dismiss a class complaint issued pursuant to § 268.204(d)(7) within 90 days of receipt of the appeal.

(c) A decision issued under paragraph (a) of this section is final within the meaning of § 268.406 unless the Board issues a final decision under paragraph (d) of this section or unless a timely request for reconsideration is filed by a party to the case. A party may request reconsideration within 30 days of receipt of a decision of the Commission, which the Commission in its discretion may grant, if the party demonstrates that:

(1) The appellate decision involved a clearly erroneous interpretation of material fact or law; or

(2) The decision will have a substantial impact on the policies, practices, or operations of the Board.

(d) The Board, within 30 days of receiving a decision of the Commission, may issue a final decision based upon that decision, which shall be final within the meaning of § 268.406.

■ 17. In § 268.502, revise paragraphs (b)(2) and (c) to read as follows:

§ 268.502 Compliance with final Commission decisions.

* * * * *

(b) * * *

(2) When the Board requests reconsideration, it may delay the payment of any amounts ordered to be paid to the complainant until after the request for reconsideration is resolved. If the Board delays payment of any

amount pending the outcome of the request to reconsider and the resolution of the request (including under § 268.405(d)) requires the Board to make the payment, then the Board shall pay interest from the date of the original appellate decision until payment is made.

* * * * *

(c) When no request for reconsideration or final decision under § 268.405(d) is filed or when a request for reconsideration is denied, the Board shall provide the relief ordered and there is no further right to delay implementation of the ordered relief. The relief shall be provided in full not later than 120 days after receipt of the final decision unless otherwise ordered in the decision.

■ 18. In § 268.504 revise paragraph (c) to read as follows:

§ 268.504 Compliance with settlement agreements and final actions.

* * * * *

(c) Prior to rendering its determination, the Commission may request that the parties submit whatever additional information or documentation it deems necessary or may direct that an investigation or hearing on the matter be conducted. If the Commission determines that the Board is not in compliance with a decision or a settlement agreement, and the noncompliance is not attributable to acts or conduct of the complainant, it may order such compliance with the decision or settlement agreement, or, alternatively, for a settlement agreement, it may order that the complaint be reinstated for further processing from the point processing ceased. Allegations that subsequent acts of discrimination violate a settlement agreement shall be processed as separate complaints under §§ 268.105 or 268.204, as appropriate, rather than under this section.

■ 19. Amend § 268.710 by:

■ a. Removing the words ''EEO'' each place it appears;

■ b. Removing the words ''Staff Director for Management'' each place they appear and replace them with the words ''Chief Operating Officer'';

■ c. Revising paragraph (c) to remove the words ''EEO Programs Director'' and replace them with the words ''Office of Diversity and Inclusion Programs Director'' (''Programs Director'')'';

■ d. Revising the second sentence of paragraph (d)(4) to insert the words ''Office of Diversity and Inclusion'' after the words ''Programs Director'' and before the words ''Board of Governors.''

The revisions read as follows:

§ 268.710 Compliance procedures.

* * * * *

(c) *Responsible official.* The Office of Diversity and Inclusion Programs Director'' (''Programs Director'') shall be responsible for coordinating implementation of this section.

(d) * * *

(4) * * * *How to file.* Complaints may be delivered or mailed to the Administrative Governor, the Chief Operating Officer, the EEO Programs Director, the Federal Women's Program Manager, the Hispanic Employment Program Coordinator, or the People with Disabilities Program Coordinator. Complaints should be sent to the Programs Director, Office of Diversity and Inclusion, Board of Governors of the Federal Reserve System, 20th and C Street NW, Washington, DC 20551. If any Board official other than the Programs Director receives a complaint, he or she shall forward the complaint to the Programs Director.* * *

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 1, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–24613 Filed 11–14–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

12 CFR Chapter II

[Docket No. OP–1625]

Potential Federal Reserve Actions To Support Interbank Settlement of Faster Payments, Request for Comments

SUMMARY: As part of its overall mission, the Federal Reserve has a fundamental interest in ensuring there is a safe and robust U.S. payment system, including a settlement infrastructure on which the private sector can provide innovative faster payment services that serve the broad public interest. Accordingly, the Board of Governors of the Federal Reserve System (Board) is seeking input on potential actions that the Federal Reserve could take to promote ubiquitous, safe, and efficient faster payments in the United States by facilitating real-time interbank settlement of faster payments. While the Board is not committing to any specific actions, potential actions include the Federal Reserve Banks developing a service for 24x7x365 real-time interbank settlement of faster payments; and a liquidity management tool that would enable transfers between Federal Reserve accounts on a 24x7x365 basis to support services for real-time interbank settlement of faster payments, whether those services are provided by the private sector or the Federal Reserve Banks. The Board is seeking input on whether these actions, separately or in combination, or alternative approaches, would help achieve ubiquitous, nationwide access to safe and efficient faster payments.

DATES: Comments on the potential actions must be received on or before December 14, 2018.

ADDRESSES: You may submit comments, identified by Docket No. OP–1625, by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Kirstin Wells, Principal Economist (202–452–2962), Mark Manuszak, Manager (202–721–4509), Susan V. Foley, Senior Associate Director (202–452–3596), Division of Reserve Bank Operations and Payment Systems, or Gavin Smith, Senior Counsel, Legal Division (202–452–3474), Board of Governors of the Federal Reserve System; for the hearing impaired and users of Telecommunications Device for the Deaf (TDD) only, contact 202–263–4869.

SUPPLEMENTARY INFORMATION:

I. Context for Public Comment

A. The Reasons for Faster Payments

Broad trends in society based on technological advancements have changed the ways that people interact

with others, conduct commerce, and access information. While many industries have adapted, the same is not equally true for the nation's payment and settlement system that foundationally supports commerce and the economy. For example, a business in Florida can immediately deliver an invoice by email to a customer in Oregon. The receipt of the corresponding payment from its customer, however, may take days to receive, even if initiated quickly. This lack of speed has economic implications and societal costs borne by individuals, households, and businesses.

Traditional payment methods, such as checks, automated clearinghouse (ACH) payments, and debit and credit cards, form a retail payment infrastructure that is safe, reliable, and ubiquitous, albeit not necessarily quick.[1] These traditional payment methods have served our economy well over decades (and for checks, over most of the country's history).[2] The ubiquitous nature of these payment methods generally allows any two individuals or businesses (that is, end users) with accounts at banks to exchange value supporting an underlying economic transaction.[3] As a result, regardless of where they hold their accounts, individuals can receive payroll deposits from their employers, households can pay their utilities, mortgage, rent, and other bills, and businesses can exchange commercial payments. For payments to most merchants for goods and services, individuals can similarly use debit cards to make payments from their bank accounts.[4]

Over the past two decades, however, a gap has emerged between the capabilities of traditional payment methods and end-user expectations for enhanced payment speed, convenience, and accessibility. A new method of faster payment has emerged to address this gap, with several nonbank payment service providers entering the payment market alongside—and sometimes in lieu of—banks. Faster payments allow end users to initiate and receive payments at any time of the day, any day of the year, and to complete those payments in near-real time (from the end users' perspective), such that, within seconds, the recipient has access to final funds that can be used to make other payments.

The term ''faster payments'' is broadly used in the payment industry to indicate simply that increased speed, convenience, and accessibility are essential features for the future of the payment and settlement system. However, faster payments provide more to individuals and businesses than just the ability to make payments quickly from a mobile device. For example, when funds move in and out of end-user bank accounts in real time, end users have more flexibility in managing their money. Faster payments eliminate the need to schedule bill or vendor payments well in advance and, more broadly, allow end users to make time-sensitive payments whenever needed. By increasing flexibility and accessibility, end users may also have greater scope to avoid penalties such as late fees.

The development of payment and settlement services that are essentially real time and always available is a worldwide phenomenon. Both advanced and emerging economies have undertaken efforts to develop faster payment services, and those services are now broadly accessible to the general public in an increasing number of countries.[5]

Efforts to implement faster payments in other countries often reflect a collaborative, strategic endeavor that involves the payment industry, central banks, and other authorities. The deployment of accessible faster payment services generally requires extensive upgrades to a country's or region's payment and settlement infrastructure, involving significant coordination among all stakeholders. As part of these upgrades, central banks in various jurisdictions have implemented or planned changes to their settlement services in support of faster payments, reflecting the foundational role that central banks play worldwide in the settlement of obligations between financial institutions. The ability to reliably settle interbank obligations using balances at the central bank (also referred to as central bank money) is vital not only to the smooth functioning of the payment system but also to financial stability more broadly.

As the U.S. central bank, the Federal Reserve initiated a broadly collaborative effort with the payment industry and other stakeholders in 2013, to support development of ubiquitous, nationwide access to safe and efficient faster payments in the United States. While the private sector has to date implemented certain faster payment services for the public, there are still challenges related to achieving these broader goals. As part of its central mission, the Federal Reserve has a fundamental responsibility to ensure that there is a flexible and robust infrastructure supporting the U.S. payment system on which the private sector can develop innovative payment services that serve the broadest public interests.[6] The settlement infrastructure concepts outlined in this notice are intended to advance the development of faster payments and to help support the modernization of the financial services sector's provision of payment services.[7]

B. The Federal Reserve's Role in the Payment System

A safe and efficient payment and settlement system that works in the interest of the public is vital to the U.S. economy, and the Federal Reserve plays important roles in helping maintain the integrity of that system.[8]

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[1] Retail payment systems are those that handle large volumes of lower-value payments, such as those among individuals or between an individual and a business. For more information, see Committee on Payments and Market Infrastructures, ''A glossary of terms used in payments and settlement systems,'' the Bank for International Settlements, updated October 17, 2016. Available at: *https://www.bis.org/cpmi/publ/d00b.htm.*

[2] According to the Federal Reserve Payments Study, in 2015, checks, the ACH system, and payment cards, including debit and credit cards, accounted for over 144 billion payments and nearly $178 trillion in value. Federal Reserve Board, ''The Federal Reserve Payments Study 2016.'' Available at *https://www.federalreserve.gov/paymentsystems/files/2016-payments-study-20161222.pdf.*

[3] Throughout this notice, the term ''bank'' will be used to refer to any type of depository institution. Depository institutions include commercial banks, savings banks, savings and loan associations, and credit unions.

[4] Although credit cards form part of the retail payments infrastructure, they do not operate using deposit balances and deposit accounts, but instead operate on the basis of credit and credit card accounts.

[5] For a discussion of global developments related to faster payments, see Committee on Payments and Market Infrastructures, ''Fast payments—Enhancing the speed and availability of retail payments,'' Bank for International Settlements, November 2016. Available at *https://www.bis.org/cpmi/publ/d154.pdf.*

[6] For example, in 2017, the Board approved final guidelines for evaluating requests for joint accounts at the Federal Reserve Banks intended to facilitate settlement between and among depository institutions participating in private-sector payment systems. Available at *https://www.federalreserve.gov/newsevents/pressreleases/files/other20170809a1.pdf.* The original impetus for adopting these guidelines was to broaden access to joint accounts in support of private-sector developments in faster payments.

[7] In a recent report, the U.S. Treasury recommended that the Federal Reserve move quickly to facilitate a faster retail payments system, such as through the development of a real-time settlement service, that would also allow for more efficient and ubiquitous access to innovative payment capabilities. In particular, smaller financial institutions, like community banks and credit unions, should also have the ability to access the most-innovative technologies and payment services. See U.S. Treasury, ''A Financial System That Creates Economic Opportunity: Nonbank Financials, Fintech, and Innovation,'' July 2018. Available at *https://home.treasury.gov/sites/default/files/2018–07/A-Financial-System-that-Creates-Economic-Opportunities---Nonbank-Financi....pdf.*

[8] The Federal Reserve has long provided payment services under authority of the Federal Reserve Act

Fundamentally, the payment and settlement system facilitates financial transactions, purchases of goods and services, and the associated movement of funds on behalf of individuals, households, businesses, and other parties (such as government entities and nonprofit organizations). The importance of the payment and settlement system in daily lives and, more broadly, for all financial transactions underscores the significance of its safe and proper functioning for the U.S. economy.

One of the Federal Reserve's most significant roles in that system involves providing mechanisms for the settlement of payment obligations between and among banks. Banks process payments on their own behalf as well as on behalf of their end-user customers, including individuals, households, businesses, and other parties. Banks—small, medium, and large—settle payments at the Federal Reserve through their accounts and balances at the Federal Reserve Banks (Reserve Banks).[9] This core central banking function stems from the Federal Reserve's unique ability to transfer balances that are free of counterparty credit risk and provide certainty that payments between banks are complete.[10] In addition to providing settlement, the Reserve Banks provide payment services to clear and settle check, ACH, and wire transfer payments between banks. The Reserve Banks also process these payments on behalf of the U.S. Treasury in their capacity as fiscal agents.[11]

Through the services that it provides to the banking industry and the U.S. government, the Federal Reserve seeks to foster the safety and efficiency of the payment and settlement system. In doing so, the Federal Reserve provides payment and settlement services on an equitable basis and maintains a fundamental commitment to competitive fairness, which is essential to fostering end-user choice and innovation across the financial services sector as a whole.

When evaluating the potential introduction of a new payment service or major enhancements to an existing service, the Federal Reserve looks to its statutory obligations as well as long-standing principles and criteria.[12] These include expectations that (i) the Federal Reserve will achieve full cost recovery over the long run, (ii) the service will yield a clear public benefit, and (iii) the service is one that other providers alone cannot be expected to provide with reasonable effectiveness, scope, and equity.[13] The Board also conducts a competitive-impact analysis for any new service or major enhancement that would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services.[14] Recently, at the request of Congress, the Government Accountability Office (GAO) conducted a review of the Federal Reserve's role in providing payment services and the effect of the Federal Reserve on competition in the market for payments. The GAO found that the activities of the Federal Reserve in the payment system generally have been beneficial, with benefits that include lowered cost of processing payments for end users.[15]

In addition to providing payment and settlement services, the Federal Reserve plays other roles, including serving as a convener of industry stakeholders, in support of its mission to foster safety and efficiency of the payment and settlement system. The next section discusses the broad initiative that the Federal Reserve launched five years ago to collaborate with the payment industry to foster payment system improvements.

C. Background on the Strategies for Improving the U.S. Payment System Initiative

Beginning in 2013, the Federal Reserve established a new initiative—Strategies for Improving the U.S. Payment System (SIPS)—with the objective of engaging with the payment industry and other stakeholders to upgrade and enhance the nation's payment system. The collaborative work began with a consultation paper that requested public views on gaps, opportunities, and desired outcomes related to the goal of improving the speed and efficiency of the U.S. payment and settlement system from end-to-end while maintaining a high level of safety and efficiency.[16] The consultation paper prompted responses from a wide variety of payment industry stakeholders, including banks, processors and other nonbank providers of payment services, technology firms, and business end users.[17]

Based on responses to the initial consultation paper, the Federal Reserve published in 2015 a set of strategies that it would pursue in collaborative engagement with payment industry stakeholders to improve the safety and efficiency of the U.S. payment and settlement system.[18] For faster payments, the specific strategy was to ''identify effective approach(es) for implementing a safe, ubiquitous, faster payments capability in the United States.'' This 2015 paper identified a number of tactics for each strategy, including the establishment of an

(*See e.g.,* Federal Reserve Act section 13(1) (12 U.S.C. 342), section 19(f) (12 U.S.C. 464), and section 16(14) (12 U.S.C. 248(o))).

[9] Section 13(1) of the Federal Reserve Act (FRA) permits Reserve Banks to receive deposits from member banks or other depository institutions. 12 U.S.C. 342. Section 19(b)(1)(A) of the FRA includes as depository institutions any federally insured bank, mutual savings bank, savings bank, savings association, or credit union, as well as any of those entities that are eligible to make application to become a federally insured institution. 12 U.S.C. 461(b). In addition, there are certain statutory provisions allowing Reserve Banks to act as a depository or fiscal agent for the U.S. Treasury and certain government-sponsored entities (*See e.g.,* 12 U.S.C. 391, 393–95, 1823, 1435) as well as for certain international organizations (*See e.g.,* 22 U.S.C. 285d, 286d, 290o–3, 290i–5, 290l–3). In addition, Reserve Banks are authorized to offer deposit accounts to designated financial market utilities (12 U.S.C. 5465), Edge and Agreement corporations (12 U.S.C. 601–604a, 611–631), branches or agencies of foreign banks (12 U.S.C. 347d), and foreign banks and foreign states (12 U.S.C. 358).

[10] As mentioned earlier, these balances are referred to as central bank money. The Committee on Payment and Market Infrastructures defines central bank money in its glossary of terms as ''a liability of a central bank, in this case in the form of deposits held at the central bank, which can be used for settlement purposes.'' Available at *https://www.bis.org/cpmi/publ/d00b.htm.*

[11] Additional information about the Federal Reserve's role in the payment system is available in ''The Federal Reserve System Purposes & Functions,'' October 2016. Available at *https://www.federalreserve.gov/aboutthefed/pf.htm.*

[12] *See* Monetary Control Act of 1980, Public Law 96–221, 94 Stat. 132 (1980). The Federal Reserve also considers, as appropriate, the effect of a potential new service or major enhancement on other critical missions, including conducting monetary policy and promoting financial stability.

[13] *See* Board of Governors of the Federal Reserve System, ''The Federal Reserve in the Payments System,'' Issued 1984; revised 1990. Available at *https://www.federalreserve.gov/paymentsystems/pfs_frpaysys.htm.*

[14] *See id.* at Competitive-Impact Analysis for more information on what the Board considers in a competitive-impact analysis.

[15] *See* U.S. Gov't Accountability Off., GAO–16–614, ''Federal Reserve's Competition with Other Providers Benefits Customers, but Additional Reviews Could Increase Assurance of Cost Accuracy'' (2016.) Available at *https://www.gao.gov/products/GAO-16-614.*

[16] The Federal Reserve Banks, ''Payment System Improvement—Public Consultation Paper,'' September 10, 2013. Available at *https://fedpaymentsimprovement.org/wp-content/uploads/2013/09/Payment_System_Improvement-Public_Consultation_Paper.pdf.*

[17] The responses are available at *https://fedpaymentsimprovement.org/about/consultation-paper/.*

[18] Federal Reserve System, ''Strategies for Improving the U.S. Payment System,'' January 26, 2015. Available at *https://fedpaymentsimprovement.org/wp-content/uploads/strategies-improving-us-payment-system.pdf.*

industry task force to pursue the strategy related to faster payments.[19]

In 2015, the Federal Reserve also convened the Faster Payments Task Force (FPTF), a 320-member group comprised of banks of varying sizes, nonbank providers of payment services, business and government end users, consumer interest organizations, governmental organizations, and other industry participants.[20] In order to evaluate possible faster payment services, the task force developed a set of effectiveness criteria.[21] These criteria addressed various features of a faster payment service, including ubiquity, efficiency, safety and security, and speed.[22]

The FPTF's effectiveness criteria provide important benchmarks for both end-user capabilities of faster payments and interbank settlement arrangements. With respect to service availability and payment speed for end users, the FPTF viewed service availability on any day, at any time of the day (that is, 24x7x365 service availability), and final funds provided to the recipient within one minute as characteristics of a ''very effective'' faster payment service.[23] With respect to interbank settlement, the FPTF considered a faster payment service to be ''very effective'' if, among other things, (i) interbank settlement occurs within 30 minutes of the completion of a faster payment for end users, (ii) the service manages credit and liquidity risks arising from any time lag between payment completion for end users and interbank settlement, particularly if the service is available to end users on a 24x7x365 basis but interbank settlement is not, and (iii) interbank credit exposures related to settlement can be fully covered.[24] As subsequent sections of this notice will explain, these criteria reflect the importance of the speed of interbank settlement given the speed of faster payments for end users and the risk, specifically credit risk, that results when interbank settlement is slower. The Board recognizes that interbank settlement for faster payments using existing settlement services offered by the Reserve Banks would be unable to meet fully the FPTF's criteria.

In its final report, released in 2017, the FPTF published a set of consensus recommendations for achieving its vision of ubiquitous, safe, and efficient faster payment capabilities for the United States.[25] As part of its recommendations, the task force asked the Federal Reserve (i) to develop a 24x7x365 settlement service to support faster payments and (ii) to explore and assess the need for other Federal Reserve operational role(s) in faster payments. Following that report, the Federal Reserve stated its intention to pursue these recommendations.[26]

D. Summary of Potential Actions by the Federal Reserve

The Board has worked with the Reserve Banks to identify the potential actions described in this notice. The Board believes it is important to present these conceptual approaches for supporting interbank settlement of faster payments to the public and to gather initial public comments while faster payment services are still in the early stages of their development. The Board is not committing to any further actions at this time or in the future, but is committed to transparent communication with the public after analyzing the responses to this notice and determining further steps, should any be taken. As outlined earlier, any new services or service enhancements proposed by the Board would be expected to meet longstanding principles and criteria established under Federal Reserve policy as part of meeting its statutory requirements and would also be subject to request for public comment.[27]

First, the Board is seeking comment on whether the Reserve Banks should consider developing a service for real-time gross settlement (RTGS) of faster payments that is available to conduct settlement on a 24x7x365 basis (24x7x365 RTGS settlement service). Such a service would involve interbank settlement of faster payments using banks' balances in accounts at the Reserve Banks. Reflecting the characteristics of faster payments, the service would provide payment-by-payment interbank settlement in real time and at any time, on any day, including weekends and holidays. A 24x7x365 RTGS settlement service could be similar, in certain respects, to the Fedwire® Funds Service, the RTGS service that the Reserve Banks currently provide for banks to clear and settle payments on behalf of their customers and for their own purposes.[28]

Second, the Board is seeking comment on whether the Reserve Banks should consider developing a liquidity management tool that would operate on a 24x7x365 basis in support of services for real-time interbank settlement of faster payments, whether those services are provided by the private sector or the Reserve Banks (liquidity management tool). Such a tool would enable movement of funds during hours when traditional settlement systems are not open (nonstandard business hours) between banks' master accounts at the Reserve Banks and an account (or accounts) at the Reserve Banks used to conduct or support 24x7x365 real-time settlement of faster payments.[29] A liquidity management tool could involve simultaneous liquidity transfers among multiple accounts that are coordinated by an authorized agent in the settlement process and could be based on the existing National Settlement Service (NSS) or a similar service.[30] Alternatively, the tool could

[19] In addition to the task force on faster payments, other efforts under the SIPS initiative have included a Secure Payments Task Force and a Business Payments Coalition. More information on these efforts and the broader SIPS initiative is available at *https://fedpaymentsimprovement.org/.*

[20] Information about the FPTF and its participants is available at *https://fasterpaymentstaskforce.org/.*

[21] Faster Payments Task Force, ''Faster Payments Effectiveness Criteria,'' January 26, 2016. Available at *https://fedpaymentsimprovement.org/wp-content/uploads/fptf-payment-criteria.pdf.*

[22] The FPTF developed the criteria to evaluate ''faster payment solutions,'' where the FPTF defined a ''faster payment solution'' as ''the collection of components and supporting parties that enable the end-to-end payment process.'' This definition is analogous to the concept of a ''faster payment service'' that is used in this notice.

[23] *See* ''Faster Payments Effectiveness Criteria,'' *supra* note 21 at criteria U.2 (Usability) and F.3 (Fast Availability of Good Funds to the Payee). In this notice, references to ''real time,'' ''instant,'' and ''immediate'' are intended to denote availability of final funds within one minute, consistent with the task force's criteria for a service to be very effective, and ideally within just a few seconds.

[24] *See* ''Faster Payments Effectiveness Criteria,'' *supra* note 21 at criteria F.4 (Fast Settlement among Depository Institutions and Regulated Non-bank Account Providers) and S.4 (Settlement Approach).

[25] In its recent report on the financial system, the U.S. Treasury recommended that the Federal Reserve set public goals consistent with the FPTF's final report. See ''A Financial System That Creates Economic Opportunity: Nonbank Financials, Fintech, and Innovation,'' *supra* note 7.

[26] The Federal Reserve System, ''Federal Reserve Next Steps in the Payments Improvement Journey,'' September 6, 2017. Available at *https://fedpaymentsimprovement.org/wp-content/uploads/next-step-payments-journey.pdf.*

[27] *See* ''The Federal Reserve in the Payments System,'' *supra* note 13.

[28] In contrast to a potential 24x7x365 RTGS settlement service, the Reserve Banks' Fedwire Funds Service does not operate 24x7x365. Much of the value transferred through the Fedwire Funds Service reflects large-value, time-critical payments between banks.

[29] A master account is the record of financial rights and obligations between account-holding banks and a Reserve Bank. The account is where opening, intraday, and closing balances are determined.

[30] NSS is a multilateral settlement service offered to banks that settles for participants in private-sector clearing and settlement arrangements. The service requires a designated agent to submit a settlement file to a Reserve Bank, which initiates debits and credits to participant accounts at the Reserve Banks.

involve individual bank-initiated transfers between specific sets of accounts and could function similarly to the existing Fedwire Funds Service or a similar service. Regardless of its structure, such a tool would enable transfers to support liquidity (or funding) needs associated with real-time settlement of faster payments during nonstandard business hours, such as weekends and holidays.

Later sections of this notice expand on these possible actions to support interbank settlement of faster payments, as well as the general concepts that underlie them. The Board is seeking input on the proposition that RTGS is the appropriate strategic foundation for interbank settlement of faster payments. The Board is also seeking input on whether the provision of a 24x7x365 RTGS settlement service and a liquidity management tool, separately or in combination, would help achieve the goals of ubiquitous, nationwide access to safe and efficient faster payments in the long run. The Board is further interested in receiving comment about whether other approaches, not explicitly considered in this notice, might help achieve those goals.

II. Discussion of Faster Payments

A. General Elements of a Payment

Payments are essential to the conduct of economic activity. When a good is purchased, a service is rendered, or a debt is repaid, a payment is typically involved. For example, an individual's purchase of a product from a business involves the business providing something of value, namely the product itself, to the buyer. As compensation for the product, the business needs to receive something of financial value from the buyer in return. This act of transferring financial value from the buyer to the seller, or, more generally, from one party in a transaction to another, constitutes a payment.

In the United States, as in other modern economies, the value transferred in a payment typically involves monetary assets. Individuals, households, businesses, and other parties in the economy (for example, governments and nonprofit organizations) hold these monetary assets in various forms. For example, some monetary assets may be held as currency and coin. Other monetary assets may involve funds held with specialized financial institutions. In the United States, deposits in accounts with banks comprise the monetary asset that is most widely held by the general public to conduct payments.[31]

In broad terms, the function of the payment and settlement system is to enable the transfer of these monetary assets between their holders for the purposes of exchanging value to pay for goods and services, remitting funds to pay bills and meet other obligations, managing business balance sheets, and conducting other activities. This transfer can occur in various ways. For example, in a face-to-face payment, the handover of currency serves to transfer a monetary asset from the individual to the business and, hence, to complete a payment between them. When the monetary asset used for payment is deposits held in accounts with banks or other institutions, transfers require adjustments to the amount of funds in the respective accounts of each party in a payment. Thus, the balance in the individual's account with their bank must be decreased by the amount of the purchase, and the balance in the business's account with its bank must be increased by the same amount.

To make these adjustments, the banks involved in a payment must have a way to receive and exchange payment messages. A payment message typically contains information related to the payment, such as the identities of the parties involved, relevant account information, and the payment amount. Without a payment message and a method to exchange it, the banks involved in a payment would not know the details of a payment or even be aware of an end user's need to conduct it.

The payment between end users and associated payment message generates an obligation between the respective banks. The banks must have a mechanism to conduct a transfer of assets between one another to settle the payment. Without a mechanism to settle the interbank obligation, the banks would not have transferred the underlying funds to complete the payment.

These activities, which are known as clearing and interbank settlement, involve processes, infrastructure, rules, agreements, and law that ultimately allow end users, such as an individual and a business, to conduct payments using accounts held with banks or other institutions.

B. Levels of the Payment Process

To complete a payment between two bank accounts, three key levels of the payment process are necessary: End-user services, clearing services, and interbank settlement services.[32] Together, these three levels comprise a ''payment service'' or, as will subsequently be discussed, a ''faster payment service'' in the case of a payment service focused on faster payments.[33] In other words, a payment service encompasses everything that goes into providing an individual, a business, or another end user with the ability to conduct a payment. Figure 1 depicts the levels of the payment process when the sender initiates a payment through their bank.

An end-user service includes the tools that an individual or business uses to conduct a payment. For example, an individual wishing to pay a bill to a utility company or send money to a friend may be able to do so through a mobile phone application. Similarly, a business may be able to initiate a payment to a vendor through a bank's website. Such services allow an end user to communicate with their bank about the need to make a payment and the details of that payment. In other words, end-user services support the exchange of payment messages and other information between a bank and its end-user customers. End-user services also include other critical aspects of the overall payment experience for an individual or business, such as error resolution procedures and security measures to mitigate fraud.

Clearing services and interbank settlement services constitute the infrastructure underlying payment

[31] As of July 2018, the value of transferable deposits held by the public, including demand deposits and other checkable deposits, was $2.09 trillion, while the value of currency in circulation outside banks was $1.59 trillion. *See* Federal Reserve Board, ''Money Stock and Debt Measures—H.6 Release, Table 5'' available at *https://www.federalreserve.gov/releases/h6/current/default.htm.*

[32] This discussion focuses on a situation in which the parties to a payment hold accounts with different banks or, more broadly, different financial institutions. If these parties hold accounts with the same institution, that institution may be able to conduct payment activities internally through, for example, adjustments to an internal ledger of account balances. This scenario can apply to payments within a single bank, yielding what is termed an ''on-us'' transaction. It also applies to many payment services provided by nonbanks.

[33] A legal framework that governs the conduct of payments is also necessary and may apply across levels of the payment process. This framework may be in the form of laws, regulations, rules, or contractual agreements, which collectively determine the rights and obligations of the participants, such as end users, in the payment process. The legal framework may provide, among other things, for error resolution and fraud protection for end users. Legal requirements related to anti-money-laundering and economic sanctions may also affect the design and operation of a payment system.

services involving bank accounts. These services and the activities they perform may not be apparent to end users, but they are crucial to the transfer of information and value between banks, so that the sender of a payment can satisfy their obligation to the recipient of a payment.

In clearing services, the sending and receiving banks interact, possibly through an intermediary such as a clearing house, based on the payment information received from end users and the protocols associated with a payment service. A key element of this interaction is the exchange of the payment message between the sending and receiving banks.[34] The payment messages that are exchanged contain the necessary information for banks to make appropriate debits and credits to the accounts of their end-user customers and to notify their customers of those adjustments to account balances.

Finally, in interbank settlement services, the sending and receiving banks transfer assets to each other to satisfy the interbank obligations that arise from end-user payments. Settlement takes place by adjusting the balances in banks' settlement accounts on the books of a settlement institution. For example, interbank settlement can be performed by directly adjusting balances in accounts that banks hold with the central bank or a commercial bank.

Figure 1: Levels of the Payment Process

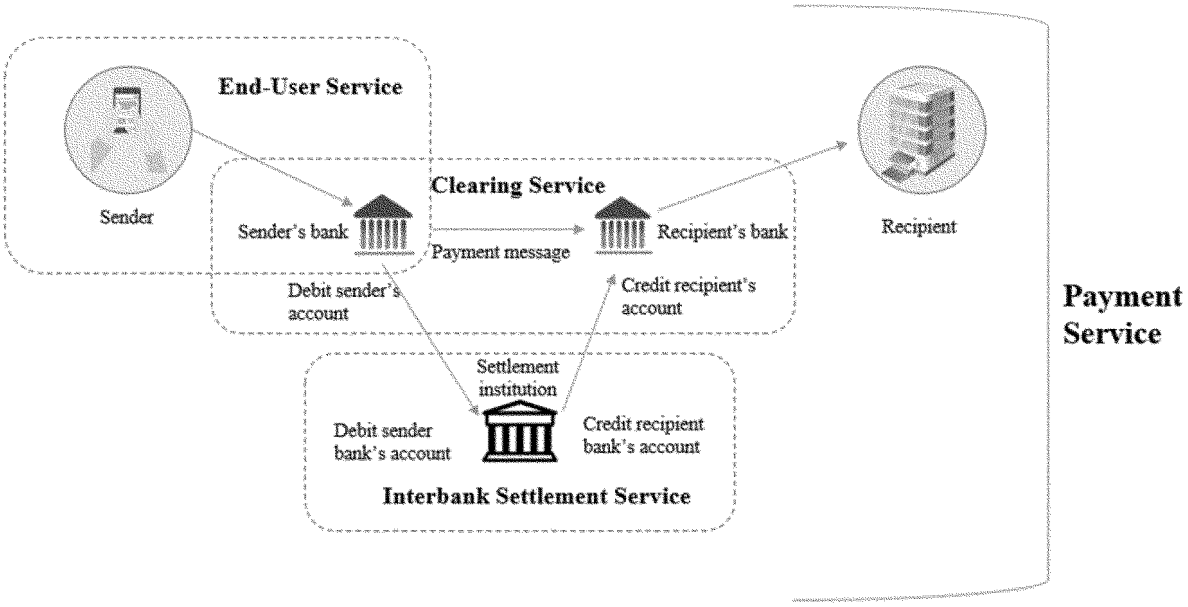

Figure 1 depicts the levels of the payment process. The end-user service allows an individual, household, or business to initiate a payment to its bank. In this example, an individual wishes to pay a bill to a utility company through a mobile phone application. Clearing includes the exchange of the payment message between a sender and recipient's bank via a payment network. The payment message contains the information for banks to make debits and credits to the sender and receiver's accounts. Settlement occurs when banks transfer assets on the books of a settlement institution to satisfy the interbank obligation created by the end-user payment.

C. An Overview of Faster Payments

In a faster payment, the three levels of the payment process are structured so that senders can immediately initiate, and recipients can immediately receive, payments at any time.[35] At the end-user service level, the sender of a payment must have an interface that allows real-time communication at any time to initiate a payment. This need for instant and always-available communication capabilities for end users explains why faster payments are often associated with payments initiated through computers or mobile devices.

At the clearing level, certain activities must similarly happen in real time and

[34] Other clearing activities include sorting and routing of payment instructions, ensuring that payment instructions comply with service-specific rules and limits, and calculating and communicating interbank obligations that arise from payment instructions. Clearing activities may also include screening for fraudulent payments and other risk-management measures.

[35] Rules or agreements that govern the conduct of faster payments are also necessary. Among other things, these rules or agreements will specify end-user rights and obligations associated with a faster payment.

at any time. In particular, the messaging between banks must occur in real time on a 24x7x365 basis, so that, at any time of the day, the banks involved in a payment are able to send and receive payment messages immediately, such that they can debit and credit their customers' accounts. By contrast, in certain traditional payments, the payment message exchange can occur sometime after an end user initiates a payment. As will be discussed in more detail in the next section, however, the interbank settlement level of a faster payment service may or may not exhibit the same speed and availability as end-user and clearing services.

Although the previous discussion focused on activities related to faster payment services involving banks, several established services in the United States that allow end users to conduct faster payments are provided by nonbank entities. These nonbank payment services usually combine all three levels of the payment process. These services often focus on enabling impromptu payments between individuals, such as friends or family members, although some also handle a wider array of payment situations, such as payments between individuals and businesses. Such a service typically provides an online portal or mobile application that allows parties who have signed up with the service to send payments to each other. The service executes payments through adjustments to balances of the sender's and recipient's service-specific accounts, which are located on the service's internal books.[36] Because end users can quickly communicate with the service, which can then rapidly make internal adjustments to end-user balances, such a service allows registered end users to conduct immediate payments at any time. However, such capabilities are only possible when both the sender and receiver of a payment have signed up with a specific service. In addition, the balances are only immediately usable within that specific service. Transfers of funds out of a nonbank service into bank accounts that are held for general use typically involve transactions through traditional payment systems that can take more than a day to complete.[37]

Recently, other faster payment services have emerged in the United States that are based on transfers between bank accounts. These include services that allow end users to send or receive faster payments using the debit card infrastructure of certain payment card networks and services that allow faster payments over newer proprietary payment networks owned by groups of banks. The end-user service can involve a service-specific website or mobile application or may be integrated into a participating bank's website or mobile application, similar to many existing online bill payment services. For business customers, the end-user service may be integrated into a bank's back-end payment processing infrastructure. To use these services, end users must typically sign up with a specific service through their banks or, in some cases, may sign up directly with the service itself. Because the sending and receiving end users may hold their accounts at different banks, their banks must exchange payment messages as part of clearing. These interbank clearing activities can occur through existing payment card networks or proprietary communication networks of the bank-owned services. To enable their customers to make payments through a specific faster payment service, banks must participate in the service or otherwise be capable of receiving payment messages initiated through the service. Interbank settlement must also occur, allowing the banks to transfer assets reflecting their customers' faster payments. At present, interbank settlement for these services is largely conducted through existing services provided by the Reserve Banks and, in one case, is performed using a private sector-owned settlement ledger that is backed by funds in a ''joint account.'' A joint account is a recently announced type of account held at a Reserve Bank that holds balances for the joint benefit of settling banks in a private-sector settlement service.

The interbank settlement models discussed in this notice specifically focus on faster payment services that involve transfers between bank accounts and do not directly address services provided by nonbank entities. At the same time, many nonbank faster payment services ultimately use deposit accounts at banks to hold funds associated with their customers' balances and further rely on established interbank payment systems for the movement of money between their customers' bank accounts and service-specific accounts. Nonbank faster payment services may also have access to Reserve Bank services when acting as agents on behalf of banks that participate in their services. As a result, interbank clearing and settlement capabilities may have implications for both bank and nonbank faster payment services.

III. Faster Payment Interbank Settlement Models

As defined above, faster payment services involving transfers between bank accounts must conduct certain activities in real time on a 24x7x365 basis. In particular, such services must accept payment messages from end users, exchange payment messages between banks, and make final funds available to recipients in real time and at any time. However, interbank settlement can be performed in two ways: On a deferred basis or in real time. These two models have important distinguishing features with risk, liquidity management, and other implications.

A. Deferred Net Settlement of Interbank Obligations

In a deferred settlement arrangement for faster payments, final funds are made available to the end-user recipient *before* interbank settlement occurs. In such an arrangement, individual payment messages are exchanged in real time between the sender's bank and the recipient's bank. The banks adjust their customer balances to reflect the outflow of funds for the sender and the inflow of funds for the receiver, and the recipient's bank immediately makes final funds available to its customer. The interbank settlement information resulting from the individual payments is collected and stored by a centralized entity (for example, a clearinghouse) for a period, such as a certain number of hours or until the next business day, before interbank settlement occurs. In some cases, settlement may be deferred for several days over weekends or holidays, depending on whether the system used for settlement is available then. Around the world, most existing implementations of deferred settlement for faster payments involve netting of interbank obligations prior to settlement, yielding what is termed deferred net settlement (DNS).[38] In a DNS arrangement, the centralized entity that collects and stores interbank settlement information offsets payment obligations owed by a bank with

[36] As noted in footnote 32, nonbank entities can often conduct key activities related to payments on an internal ledger of account balances.

[37] A nonbank service's internal ledger of end-user account balances is generally backed by a deposit account or accounts that the nonbank service holds with one or more banks. Transfers by a service's customers to fund or defund their service-specific accounts involve payments between the customers' bank accounts and the service's bank account(s). These funding and defunding transfers typically occur via payment card networks or the ACH system.

[38] *See* ''Fast payments—Enhancing the speed and availability of retail payments,'' *supra* note 5.

payment obligations due to that bank. After collecting and netting settlement information related to groups of payments, the centralized entity submits information on net obligations to an interbank settlement system, which then adjusts the account balances of all participating banks on the settlement institution's books. Alternatively, rather than relying on a centralized entity, participating banks may initiate a series of funds movements to settle the net obligations. The process of collecting, netting, and then settling a group of payments is known as a settlement cycle.

The Board understands that, at present, most faster payment services in the United States that involve transfers between bank accounts are based on a DNS model for interbank settlement. In these services, interbank settlement of net obligations is conducted using traditional payment and settlement systems, namely the Fedwire Funds Service or the ACH system, with the timing and frequency of settlement depending on, among other things, the operating hours of those systems.[39]

A number of factors may contribute to the current prevalence of DNS-based arrangements for faster payment services in the United States. First, traditional payment and settlement systems, which can be leveraged for settlement of faster payments, already have widespread participation by banks. In addition, by using the Fedwire Funds Service or the ACH system, banks can treat settlement payments for faster payment services much like other interbank payments, without the need to implement new faster payment settlement capabilities and operational procedures. As a result, it may be easier for banks to become participants in these faster payment services. Finally, DNS-based faster payment services can be attractive from a liquidity management perspective because netting reduces balances that banks need to set aside to settle obligations related to faster payments.

At the same time, DNS arrangements for faster payments involve inherent risks that need to be managed. Because the recipient's bank makes final funds available to the recipient before interbank settlement occurs, DNS arrangements for faster payments inherently generate interbank credit risk for the recipient's bank. If a sending bank in the arrangement fails to pay a net obligation, receiving banks are at risk of losing the full value of funds that they have already made available to recipients.[40] In addition, this scenario could generate liquidity risks for receiving banks if, subsequent to a sending bank's failure to pay, settlement amounts are recalculated and banks may receive less or have to pay more than expected. Such credit and liquidity risks may become particularly pronounced if, as the 24x7x365 nature of faster payments would allow, rapid withdrawals from a troubled bank were to occur outside standard business hours, increasing credit exposures and liquidity needs for receiving banks. During a period of financial stress, these risks could also further aggravate financial stability concerns.

The interbank settlement risks created in a DNS-based faster payment service may be mitigated with appropriate risk management tools. Potential tools include (i) transaction limits on individual payments or frequent settlement cycles to help prevent the emergence of large net interbank exposures, (ii) loss-sharing agreements among participants in a system to help spread the risk of a settlement failure, (iii) limits on the net negative position of each participating bank to prevent interbank exposures from becoming too large, and (iv) collateralization to back settlement activity if one or more participants were not able to meet their obligations. Credit and liquidity risk exposures can be fully mitigated by requiring participants in a DNS-based faster payment service to prefund potential exposures fully with cash held at a custodial institution, with an enforceable limit on payment transactions to prevent interbank settlement exposures from exceeding the covering funds or, potentially, a mechanism to augment prefunded cash collateral when needed. Under this risk-management structure, if a participant in a DNS system is unable to fund its settlement obligations, the obligations could be covered with prefunded cash, allowing the settlement payments to be completed and avoiding the need to recalculate settlement obligations.

In other countries, every faster payment service based on a DNS model employs measures to mitigate the resulting interbank settlement risk.[41] Most recent international examples of DNS-based faster payments typically use full cash prefunding, a risk-management approach that is reflected in the FPTF's effectiveness criterion related to full coverage of interbank credit exposures. A prominent example of full risk mitigation occurs in the United Kingdom, where faster payment participants settle their positions three times per business day using accounts at the Bank of England. Each participant in the system sets its own ''net sender cap'' that limits the participant's negative position between settlement cycles. Since 2015, these caps have been fully backed by cash collateral held in segregated accounts at the Bank of England to mitigate the overnight interbank credit risk generated by the system. In the event that a participant were unable to meet its obligation in a settlement cycle, the participant's cash collateral at the Bank of England would be immediately accessed to conduct settlement.

In addition to risk management, DNS-based faster payment services may have liquidity management implications. On the one hand, liquidity management may be simplified for banks in a DNS arrangement because netting reduces the funds that banks need to have available for settlement obligations related to faster payments. In addition, because settlement is conducted periodically, often at pre-defined times, banks in a DNS arrangement do not need to provide sufficient funds on a real-time basis to settle faster payments that are otherwise taking place in real time. On the other hand, if a DNS-based service were to use frequent settlement cycles to manage credit risk exposures, banks would need to ensure that they have adequate liquidity whenever a settlement cycle occurs. For example, if it were possible to conduct the 30-minute settlement cycles that would be applied in a DNS arrangement satisfying the FPTF's effectiveness criterion related to settlement speed, that settlement frequency would require banks to monitor and manage their liquidity over the weekend and on holidays.

Furthermore, collateral management may have implications for banks participating in a DNS-based faster payment service that employs collateral to mitigate interbank credit risk. The availability of adequate collateral to cover a bank's net obligation would need to be verified in real time for each individual faster payment, with

[39] The Reserve Banks' National Settlement Service is used by some DNS-based systems that do not involve faster payments.

[40] The risk can be particularly acute with the use of the ACH system given the time delay between file submission of the ACH payment to settle the net obligation and the actual settlement of those ACH payments at specified times during the day or next day. Debit ACH payments, if used in the settlement process, also are not final upon settlement. The extra time lapse in ACH processing and settlement and the lack of final settlement for debit ACH payments, if used, can add to interbank credit risk.

[41] *See* ''Fast payments—Enhancing the speed and availability of retail payments,'' *supra* note 5.

payments being rejected when collateral is inadequate. As a result, cash or collateral to back settlement activity in a DNS arrangement would need to be monitored, maintained, and potentially adjusted on a real-time basis, including during nonstandard business hours, to avoid rejected payments.[42] Alternatively, banks could elect to maintain higher cash or collateral balances to hedge against unexpected payment volumes; however, this choice would have other implications for banks and their ability to use cash or collateral for other purposes.

Another consideration for DNS-based faster payment services is that interoperability between services that use different risk and liquidity management arrangements may be challenging, which can be a barrier to faster payment ubiquity if end users are not able to send payments across services. For faster payment services to be interoperable, each service should have the ability to receive transactions originated from the other service and to manage the associated cross-service settlement risks.[43] Interoperability would likely be harder to achieve if two services and their chosen settlement features generate different levels of interbank settlement risk or if they use different tools to mitigate such risk.

B. Real-Time Gross Settlement of Interbank Obligations

In an RTGS arrangement for faster payments, final funds are made available to the recipient only after interbank settlement has occurred between the banks that are party to the transaction. To ensure this outcome, RTGS-based faster payments involve both completion of end-user payments and settlement of interbank obligations on a payment-by-payment basis in real time and at any time. RTGS for faster payments thus aligns the speed and 24x7x365 availability of interbank settlement with the speed and 24x7x365 availability of faster payments for end users. In such an arrangement, because the speed and timing of interbank messaging activities needed to support faster payments for end users coincide with the speed and timing of interbank settlement activities, it can be possible to avoid duplicative activities by combining interbank messaging and settlement.[44] As a result, a single payment message may be sent from the sender's bank to the recipient's bank through the settlement service with that message containing both the information needed by the banks to adjust their customers' balances and the bank information necessary to conduct interbank settlement.

RTGS arrangements inherently avoid interbank settlement risk because funds are made available to the recipient only after interbank settlement has occurred. This key feature enhances the safety of faster payment services based on the RTGS model, both for individual banks and in the aggregate, particularly during times of financial stress. The lack of inherent interbank settlement risk eliminates the need for measures to mitigate such risk, as would be needed in a DNS arrangement. In addition, by aligning interbank settlement with interbank messaging, the RTGS model can avoid activities, such as storing, netting, and submitting groups of payments for settlement, that are not generally relevant for the provision of faster payments to end users, but would be necessary in DNS-based faster payment services because of the timing mismatch between settlement and the underlying payments. In the process, the RTGS model also avoids the unanticipated liquidity effects that can occur in the event of a settlement failure when interbank settlement positions have been netted by a centralized entity. Finally, when considering interoperability between RTGS-based faster payment services, the lack of interbank settlement risk in such services may facilitate interoperability by avoiding the need to reconcile measures to mitigate cross-system settlement risk, in particular, as may be necessary with DNS-based faster payment services.

At the same time, real-time settlement for faster payments may have liquidity management implications. Because RTGS-based faster payment services process and settle each payment separately, with continuous updates to settlement accounts on a 24x7x365 basis, participants in an RTGS-based service may need to monitor and manage their settlement accounts outside standard business hours to ensure that balances are available to settle each payment. Further, even for retail payment systems, gross settlement may be more liquidity intensive than net settlement.

Based on the design, liquidity management may require tools to reallocate liquidity to support settlement of faster payments. For example, if settlement for an RTGS-based service is conducted in an account that is separate from a bank's primary settlement account (that is, a Federal Reserve master account), a liquidity management tool could allow for banks or an agent acting on their behalf, such as the provider of an RTGS service, to move liquidity to the faster payment settlement account when needed. Alternatively, liquidity management could involve automatic replenishment of the faster payment settlement account from the primary account, based on certain parameters or at certain times of the day. Liquidity management tools are discussed later in the notice.

Another consideration for RTGS-based faster payments is that faster payment services to end users are dependent on uninterrupted availability of the RTGS service to conduct faster payments. Although faster payments based on deferred settlement would require certain clearing activities to occur in real time and at any time, necessitating a high level of resiliency for those activities, end-user payments could still be completed even if the interbank settlement service is temporarily unavailable. In contrast, an RTGS service supporting faster payments would require advanced throughput capabilities and high resiliency of both the settlement service and messaging activities. In addition, to avoid failed end-user payments, enhanced contingency arrangements may be necessary to deal with situations when a primary RTGS processing service is temporarily unavailable to process transactions.

One example of an RTGS service for faster payments is the system being developed by the European Central Bank (ECB) to support ''instant payments'' in the European Union. Like faster payments in the United States, instant payments in the European Union are expected to involve services for real-time payments between end users that can be conducted on a 24x7x365 basis. To facilitate ubiquity of instant payment services across national jurisdictions,

[42] The need for collateral management during nonstandard business hours in a DNS arrangement for faster payments is similar to the need for liquidity management during nonstandard hours in an RTGS arrangement. As a result, to avoid rejected payments resulting from insufficient collateral, a collateral management tool, which could be similar to the liquidity management tool discussed in the context of RTGS arrangements, may be needed in a DNS arrangement.

[43] Currently, interoperability agreements do not exist among payment card networks or wire operators. The only interoperability agreement is in the ACH system between FedACH, provided by the Reserve Banks, and the private-sector Electronic Payments Network.

[44] For purposes of this notice, in an RTGS model, messaging and clearing can be considered synonymous since, beyond real-time message transmission, the other components of clearing that are necessary in a DNS model, such as netting of payments for settlement, are not relevant. Messaging activities may still include other risk-management measures, such as screening for fraudulent payments and ensuring that payment instructions comply with service-specific rules and limits.

the ECB system will offer final settlement for instant payments using balances held at the ECB (that is, central bank money) to banks and other eligible institutions across Europe. In line with 24x7x365 instant payment services for end users, the ECB's system will enable settlement on a 24x7x365 basis. The ECB has announced that it will implement its instant payments RTGS system using separate, dedicated cash settlement accounts for each participating institution. The ECB plans to launch its instant payments RTGS system in November 2018.[45]

Another example, albeit with a different approach, of an RTGS service for faster payments involves a system launched domestically in the United States in late 2017. This system, operated by a private-sector entity, performs immediate, round-the-clock settlement of payments on its private ledger, rather than using central bank money. Each participant in this arrangement relies on the presence of balances stored in a single joint account at a Reserve Bank that is held for the benefit of the joint account-holding banks as a method of backing the private-sector service.[46]

IV. Potential Federal Reserve Actions To Support 24x7x365 Real-Time Settlement of Faster Payments

Although both DNS and RTGS arrangements have benefits and drawbacks for settling faster payments, on balance, the Board views RTGS as offering clear benefits from a risk and efficiency perspective, making it the preferable basis for interbank settlement of faster payments over the long term in the United States. Given the round-the-clock availability of end-user faster payment services, real-time interbank settlement should likewise be possible at any time and on any day. While DNS-based faster payment services with measures to mitigate risk may be appropriate for a nascent faster payment market in the short term, the Board believes that, as the volume and value of faster payments grow in the future, an RTGS infrastructure would provide the safest and most efficient foundation for interbank settlement for the next generation of payment services. Through this notice, the Board is seeking views regarding this perspective on interbank settlement.

In addition, the Board is requesting comment about potential actions that the Federal Reserve could take to support a ubiquitous, nationwide infrastructure for 24x7x365 real-time settlement of faster payments. These actions, which could be taken separately or in combination, include the Reserve Banks' developing (i) a 24x7x365 RTGS settlement service and (ii) a liquidity management tool. In addition to seeking comment on whether the Reserve Banks should consider developing either or both of these services, the Board is interested in receiving comment about whether other approaches would help achieve the long run goals of ubiquitous, nationwide access to safe and efficient settlement services for faster payments.

A. A 24x7x365 RTGS Settlement Service Provided by the Reserve Banks

1. Characteristics of a 24x7x365 RTGS Settlement Service

As one potential action, the Reserve Banks could provide a 24x7x365 RTGS settlement service for banks that would carry out the interbank settlement of individual payments immediately, on any day, and at any time of the day. Such a service would reflect the real-time speed and 24x7x365 nature of faster payments. The service would settle interbank obligations through debits and credits to balances in banks' accounts at the Reserve Banks, constituting settlement in central bank money.[47] As it does with some of its existing services, the Federal Reserve could allow agents to submit settlement instructions to a 24x7x365 RTGS settlement service on behalf of participating banks that hold accounts at the Reserve Banks.

A 24x7x365 RTGS settlement service could involve messaging functionality, which traditionally is considered part of the clearing level, and may function much like the Fedwire Funds Service. As with the Fedwire Funds Service, a 24x7x365 RTGS settlement service could receive and deliver the entire payment message, including bank routing information needed for interbank settlement and customer information needed by receiving banks to update their customers' accounts.[48] Under this design, the service would receive settlement instructions from and deliver settlement notifications to the banks (or their agents) pursuant to the information in the payment message. As a result, the RTGS functionality could provide a straight-through processing method to conduct interbank clearing and settlement of faster payments.

The proposed 24x7x365 RTGS settlement service could make use of the existing electronic access connections and payment services network that the Reserve Banks provide to banks to enable secure payment processing for transactions involving Reserve Bank payment services. In addition, interbank settlement of faster payments could occur in Federal Reserve master accounts, similar to the way that settlement for other types of Reserve Bank payment services occurs, and could use the same account-monitoring regime that is in place for other payment services provided by the Reserve Banks. Alternatively, interbank settlement of faster payments could occur in separate, dedicated faster payment settlement accounts for each participating bank with balances that could be treated as reserves, earning interest and satisfying reserve balance requirements. With separate accounts, an approach would be needed for moving funds between a bank's master account and its faster payment settlement account during standard business hours and potentially outside those hours. In either account structure, the service would record end-of-day balances in the account and provide balance reports for each calendar day of the week (that is, a seven-day accounting regime). The Board is requesting comment on the advantages and disadvantages of these design options and features.

Additionally, a 24x7x365 RTGS settlement service might need to incorporate some auxiliary services or other service options in order to support an effective nationwide system. One example of an auxiliary service is a proxy database or directory that allows banks to route end-user payments using the recipient's alias, such as an email address or phone number, rather than

[45] More information about the ECB's RTGS system for instant payments is available at *https://www.ecb.europa.eu/paym/initiatives/html/index.en.html.*

[46] A joint account enables settlement for participants in a private-sector arrangement to be backed by funds held for a special purpose at a Reserve Bank. Although the joint account is not formally a collateral account, the funds in the joint account are held for the joint benefit of the settling participants. Accordingly, the operator of a settlement arrangement that relies on a joint account can perform real-time, payment-by-payment settlement on its own ledger, which in turn reflects how the operator, as agent for the settling participants, will attribute the balances in the joint account on its own records to each settling participant. Settlement backed by a joint account can occur at any time or on any day because the settlement takes place on the ledger of the settlement-arrangement operator.

[47] The Board expects that such a service would be used for credit transfer payments in which the party that intends to make a payment initiates the payment to the recipient.

[48] An RTGS settlement service could be designed to optionally process either the full message with bank routing and customer information or only the bank routing information needed for interbank settlement. The latter use would require third parties to separately transmit the payment message between sending and receiving banks. These design choices may raise policy, legal, and operational complexities, such as achieving payment transparency for screening and other compliance-related requirements.

their bank routing and account information. Another example of auxiliary services is enhanced fraud-monitoring capabilities, which may involve a shared database of known fraudulent accounts or automated fraud detection tools. Other service options to consider include transaction limits to manage risk or payment-by-payment offsetting functionality to economize on the use of liquidity. The Board is requesting comment on whether such auxiliary services or other service options are necessary for broad adoption of faster payments and what entity(s) should provide them.

A 24x7x365 RTGS settlement service provided by the Reserve Banks would rely on banks and other parties, such as processors and other providers of payment services, to develop end-user services and, ideally, the full suite of auxiliary services, such as a proxy database or directory, that build upon the basic functionality of the settlement service.

2. Public Benefits of a 24x7x365 RTGS Settlement Service

The Federal Reserve's longstanding public policy objectives for the payment system are that payment systems are safe, efficient, and accessible to all eligible banks on an equitable basis and, through them, to the public nationwide.[49] Based on its analysis, the Board believes the Reserve Banks' development of a 24x7x365 RTGS settlement service could yield societal benefit by advancing these objectives and serve as an important part of the foundation for the nation's future payment system. The Board is requesting comment on whether the Federal Reserve's provision of a 24x7x365 RTGS settlement service will indeed offer these potential benefits.

Accessibility

A 24x7x365 RTGS settlement service provided by the Reserve Banks could significantly improve the long-term prospect of all banks having access to a real-time interbank settlement infrastructure for faster payments. Today, the Reserve Banks provide payment services to more than 11,000 banks—the vast majority of banks in the United States. By capitalizing on its electronic access network and customer relationships, the Reserve Banks are in a position to offer equitable access to real-time interbank settlement to all eligible banks in the country, regardless of type or size.

It may be difficult for the private sector to create an infrastructure that, on its own, could provide equitable access to enough banks to achieve ubiquity. Practically, a private-sector RTGS service that does not have existing relationships with a large number of banks may have difficulties establishing those relationships for a new service. Likewise, banks without an existing relationship to the provider of a private-sector RTGS service may find it cumbersome and time-consuming to establish connections with a new provider of settlement services. However, accessibility could be greatly enhanced if existing and potential future private-sector RTGS services were able to interoperate with a Reserve Bank service, such that end-user customers of any bank could send faster payments to end-user customers of any other bank, regardless of the faster payment RTGS service used by the banks. In such a scenario, private-sector and Reserve Bank RTGS services would work in tandem to provide ubiquitous, nationwide access to real-time interbank settlement for faster payments.

Safety

As noted above, real-time settlement for faster payments avoids interbank settlement risk by aligning the speed of interbank settlement with the speed of the underlying payments. If a 24x7x365 RTGS settlement service developed by the Reserve Banks were to significantly improve the prospect that banks nationwide would use real-time settlement for faster payments, the overall safety of the faster payment market in the United States could be enhanced. In addition, a service provided by the Federal Reserve, with its focus on the stability of the overall payment system, could also contribute to the real and perceived resiliency of faster payment settlement. This would be especially true if a 24x7x365 RTGS settlement service provided by the Reserve Banks were available alongside private-sector RTGS services, giving banks an option to connect to multiple operators for resiliency, as they often do with traditional payment systems. Finally, a 24x7x365 RTGS settlement service could further support the Federal Reserve's ability to provide payment system stability in moments of financial crisis or natural disaster, as it has done in the past with its cash, check, ACH, and wire transfer services.

Efficiency

Payment system efficiency has multiple facets, including resource costs, the value of broad networks, and competition between and innovation by faster payment services. While a 24x7x365 RTGS settlement service provided by the Reserve Banks would consume societal resources and could duplicate certain costs that may already have been incurred to set up other settlement arrangements for faster payments, its net effect on the efficiency of the faster payment environment would depend on the extent to which it generates societal benefits by improving bank participation in a real-time interbank settlement infrastructure and, ultimately, public access to safe and secure faster payment services. Specifically, the value of a payment system increases as more banks join the system because all participants and end users can send payments to more recipients. As a result, incremental societal benefits realized through nationwide bank participation in a real-time interbank settlement infrastructure could outweigh the societal costs of the Reserve Banks developing a 24x7x365 RTGS settlement service.

Additional efficiency benefits could be realized through enhanced competition between and innovation by faster payment services. The development of a nationwide real-time interbank settlement infrastructure could play a strategic role in persuading more banks to develop faster payment services, creating more competition among bank-provided services and with existing nonbank services. Bank and nonbank providers of faster payment services may also be able to develop new or enhance existing services by capitalizing on the underlying interbank infrastructure. The resulting competition and innovation could ultimately benefit end users because competition typically generates lower costs and innovation advances feature-rich services.

The Board recognizes the possibility that introduction of a Reserve Bank-provided 24x7x365 RTGS settlement service could have the opposite effect and disrupt the existing faster payment market. Industry stakeholders have already made certain initial investments in faster payment services and would need to assess how, or if, to connect to a new settlement service.[50] Therefore, it is possible that Reserve Bank entry could add to market fragmentation and lower the prospects for ubiquitous faster payments in the United States, especially in the short run.

The Board also recognizes that the cost of investing in new technology for the banking industry, its customers, and

[49] *See* ''The Federal Reserve in the Payments System,'' *supra* note 13.

[50] If banks were to establish connections to multiple settlement services, doing so may generate a duplication of participant connection costs.

service providers could be significant, and it could take many years to achieve full participation across the banking system. Operational and technical challenges are inherent in the creation of any new service, and the fact that the envisioned RTGS settlement service would operate 24x7x365 may compound these challenges. The Board expects that moving to a 24x7x365 settlement environment may take a number of years of technical and operational adjustment for all stakeholders. In addition, issues with technical and operational adjustments may be exacerbated if there is more than one provider of real-time settlement. At the same time, some disruption and a period of adjustment could be acceptable, and often accompany foundational changes in infrastructure. The Board is seeking comment on whether the industry believes the costs of adjustment and potential disruption are outweighed by the benefits of the proposed interbank settlement infrastructure.

B. A Liquidity Management Tool

1. Liquidity Management Needs in RTGS-Based Faster Payment Services

RTGS for faster payments can raise liquidity management issues for banks, particularly given the 24x7x365 nature of faster payments. RTGS-based faster payments require banks to have sufficient liquidity to perform interbank settlement of individual payments. Absent sufficient liquidity, banks, and by extension their customers, would experience failed faster payments because interbank settlement, which must occur prior to the provision of final funds to the recipient in an RTGS arrangement, could not take place. Moreover, because faster payments can occur on a 24x7x365 basis, RTGS for faster payments requires banks to have sufficient liquidity to settle individual payments at any time of the day, any day of the year.

The risk of failed payments caused by insufficient liquidity in an RTGS-based faster payment service implies a general need for banks to manage their liquidity related to settlement. The nature of this liquidity management will depend on the design of a particular RTGS arrangement for faster payments. For example, a private-sector RTGS arrangement for faster payments may rely on a joint account at a Reserve Bank that backs settlement conducted on a private ledger maintained by the arrangement's operator. In such an arrangement, banks would need to ensure sufficient liquidity by making contributions to the joint account that are adequate to cover obligations recorded in the operator's ledger. In another example, depending on the design of a 24x7x365 RTGS settlement service provided by the Reserve Banks, participating banks may have individual accounts at the Reserve Banks, separate from their master accounts, that are dedicated to the interbank settlement of faster payments.[51] In this case, banks would need to manage their liquidity on a 24x7x365 basis across their master accounts and their dedicated faster payment settlement accounts at the Reserve Banks.[52]

In either of these examples, liquidity management by banks requires methods to transfer liquidity between accounts at the Reserve Banks. Because RTGS arrangements for faster payments require liquidity management outside standard business hours, these methods for liquidity transfers may need to be available during nonstandard business hours.

At present, the Reserve Banks do not offer a service that would allow banks to move liquidity as needed to support 24x7x365 real-time settlement of faster payments. Various Reserve Bank services enable transfer of funds between accounts at the Reserve Banks, including the Fedwire Funds Service and the National Settlement Service; however, none of them fulfill the around-the-clock requirement. Over time, the Reserve Banks have extended operating hours for these services.[53] However, current operating hours limit liquidity management based on these services, particularly during weekends and holidays.

2. Characteristics of a Liquidity Management Tool

As a result of the potential need for liquidity management outside standard business hours in certain RTGS-based systems for faster payments, and the limitations of existing Federal Reserve services to support such liquidity management, the Board is requesting comment on whether the Reserve Banks should consider providing a liquidity management tool that would enable movement of funds during nonstandard business hours between banks' master accounts at the Reserve Banks and an account (or accounts) at the Reserve Banks used to conduct or support 24x7x365 real-time settlement of faster payments.[54] To provide such a tool for liquidity transfers during nonstandard business hours, the Federal Reserve could enhance an existing service by extending that service's operating hours, potentially up to 24x7x365, or providing special operating windows outside current operating hours. Alternatively, the Reserve Banks could develop a new service. Regardless of whether the Reserve Banks enhance an existing service or develop a new service, the Board envisions such a service being used, at least initially, only for the purpose of liquidity management related to RTGS-based faster payment services. The Board recognizes, however, that depending on its design, a liquidity management tool could have functionality that would be useful for other purposes. In particular, the ability to move funds outside standard business hours could be used to manage cash collateral in a DNS arrangement for faster payments that uses full cash collateral at the Reserve Banks to mitigate credit risk associated with deferred settlement.

To determine how the Reserve Banks could best provide a liquidity management tool that meets industry needs, the Board is further seeking input on the characteristics and capabilities that such a tool might have. A key area of interest to the Board is the level of involvement that individual banks would wish to have in establishing the timing of liquidity transfers and in initiating specific transfers. For example, a tool could allow a designated agent to coordinate liquidity transfers simultaneously across a large number of participants in a settlement

[51] Globally, a number of central banks that provide or are planning to provide RTGS services for faster payments, including the ECB and the Reserve Bank of Australia, require banks to have separate, dedicated accounts for the settlement of faster payments through those services.

[52] If faster payments settle through banks' master accounts at the Reserve Banks, then liquidity management would involve a bank's overall liquidity available for settlement, as opposed to its allocation of liquidity specifically available for settlement of faster payments.

[53] The Fedwire Funds Service operating hours for each business day begin at 9:00 p.m. eastern time (ET) on the preceding calendar day and end at 6:30 p.m. ET, Monday through Friday, excluding designated holidays. For example, processing on a Monday begins at 9:00 p.m. ET on Sunday night and ends at 6:30 p.m. ET Monday night. The Reserve Banks last expanded the Fedwire Funds Service operating hours in 2004, moving from an eighteen-hour business day to the current twenty-one and one-half hour business day. Current operating hours for NSS are 7:30 a.m. to 5:30 p.m. ET, Monday through Friday, excluding designated holidays. The Reserve Banks announced in 2015, that they are prepared to accept requests from current settlement agents to open the NSS settlement window as early as 9:00 p.m. ET the previous calendar day for the next business day. To date, no settlement agent has requested an earlier opening.

[54] As a baseline, it is assumed that liquidity transfers to or from settlement accounts are routinely available during existing operating hours for the Fedwire Funds Service.

arrangement, thereby removing the need for those participants to continuously monitor liquidity and initiate corresponding liquidity transfers. Such a tool could also support automated liquidity transfers, particularly during nonstandard business hours, based on thresholds established by a bank working with a designated agent. Such capabilities could be possible through NSS (or a similarly designed service) for the multilateral movement of funds between accounts at the Reserve Banks. Alternatively, if banks prefer to have more direct involvement in the timing and tailoring of their liquidity transfers, a tool could involve individual liquidity transfers initiated by individual banks. Such a structure for liquidity management could be provided through the Fedwire Funds Service (or a similarly designed service). In either case, expanded operating hours for such a service would support liquidity management outside standard business hours, possibly up to 24x7x365.

3. Public Benefits of a Liquidity Management Tool

The Board believes a liquidity management tool could improve the level of participation by banks in real-time settlement infrastructure for faster payments. Such a tool could be an efficient and economical way to close potential gaps in account funding times for existing and potential future private-sector 24x7x365 real-time interbank settlement systems. Thus, the tool might make private-sector systems more attractive to a broader range of banks and boost the prospect of more banks joining private-sector systems. It could similarly increase participation in a 24x7x365 RTGS settlement service provided by the Reserve Banks. The end result might be a combination of RTGS arrangements for faster payments, enabling broader access to real-time interbank settlement infrastructure in the long term with similar safety, resiliency, and efficiency benefits discussed in relation to a Reserve Bank-provided RTGS settlement service. In addition, the liquidity management functionality itself would mitigate liquidity risk that can arise for banks in 24x7x365 real-time settlement of faster payments and the concomitant possibility that end users will experience individually rejected payments and broader scale payment interruptions.

V. Request for Comment

The Board is seeking feedback on all aspects of the discussion presented in this notice and the specific questions posed below. The Board will use this feedback to assess what steps, if any, it should take related to the actions discussed or alternative approaches offered by the payment industry or other stakeholders. As previously mentioned, these actions are subject to the longstanding principles and criteria on new services or major service enhancements as part of the Federal Reserve's statutory requirements. As part of assessing these actions, the Board would continue its due diligence related to those requirements.

The Board intends to publish the results of this request for comment and, as appropriate, to seek further comment on any specific actions that the Board determines that the Federal Reserve might pursue. The Board recognizes that a decision to undertake these actions, in particular the development of a 24x7x365 RTGS settlement service, will require close partnership and collaboration with industry stakeholders. The Federal Reserve would work with stakeholders to implement new infrastructure within a sensible timeline that provides stakeholders enough advance information to calibrate resource planning and operational readiness. The Board also seeks feedback on specific areas, such as liquidity management, interoperability, accounting processes, or payment routing, that stakeholders believe may require joint Federal Reserve and industry teams to identify approaches for implementation in a 24x7x365 RTGS settlement service.

Questions

1. Is RTGS the appropriate strategic foundation for interbank settlement of faster payments? Why or why not?

2. Should the Reserve Banks develop a 24x7x365 RTGS settlement service? Why or why not?

3. If the Reserve Banks develop a 24x7x365 RTGS settlement service,

a. Will there be sufficient demand for faster payments in the United States in the next ten years to support the development of a 24x7x365 RTGS settlement service? What will be the sources of demand? What types of transactions are most likely to generate demand for faster payments?

b. What adjustments would the financial services industry and its customers be required to make to operate in a 24x7x365 settlement environment? Are these adjustments incremental or substantial? What would be the time frame required to make these adjustments? Are the costs of adjustment and potential disruption outweighed by the benefits of creating a 24x7x365 RTGS settlement service? Why or why not?

c. What is the ideal timeline for implementing a 24x7x365 RTGS settlement service? Would any potential timeline be too late from an industry adoption perspective? Would Federal Reserve action in faster payment settlement hasten or inhibit financial services industry adoption of faster payment services? Please explain.

d. What adjustments (for example, accounting, operations, and agreements) would banks and bank customers be required to make under a seven-day accounting regime where Reserve Banks record and report end-of-day balances for each calendar day during which payment activity occurs, including weekends and holidays? What time frame would be required to these changes? Would banks want the option to defer receipt of such information for nonbusiness days to the next business day? If necessary changes by banks represent a significant constraint to timely adoption of seven-day accounting for a 24x7x365 RTGS settlement service, are there alternative accounting or operational solutions that banks could implement?

e. What incremental operational burden would banks face if a 24x7x365 RTGS settlement service were designed using accounts separate from banks' master accounts? How would the treatment of balances in separate accounts (for example, ability to earn interest and satisfy reserve balance requirements) affect demand for faster payment settlement?

f. Regarding auxiliary services or other service options,

i. Is a proxy database or directory that allows faster payment services to route end-user payments using the recipient's alias, such as email address or phone number, rather than their bank routing and account information, needed for a 24x7x365 RTGS settlement service? How should such a database be provided to best facilitate nationwide adoption? Who should provide this service?

ii. Are fraud prevention services that provide tools to detect fraudulent transfers needed for a 24x7x365 RTGS settlement service? How should such tools be provided? Who should provide them?

iii. How important are these auxiliary services for adoption of faster payment settlement services by the financial services industry? How important are other service options such as transaction limits for risk management and offsetting mechanisms to conserve liquidity? Are there other auxiliary services or service options that are needed for the settlement service to be adopted?

g. How critical is interoperability between RTGS services for faster payments to achieving ubiquity?

h. Could a 24x7x365 RTGS settlement service be used for purposes other than interbank settlement of retail faster payments? If so, for what other purposes could the service be used? Should its use be restricted and, if so, how?

i. Are there specific areas, such as liquidity management, interoperability, accounting processes, or payment routing, for which stakeholders believe the Board should establish joint Federal Reserve and industry teams to identify approaches for implementation of a 24x7x365 RTGS settlement service?

4. Should the Federal Reserve develop a liquidity management tool that would enable transfers between Federal Reserve accounts on a 24x7x365 basis to support services for real-time interbank settlement of faster payments, whether those services are provided by the private sector or the Reserve Banks? Why or why not?

5. If the Reserve Banks develop a liquidity management tool,

a. What type of tool would be preferable and why?

i. A tool that requires a bank to originate a transfer from one account to another

ii. A tool that allows an agent to originate a transfer on behalf of one or more banks

iii. A tool that allows an automatic transfer of balances (or ''sweep'') based on pre-established thresholds and limits

iv. A combination of the above

v. An alternative approach

b. Would a liquidity management tool need to be available 24x7x365, or alternatively, during certain defined hours on weekends and holidays? During what hours should a liquidity management tool be available?

c. Could a liquidity management tool be used for purposes other than to support real-time settlement of retail faster payments? If so, for what other purposes could the tool be used? Should its use be restricted and, if so, how?

6. Should a 24x7x365 RTGS settlement service and liquidity management tool be developed in tandem or should the Federal Reserve pursue only one, or neither, of these initiatives? Why?

7. If the Federal Reserve pursues one or both of these actions, do they help achieve ubiquitous, nationwide access to safe and efficient faster payments in the long run? If so, which of the potential actions, or both, and in what ways?

8. What other approaches, not explicitly considered in this notice, might help achieve the broader goals of ubiquitous, nationwide access to faster payments in the United States?

9. Beyond the provision of payment and settlement services, are there other actions, under its existing authority, the Federal Reserve should consider that might help its broader goals with respect to the U.S. payment system?

By order of the Board of Governors of the Federal Reserve System, September 28, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–24667 Filed 11–14–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0643; Product Identifier 2018–NM–084–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposal for certain Dassault Aviation Model FALCON 7X airplanes. This action revises the notice of proposed rulemaking (NPRM) by proposing to require the incorporation of revised and more restrictive airworthiness limitations. We are proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, we are reopening the comment period to allow the public the chance to comment on these changes.

DATES: The comment period for the NPRM published in the **Federal Register** on August 10, 2018 (83 FR 39630), is reopened.

We must receive comments on this SNPRM by December 31, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0643; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this SNPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0643; Product Identifier 2018–NM–084–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this SNPRM. We will consider all comments received by the closing date and may amend this SNPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this SNPRM.

Discussion

We issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain Dassault Aviation Model FALCON 7X airplanes. The NPRM published in the **Federal Register** on August 10, 2018 (83 FR 39630). The NPRM was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new and more restrictive maintenance requirements and airworthiness limitations for airplane structures and systems.

Actions Since the NPRM Was Issued

Since we issued the NPRM, additional airworthiness limitations have been issued, and we have determined that it is necessary to revise the existing maintenance or inspection program to incorporate the new and more restrictive requirements in the revised service information. We have changed paragraph (g) of this proposed AD to require revising the existing maintenance or inspection program to incorporate the information specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X Maintenance Manual (MM).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0101, dated May 3, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Dassault Aviation Model FALCON 7X airplanes. The MCAI states:

> The airworthiness limitations and certification maintenance instructions for Dassault Falcon 7X aeroplanes, which are approved by EASA, are currently defined and published in Dassault Falcon 7X AMM [airplane maintenance manual], Chapter 5–40. These instructions have been identified as mandatory for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition [*i.e.,* reduced structural integrity and reduced control of these airplanes due to the failure of system components].
>
> Previously, EASA issued AD 2015–0095 [which corresponds to FAA AD 2016–16–09, Amendment 39–18607 (81 FR 52752, August 10, 2016) (''AD 2016–16–09'')] to require accomplishment of the maintenance tasks, and implementation of the airworthiness limitations, as specified in Dassault Falcon 7X AMM, Chapter 5–40, at Revision 4.
>
> Since that [EASA] AD was issued, Dassault issued the ALS [airworthiness limitations section], which introduces new and more restrictive maintenance requirements and/or airworthiness limitations.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2015–0095, which is superseded, and requires accomplishment of the actions specified in the ALS.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0643.

Related Service Information Under 1 CFR Part 51

Dassault Aviation has issued Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X MM. This service information introduces new and more restrictive maintenance requirements and airworthiness limitations for airplane structures and systems. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Comments

We gave the public the opportunity to participate in developing this proposed AD. We received no comments on the NPRM or on the determination of the cost to the public.

FAA's Determination and Requirements of This SNPRM

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Costs of Compliance

We estimate that this proposed AD affects 67 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

We have determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Dassault Aviation: Docket No. FAA–2018–0643; Product Identifier 2018–NM–084–AD.

(a) Comments Due Date

We must receive comments by December 31, 2018.

(b) Affected ADs

This AD affects AD 2014–16–23, Amendment 39–17947 (79 FR 52545, September 4, 2014) (''AD 2014–16–23'') and AD 2016–16–09, Amendment 39–18607 (81 FR 52752, August 10, 2016) (''AD 2016–16–09'').

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 7X airplanes, certificated in any category, with an original certificate of airworthiness or original export certificate of airworthiness issued on or before August 24, 2018.

Note 1 to paragraph (c) of this AD: Dassault Aviation Model FALCON 7X airplanes with modifications M1000 and M1254 incorporated are commonly referred to as ''Model FALCON 8X'' airplanes as a marketing designation.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time limits/maintenance checks.

(e) Reason

This AD was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. We are issuing this AD to address reduced structural integrity and reduced control of airplanes due to the failure of system components.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, by incorporating the information specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X Maintenance Manual (MM). The initial compliance times for the tasks specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X MM are at the applicable compliance times specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X MM, or within 90 days after the effective date of this AD, whichever occurs later.

(h) Terminating Action for Other ADs

(1) Accomplishing the actions required by paragraph (g) of this AD terminates the requirements of paragraph (q) of AD 2014–16–23.

(2) Accomplishing the actions required by paragraph (g) of this AD terminates all requirements of AD 2016–16–09.

(i) No Alternative Actions, Intervals, and Critical Design Configuration Control Limitations (CDCCLs)

After the existing maintenance or inspection program, as applicable, has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), intervals, or CDCCLs may be used unless the actions, intervals, and CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0101, dated May 3, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0643.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3226.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; phone: 201–440–6700; internet: *http://www.dassaultfalcon.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on November 6, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–24854 Filed 11–14–18; 8:45 am]

BILLING CODE 4910–13–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 401

[Docket No. SSA–2018–0004]

34RIN 0960–AH97

Security and Suitability Files

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Social Security Administration (SSA) separately published, in today's **Federal Register**, notice of a new system of records, entitled Security and Suitability Files. This rulemaking proposed to remove two systems of records listed in our exemptions, but which do not exist, and will replace them with a new exemption for this specified system of records from specific provisions of the Privacy Act, under 5 U.S.C. 552a(k)(5).

DATES: To ensure that your comments are considered, we must receive them no later than December 17, 2018.

ADDRESSES: You may submit comments by any one of three methods—internet,

fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2018–0004, so that we may associate your comments with the correct regulation.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the Search function to find docket number SSA–2018–0004. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. Fax: Fax comments to (410) 966–2830.

3. Mail: Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Jasson Seiden, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 597–4307, email: *Jasson.Seiden@ssa.gov.* For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Privacy Act (5 U.S.C. 552a) we are issuing public notice of our intent to establish a new system of records entitled, Security and Suitability Files (60–0377).

We are establishing the Security and Suitability Files to govern the information we generate in conducting personnel security and suitability background investigations. With limited exceptions, persons appointed to, and under consideration for, Federal service or contract employment are required to submit to a suitability background investigation. The Deputy Commissioner for Human Resources, Office of Personnel, Center for Suitability and Personnel Security (CSPS) oversees and is responsible for adjudicating these investigations. Information collected as part of the agency's suitability and background investigations process that is sent to the Office of Personnel Management (OPM) is covered by OPM/Central-9, Personnel Investigations Records. The Security and Suitability Files we are creating covers any additional security and suitability related information generated by SSA that is not sent to OPM. We will use the information we collect to conduct background investigations to establish that individuals employed by SSA, working for SSA under contract, or otherwise granted access to agency facilities and records are suitable for such employment or access.

Due to the investigatory nature of information that will be maintained in this system of records, this rule would add the Security and Suitability Files to the list of SSA systems that are exempt from specific provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(5).

Rulemaking Analyses and Notices

All comments received on or before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. A final rule may be published at any time after close of the comment period.

Clarity of This Rule

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on this interim final rule, we invite your comments on how to make the rule easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rule clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format make the rule easier to understand, *e.g.* grouping and order of sections, use of headings, paragraphing?

Regulatory Procedures

SSA will publish a final rule responding to any comments received and, if appropriate, will amend provisions of the rule.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this proposed rule does not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563.

We also determined that this proposed rule meets the plain language requirement of Executive Order 12866.

Executive Order 13132 (Federalism)

This proposed rule was analyzed in accordance with the principles and criteria established by Executive Order 13132, and SSA determined that the proposed rule will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. SSA also determined that this proposed rule will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations effectuating Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this proposed rule.

Regulatory Flexibility Act

We certify that this proposed rule will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require Office of Management and Budget approval under the Paperwork Reduction Act.

List of Subjects in 20 CFR Part 401

Privacy and disclosure of official records and information.

Nancy A. Berryhill,

Acting Commissioner of Social Security.

For the reasons stated in the preamble, we propose to amend part 401 of title 20 of the Code of Federal Regulations as set forth below:

PART 401—PRIVACY AND DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 205, 702(a)(5), 1106, and 1141 of the Social Security Act (42 U.S.C. 405, 902(a)(5), 1306, and 1320b-11); 5 U.S.C. 552 and 552a; 8 U.S.C. 1360; 26 U.S.C. 6103; 30 U.S.C. 923.

■ 2. Amend § 401.85 by revising paragraph (b)(2)(iii)(A) and removing and reserving paragraph (b)(2)(iii) (B):

* * * * *

(b) * * *

(2) * * *

(iii) * * *

(A) Security and Suitability Files.

* * * * *

[FR Doc. 2018–24851 Filed 11–14–18; 8:45 am]

BILLING CODE 4191–02–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. 2017–0015]

RIN 0960–AI09

Setting the Manner for the Appearance of Parties and Witnesses at a Hearing

AGENCY: Social Security Administration.

ACTION: Notice of proposed rule making.

SUMMARY: We propose to revise our rules to explain that the agency retains the right to determine how parties and witnesses will appear at a hearing before an administrative law judge (ALJ) at the hearing level of our administrative review process, and we will set the time and place for the hearing accordingly. We also propose to revise our rules to explain the State agency or the Associate Commissioner for Disability Determinations, or his or her delegate, will determine how parties and witnesses will appear, and will set the time and place for a hearing, before a disability hearing officer (DHO) at the reconsideration level in continuing disability review (CDR) cases. At both levels, we propose to schedule the parties to a hearing to appear by video teleconference (VTC), in person, or, in limited circumstances, by telephone. We propose that parties to a hearing will not have the option to opt out of appearing by the manner of hearing we choose. We also propose rules that explain how we will determine the manner of a party's or a witness's appearance. We expect these proposed changes would improve our service to the public by increasing the efficiency of our hearings processes and reducing the amount of time it takes us to schedule and hold hearings.

DATES: To ensure that your comments are considered, we must receive them no later than January 14, 2019.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2017–0015 so that we may associate your comments with the correct rule.

CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the *Search* function to find docket number SSA–2017–0015. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Mail your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Susan Swansiger, Office of Hearings Operations, Social Security Administration, 5107 Leesburg Pike, Falls Church, VA 22041, (703) 605–8500. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Background

When we determine whether you are disabled under the old-age, survivors, and disability insurance program under title II of the Social Security Act (Act) or the Supplemental Security Income (SSI) program under title XVI of the Act, we follow an administrative review process that usually consists of the following steps: [1] An initial determination, a reconsideration,[2] a hearing before an ALJ, and Appeals Council review. If you are dissatisfied with the initial determination of your disability claim(s), you may request reconsideration. In most cases, the reconsideration step of the administrative review process, which is technically the first level of appeal in the administrative review process for Social Security disability claims in most States,[3] consists of a case review by Disability Determination Services (DDS) personnel who were not involved in the initial determination. If you are dissatisfied with your reconsidered determination, you may request a hearing, which is held by an ALJ.[4] If you are dissatisfied with an ALJ's decision, you may ask the Appeals Council to review that decision. After you have completed these steps of the administrative review process, you may request judicial review of our final decision by filing a civil action in a Federal district court.

Once you are receiving benefits under title II or XVI of the Act, we are required to conduct CDRs periodically to determine whether your disability continues.[5] When we make a medical cessation determination that you are no longer disabled because your medical impairment(s) has ceased, did not exist,

[1] 20 CFR 404.902, 416.1402; 20 CFR 404.909, 416.1409; 20 CFR 404.933, 416.1433; 20 CFR 404.968, 416.1468.

[2] In certain States, which we refer to as ''prototype States,'' we modified the disability determination process by eliminating the reconsideration step of the administrative review process. If an individual in a prototype State is dissatisfied with the initial determination on his or her disability claim(s), he or she may request a hearing before an ALJ. 20 CFR 404.906(b)(4), 416.1406(b)(4). Beginning January of 2019, this prototype process is being phased out, and the reconsideration step reinstated in ten states. Reconsideration reinstatement will be complete by mid Fiscal Year 2020.

[3] The exception would be the prototype States.

[4] 20 CFR 404.930, 416.1430.

[5] Section 221(i) of the Act, 42 U.S.C. 421(i) and 1614(a)(4) of the Act, 42 U.S.C. 1382c.

or is no longer disabling, you may appeal that determination. The steps in the CDR administrative review process parallel those in the initial disability determination administrative appeals cycle in that both contain some type of: An initial determination, a reconsideration, a hearing before an ALJ, and Appeals Council review. In the CDR administrative review process, however, an evidentiary hearing before a DHO is held at the reconsideration step for a CDR. Specifically, when we make an initial CDR determination and you want to contest our determination that you are no longer disabled, you may request an evidentiary hearing before a DHO [6] on reconsideration; if you are dissatisfied with your reconsidered determination, you may request a hearing before an ALJ; and if you are dissatisfied with the ALJ's decision, you may ask the Appeals Council to review that decision. When you have completed the administrative review process, you may request judicial review of our final decision by filing a civil action in a Federal district court.

Since Congress established Social Security in 1935, the size and scope of the programs we administer have grown tremendously. During the 1940s and 1950s, Congress extended coverage under title II to nearly the entire American workforce. In the 1950s, Congress revised the Act and created the disability insurance program, and in the 1970s, Congress created the Supplemental Security Income (SSI) program, both of which greatly expanded the size and scope of our programs. The aging of the baby boomers and the changing demographics of our nation have also significantly affected the size and scope of our workloads. The Supreme Court has aptly observed that we are ''probably the largest adjudicative agency in the western world,'' where ''[t]he need for efficiency is self-evident.'' [7]

When we began our hearings process in 1940, we handled a comparatively small number of claims involving retirement and survivors insurance, and received only about 16,000 hearing requests in our first decade.[8] At present, we continue to face an unprecedented service challenge with nearly 860,000 individuals waiting an average of 19 months for a hearing before an ALJ.[9] We currently process several hundred thousand hearing requests before an ALJ each year through an extensive network of 164 hearing offices, 5 National Hearing Centers (NHCs) and several hundred remote sites. Due to factors inherent to managing a nationwide program, including differences in the number of hearing requests received and the availability of administrative resources in a hearing office service area, we have a significant disparity in wait times for a hearing across the nation. For example, in fiscal year (FY) 2018, the average wait time for a hearing before an ALJ was 595 days. However, 76% of our hearing offices had average wait times between 500 and 700 days, 10% of our offices had average wait times over 700 days, and 14% of our offices had wait times below 500 days.[10]

We face the same workload challenges with regard to the reconsideration disability hearings before a DHO for CDRs. According to our internal data sources, from 2007 to 2018 the number of requests for a disability hearing at the reconsideration level increased from 19,898 to 82,604.[11] With this tremendous increase in the number of pending disability hearing requests, the length of time it takes us to conduct a disability hearing has increased as well. Our internal data shows that, nationally, the average processing time from the date we receive a request for disability hearing before a DHO to the date the DHO issues a reconsidered determination was 194 days.[12] Additionally, nearly 10.5% of disability hearings at the reconsideration level have been pending for 240 to 359 days, and 14.9% have been pending for 360 or more days.[13] Increased processing times for disability hearings at the reconsideration level correlate to increased overpayments due to the individual's right to continue to receive disability benefits under title II, or disability or blindness payments under title XVI, while their claims are pending at the reconsideration or ALJ hearing level.[14]

Our Office of the Inspector General (OIG) evaluated the financial impact of individuals continuing to receive benefit payments during CDR appeals. In 2006, OIG found that individuals waited an average of 648 days (in title II cases) and 694 days (in title XVI cases) from the time they requested reconsideration of an initial medical cessation determination and the time they received an ALJ decision.[15] By May 2017, the average processing time for medical cessation appeals had increased to 766 days (title II) and 831 days (title XVI) for sampled recipients.[16] To reduce or avoid overpayments resulting from continued benefit payments, OIG recommended that we enhance our business process to allow more timely determinations and decisions on medical cessation appeals.[17]

Efficiently managing these workloads while preserving the accuracy and fundamental fairness of our hearings has required, and continues to require, creative thinking and strategic planning. Since the mid-1990s, we have recognized that electronic service delivery, based on proven secure technology, can provide our customers with new ways to conduct business with us. These new ways of conducting business with us are both convenient for claimants and efficient for claimants and us. We have continuously explored expanding the service options available to our customers in new and innovative ways as technological advances allow.[18]

For about 20 years we have explored the use of VTC to conduct fair and accurate hearings more efficiently. In the late 1990s, we tested our capacity to conduct ALJ hearings by VTC in Iowa. We received positive feedback from participants, and test data showed that processing times for VTC hearings were substantially lower than the processing time for in-person hearings held by ALJs at remote locations during the same

[6] 20 CFR 404.913(b), 404.914 and 416.1413(d), 416.1414.

[7] *Barnhart* v. *Thomas,* 540 U.S. 20, 28–29 (2003) (internal quotation marks omitted).

[8] ''Appeals Under Old-Age and Survivors Insurance,'' *Social Security Bulletin,* vol. 15, no. 1, p. 15 (January 1952) (*https://www.ssa.gov/policy/docs/ssb/v15n1/v15n1p15.pdf*).

[9] Hearings and Appeals Homepage, Public Data files, *http://www.ssa.gov/appeals/*; See: Age distribution of pending hearings FY 2014–FYTD 2018 Quarter 2.

[10] Hearing Office Average Processing Time Ranking Report FY 2017 (For reporting purposes: 10/01/2016 through 09/29/2017), available at: *https://www.ssa.gov/appeals/DataSets/archive/05_FY2018/05_September_Average_Processing_Time_Report.html.*

[11] *Source:* Disability Operational Data Store (DIODS), an SSA internal data storage system. The supporting documentation describing DIODS is available at *www.regulations.gov,* under ''supporting and related material'' for this docket, SSA–2017–0015.

[12] *Source:* Executive Management Information System (EMIS) MI Central, an SSA internal data storage system. The supporting documentation describing EMIS is available at *www.regulations.gov,* under ''supporting and related material'' for this docket, SSA–2017–0015.

[13] *Source:* Disability Operational Data Store (DIODS), an SSA internal data storage system. The supporting documentation describing DIODS is available at *www.regulations.gov,* under ''supporting and related material'' for this docket, SSA–2017–0015.

[14] 20 CFR 404.1597a, 416.996.

[15] SSA, OIG, Statutory Benefit Continuation During the Appeals Process for Medical Cessations, A–07–17–50127 (May 2017), at 6, available *https://oig.ssa.gov/sites/default/files/audit/full/pdf/A-07-17-50127.pdf.*

[16] *Id.* at 3.

[17] *Id.*

[18] See Social Security Ruling 96–10p.

period.[19] In 2003, we published rules that directed ALJs to schedule hearings by VTC in any case where VTC technology was available, it was more efficient to do so, and no circumstance in the case prevented the use of VTC technology.[20] Under these rules, the claimant could opt out of a VTC hearing at any time, including the day of the hearing.[21]

As we gained experience with VTC for hearings before an ALJ, we and others have studied the efficacy of these hearings; those studies have found that the use of VTC provides us a number of benefits, including additional flexibility, especially with respect to aged and backlogged hearing requests, improved case processing times, and reduced ALJ travel.[22] For example, in 2011, our OIG found that the most important capability provided by the use of VTC hearings is the ease with which pending cases can be reassigned from heavily backlogged offices to virtually any video-equipped ALJ anywhere in the country who has excess hearing capacity.[23] OIG identified several concrete instances in which VTC improved the functioning of our hearings process. We have also observed that VTC technologies offer expanded service options for parties, especially for geographically and otherwise isolated claimants.

The Administrative Conference of the United States (ACUS), an independent, nonpartisan Federal agency that studies and recommends improvements to administrative process and procedures, also has noted a number of advantages to the use of VTC hearings before an ALJ.[24] In 2011, ACUS adopted its Recommendation 2011–4,[25] which noted that agencies with high volume caseloads were likely to receive the most benefit or cost savings (or both) from the use of VTC. ACUS therefore encouraged all agencies (including those with lower volume caseloads) to consider whether the use of VTC would be beneficial as a way to improve efficiency and reduce costs, while also preserving the fairness and participant satisfaction. In 2015, ACUS also published a Handbook on Best Practices for Using Video Teleconferencing in Adjudicatory Hearings. This handbook provides many recommendations regarding physical space, lighting, and technology. We will consult ACUS's recommendations as we continue to modernize our infrastructure, and ensure we are up to date on the latest technology available.[26]

As we continue to seek ways to improve the efficiency of our hearings process, we also are mindful of recommendations from our Inspector General. For example, in 2012, our OIG studied the operation of our National Hearing Centers (NHC), which primarily use VTC to conduct hearings, and raised concerns that claimants were opting out of VTC hearings after they had already been scheduled, sometimes even on the day of the hearing, and that representatives were opting out to avoid appearing before certain ALJs.[27] In response, we revised our regulations in 2014 to provide that claimants, or their representatives, must object to appearing by VTC within 30 days after receiving a notice acknowledging receipt of their hearing request, unless they had good cause for failing to meet that deadline.[28] While this regulatory change allowed us to forestall last-minute cancellation of VTC hearings, the percentage of claimants who choose an in person hearing over the VTC option remains high. In FY 2015, approximately 30% of claimants who requested an ALJ hearing that year objected to appearing by VTC[29]. In FY 2017, approximately 32% of claimants who requested an ALJ hearing that year objected to appearing by VTC.[30]

At the reconsideration level at CDR, our rules state we will set the time and place of a disability hearing,[31] but do not specifically set out the manner in which parties and witnesses will appear. We currently conduct disability hearings at the reconsideration level before a DHO in person, by VTC, and, in limited circumstances, by telephone.[32] Similar to the ALJ hearing level, we have used VTC to conduct disability hearings at the reconsideration level for approximately 20 years. However, before a DHO may conduct a disability hearing by VTC, we currently require a beneficiary or recipient sign and return a statement to the DHO stating that he or she voluntarily elects to appear by VTC.[33] This policy causes delays in scheduling disability hearings and results in increased case processing times.

When an individual objects to appearing by VTC at an ALJ hearing or does not elect to appear by VTC at a reconsideration hearing before a DHO at CDR, the efficiency of our hearings process is set back without any corresponding increase in the fairness of the process, and the individual may wait longer for an in person hearing. At the ALJ hearing level, the number of ALJs available to conduct an in person hearing is generally limited to those ALJs stationed at, or geographically close to, the assigned hearing office or within travel distance to one of our permanent remote sites. Requiring an ALJ to travel to a remote hearing site for an in person hearing reduces the amount of time the ALJ can devote to holding other hearings and issuing decisions from his or her assigned hearing office. We expect the ten-year savings due to decreased reimbursements for all ALJ hearings

[19] 68 FR 5210, 5211 (2003). At approximately the same time, we also tested our capacity to conduct ALJ hearings by VTC between the Huntington, West Virginia hearing office and its Prestonburg, Kentucky remote location and between the Albuquerque, New Mexico hearing office and its El Paso, Texas remote location. 66 FR 1059, 1060 (2001). However, participation rates at these other test sites were too low for us to draw inferences about customer service or satisfaction. *Id.*

[20] 68 FR 5210 (2003), 68 FR 69003 (2003).

[21] If a party objected to appearing by VTC, he or she was required only to notify the ALJ at the earliest possible opportunity before the time set for the hearing. 68 FR 69003, 69006 (2003).

[22] OIG, *Congressional Response Report: Current and Expanded Use of Video Hearings,* A–05–12–21287, at 3 (June 18, 2012), available at: *https://oig.ssa.gov/sites/default/files/audit/full/pdf/A-05-12-21287.pdf*; OIG, *Use of Video Hearings to Reduce the Hearing Case Backlog,* A–05–08018079, at 3 (April 22, 2011), available at: *https://oig.ssa.gov/sites/default/files/audit/full/pdf/A-05-08-18070.pdf.*

[23] SSA, OIG, *Use of Video Hearings to Reduce the Hearing Case Backlog,* A–05–08–18070, at 12–13 (April 2011), available at: *https://oig.ssa.gov/sites/default/files/audit/full/pdf/A-05-08-18070.pdf.*

[24] ACUS, *Memorandum on the History of Agency Video Teleconferencing Adjudications,* at 20–21 (November 26, 2014), available at: *https://www.acus.gov/sites/default/files/documents/VTC%20Hearing%20History_FINAL.pdf* (noting that agencies use VTC hearings for a number of reasons, including lowering direct and indirect costs, improving efficiency, decreasing processing time, and providing greater flexibility in scheduling hearings).

[25] ACUS Recommendation 2011–4, *Agency Use of Video Hearings: Best Practices and Possibilities for Expansion,* 76 FR 48789, 48795 (2011), available at: *https://www.acus.gov/recommendation/agency-use-video-hearings-best-practices-and-possibilities-expansion.*

[26] ACUS, *Handbook on Best Practices for Using Video Teleconferencing in Adjudicatory Hearings* (Dec. 22, 2015), available at *https://www.acus.gov/sites/default/files/documents/handbook-on-best-practices-for-using-VTC-in-adjudicatory-hearings.pdf.*

[27] OIG, *The Role of National Hearing Centers in Reducing the Hearings Backlog,* A–12–11–111147, at 11 (Apr. 3, 2012), available at: *http://oig.ssa.gov/sites/default/files/audit/full/pdf/A-12-11-11147_0.pdf.*

[28] 79 FR 35926 (June 25, 2014).

[29] Video Hearing (VH) Opt-Out Numbers and Rates for Hearing Requests Received FY 2015, available at: *http://www.ssa.gov/appeals/DataSets/archive/00_FY2015/00_September_A01_VH_Opt-Out.html.*

[30] Video Hearing (VH) Opt-Out Numbers and Rates for Hearing Requests Received FY 2017, available at: *http://www.ssa.gov/appeals/DataSets/A01_VH_Opt-Out.html.*

[31] See 20 CFR 404.914, 416.1414.

[32] Program Operations Manual System (POMS) DI 33025.080 available at: *https://secure.ssa.gov/poms.nsf/lnx/0433025080*; DI 33025.085 available at: *https://secure.ssa.gov/apps10/poms.nsf/lnx/0433025085.*

[33] POMS DI 33025.080 available at: *https://secure.ssa.gov/poms.nsf/lnx/0433025080.*

participants, including ALJs, representatives, claimants, and contractors, to be $67.2M. At the reconsideration level for CDRs, scheduling an in person hearing may require significant travel by the DHO and the beneficiary or recipient, along with the time and costs associated with such travel. An in person reconsideration hearing requires additional time for the DHO and reduces the time available for the DHO to hold other hearings and issue determinations.

We expect that expanding our use of VTC technology will help us in two ways. First, increased use of VTC technology will reduce these discrepancies in the wait time among the hearing offices. Second, increased use of VTC will allow us to decrease the total number of cases pending at the ALJ hearing level by allowing us to shift cases from overburdened hearing offices to hearing offices with fewer requests for hearing pending per ALJ. Balancing our workloads by using VTC has been key to addressing our oldest pending cases, and it has allowed us to act quickly as service needs arise from unanticipated emergencies, *e.g.,* by transferring cases to another part of the country.

As documented in ACUS's studies and in feedback from multiple other sources, our use of VTC has been widely accepted as an important tool that increases our ability to hold hearings and improve public service. For example, in 2006, the Social Security Advisory Board (SSAB), a bipartisan, independent body that advises the President, Congress, and the Commissioner of Social Security on matters of policy and administration of the disability insurance and Supplemental Security Income programs,[34] reported receiving overwhelmingly positive comments on the use of VTC hearings.[35] In 2011, OIG received mostly positive comments about the role of VTC in the hearings process from representatives from the National Organization of Social Security Claimants' Representatives and the National Association of Disability Representatives.[36] In 2012, in a report estimating the cost savings of VTC hearings in the Social Security context, OIG estimated annual cost savings of $5.2 to 10.9 million.[37]

Moreover, there is no evidence that the use of VTC technology adversely affects the outcome of the decision making process. An internal report prepared in FY 2017 by our Office of Quality Review (OQR) showed there was not a significant difference in outcome or policy compliance for VTC and in person hearings. OQR found a high degree of policy compliance and quality for both types of hearings. We included this report as part of the rulemaking docket, which is publicly available at *www.regulations.gov,* and we invite comments on it.

We also have made great strides in increasing our video capabilities in order to improve our business processes. Since 2016, we have refreshed all VTC equipment and infrastructure, which has resulted in better technological quality of video hearings. Additionally, the dramatic reduction in the number of cases that involve paper claims folders over the past ten years has allowed for smoother workload balancing, ensuring consistent service on a national level. With the infrastructure and equipment we have in place, the use of VTC technology ensures that we can deliver service in a modern, seamless, and flexible manner. All video hearings rooms are section 504 compliant based on the capacity for individuals attending a hearing, providing equal access to hearings for claimants with disabilities.

We expect that this proposed rule will ensure that as we expand our ability to conduct appearances by VTC, we are able to schedule hearings more fairly and efficiently. The preferred methods for conducting hearings are by VTC and in person. However, an ALJ or DHO may conduct a hearing by telephone under two circumstances: (1) When it is physically impossible to conduct the hearing by VTC or in person, such as incarceration in a facility without VTC ability; and (2) extraordinary circumstances, such as when a natural disaster occurs and our VTC facilities are unavailable.[38] When using a telephone to conduct a hearing, the telephone technology used must allow for the beneficiary or recipient and his or her representative to hear and respond to all testimony presented at the hearing.[39]

Changes

To increase our ability to schedule hearings more fairly, flexibly, and efficiently and address the unprecedented service challenges we face at the reconsideration and ALJ hearing levels of our administrative review process, we propose the following changes to our rules:

- We propose to revise and unify some of the rules that govern how, where, and when individuals appear for hearings before an ALJ at the hearings level and before a DHO at the reconsideration level of our administrative review process.
- At the hearings level, we will determine the time and place of a hearing before an ALJ and determine how parties and witnesses will appear at the hearing.
- At the reconsideration level for CDRs, the State agency or the Associate Commissioner for Disability Determinations, or his or her delegate, will determine the time and place of a hearing before a DHO and determine how parties and witnesses will appear at the hearing. Under the proposed rules, while we will evaluate the specific circumstances of each claimant's or beneficiary's case to determine what is the most efficient and appropriate manner of hearing, we would not permit individuals to object to appearing by the manner of hearing we choose.
- At both the CDR reconsideration and ALJ levels of our administrative review process, when we schedule a hearing, we propose that we will determine the manner in which the parties to the hearing will appear: By VTC, in person, or, under the limited circumstances specified here, by telephone. In determining whether a party will appear by VTC or in person, we would consider whether VTC technology is available; whether it would be more efficient for an individual to appear by VTC or in person; and whether there are circumstances in the case that provide a good reason to schedule an individual to appear by VTC or in person. Under the proposed rules, we would not permit individuals to opt out of or objecting to appearing by the manner of hearing we chose.
- We also propose that we would determine the manner in which witnesses to a hearing will appear. In general, we would schedule witnesses to appear at hearings by VTC or telephone, unless VTC or telephone equipment are not available; we determine that it would be more efficient for a witness to appear in

[34] Section 703 of the Act, 42 U.S.C. 903.

[35] SSAB, *Improving the Social Security Administration's Hearing Process,* at 21 (2006), available at: *http://www.ssab.gov/Portals/0/OUR_WORK/REPORTS/HearingProcess_2006.pdf.*

[36] SSA, OIG, *Use of Video Hearings to Reduce the Hearing Case Backlog,* A–05–08–18070, at 10 (April 2011), available at: *https://oig.ssa.gov/sites/default/files/audit/full/pdf/A-05-08-18070.pdf.*

[37] SSA, OIG, *Current and Expanded Use of Video Hearings,* A–05–12–21287, at 3 (June 2012), available at: *http://oig.ssa.gov/sites/default/files/audit/full/pdf/A-05-12-21287.pdf.*

[38] 20 CFR 404.936(c)(1).

[39] 20 CFR 404.936(c)(1), 416.1436(c)(1); POMS DI 33025.085 available at: *https://secure.ssa.gov/apps10/poms.nsf/lnx/0433025085.*

person; or there are circumstances in the case that provide a good reason to schedule a witness to appear in person.

- We also propose that an ALJ may continue to identify case-specific facts that affect which manner of appearance is most efficient. However, the agency will have the final responsibility to determine in which manner the individual must appear.
- At the Appeals Council level, if the Appeals Council grants an individual's request to appear to present oral argument, the individual will appear before the Appeals Council by VTC or in person, or, when the circumstances described in § 404.936(c)(2) exist, by telephone.

We believe that we can best serve individuals involved in our disability program by maximizing the case processing efficiencies and flexibility allowed by VTC hearings. Supporting this, OIG and ACUS have repeatedly recommended that we increase use of VTC hearings for greater efficiency. The SSAB has also recommended we eliminate the ability to object to appearing by VTC.[40] The SSAB has stated that allowing a claimant to opt out of a VTC hearing reduces the hearing process's productivity and delays processing of not only that individual's case, but also others who are waiting for their opportunity for a hearing.[41]

The changes we propose will provide us with the flexibility we need to address the ongoing service challenges we face by balancing our hearing workloads in a way that we expect will reduce overall wait and processing times across the country and reduce the processing time disparities that exist from region to region.

In addition to the changes we propose for setting the manner for appearing at a hearing, we also propose to make one clarification to our rules regarding the notice of hearing at the ALJ hearings level. Under our current rules, we send a notice of hearing at least 75 days prior to the date of the scheduled hearing to all parties and their representatives, if any.[42] In addition to setting the time and place of a hearing, the notice has additional information, including the issues to be decided, the right to representation, how to request a change in the time of the hearing, and who will be present at the hearing, such as any expert witnesses we call. We propose to clarify that when we send an amended notice of hearing updating any information, we will send the amended notice at least 20 days prior to the hearing.

If we need to change the date of a hearing, the date we choose will always be at least 75 days from the date we first sent the claimant a notice of hearing, unless the claimant has waived his or her right to advance notice. We believe sending an amended notice of hearing at least 20 days prior to the hearing would give the individual ample time to fully prepare for the hearing because the individual would have already received the initial notice of hearing, sent at least 75 days before the hearing. In many cases, sending an amended notice of hearing at least 75 days before the date of the hearing would require us to reschedule and unnecessarily delay the hearing, which would inhibit us from providing better public service by having a hearing as soon as we can do so. Therefore, we propose to send an amended notice of hearing at least 20 days prior to the hearing, which is the same amount of advance notice we used to provide most claimants before we implemented the 75-day notice period. Similarly, if we schedule a supplemental hearing, after the initial hearing was continued by the assigned ALJ, we will send a notice of hearing at least 20 days before the date of the hearing.

Regulatory Procedures

Clarity of These Rules

Executive Order 12866 as supplemented by Executive Order 13563 requires each agency to write all rules in plain language. In addition to your substantive comments on this NPRM, we invite your comments on how to make rules easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rule clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format make the rule easier to understand, *e.g.,* grouping and order of sections, use of headings, paragraphing?

Executive Order 12866 as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the requirements for a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Thus, OMB reviewed these proposed rules.

Executive Order 13771 and Cost Information

This proposed rule is not subject to the requirements of Executive Order 13771 because it is administrative in nature.

SSA's Office of the Chief Actuary estimates that the actuarial impact of the rule will be de minimis.

SSA's Office of Budget estimates that the proposal, if implemented, will result in administrative savings of $118 million over a 10-year period. These savings stem from reduced costs of claimant and representative travel, a reduced number of workyears needed, and fewer forms processed.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities because they only affect individuals. Accordingly, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed rules do not create any new or affect any existing collections and, therefore, do not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public Assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Nancy A. Berryhill,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend 20 CFR

[40] SSAB, *Improving the Social Security Administration's Hearing Process,* at 21 (Sep. 2006), available at: *http://www.ssab.gov/Portals/0/OUR_WORK/REPORTS/HearingProcess_2006.pdf.*

[41] *Id.*

[42] 20 CFR 404.938(a), 416.1438(a).

chapter III, parts 404 and 416, as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart J—Determinations, Administrative Review Process, and Reopening of Determinations and Decisions

■ 1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 204(f), 205(a)–(b), (d)–(h), and (j), 221, 223(i), 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a)–(b), (d)–(h), and (j), 421, 423(i), 425, and 902(a)(5)); sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend § 404.914 by revising paragraphs (c), (d), and (e) and adding paragraphs (f), (g), and (h) to read as follows:

§ 404.914 Disability hearing-general.

* * * * *

(c) *Combined issues.* If a disability hearing is available to you under paragraph (a), and you file a new application for benefits while your request for reconsideration is still pending, we may combine the issues on both claims for the purpose of the disability hearing and issue a combined initial and reconsideration determination which is binding with respect to the common issues on both claims.

(d) *Definition.* For purposes of the provisions regarding disability hearings (§§ 404.914 through 404.918) *we, us* or *our* means the Social Security Administration or the State agency.

(e) *Notice of disability hearing.* We will send you a notice of the time and place of your disability hearing at least 20 days before the date of the hearing. The notice of hearing will tell you the scheduled time and place of the hearing and will notify you whether your appearance will be by video teleconference, in person, or by telephone. You may be expected to travel to your disability hearing. (See §§ 404.999a through 404.999d regarding reimbursement for travel expenses.)

(f) *Time and place for a disability hearing.* (1) *General.* Either the State agency or the Associate Commissioner for Disability Determinations or his or her delegate, as appropriate, will set the time and place of your disability hearing. We may change the time and place of the hearing, if it is necessary and there is good cause for doing so.

(2) *Where we hold hearings.* The ''place'' of the hearing is the office or other site(s) at which you and any other parties to the hearing are located when you make your appearance(s) before the disability hearing officer by video teleconferencing, in person, or, when the circumstances described in paragraph (f)(4) of this section exist, by telephone.

(3) *When we will schedule your hearing by video teleconferencing or in person.* We will generally schedule you or any other party to the hearing to appear either by video teleconferencing or in person. When we determine whether you will appear by video teleconferencing or in person, we consider the following factors:

(i) The availability of video teleconferencing equipment to conduct the appearance;

(ii) Whether use of video teleconferencing to conduct the appearance would be less efficient than conducting the appearance in person; and

(iii) Any facts in your particular case that provide a good reason to schedule your appearance by video teleconferencing or in person.

(4) *When we will schedule your appearance by telephone.* Subject to paragraph (f)(5), we will schedule you or any other party to the hearing to appear by telephone when we find an appearance by video teleconferencing or in person is not possible or other extraordinary circumstances prevent you from appearing by video teleconferencing or in person.

(5) *Scheduling a hearing when you or any other party to the hearing is incarcerated or otherwise confined.* If you are incarcerated or otherwise confined and video teleconferencing is not available, we will schedule your appearance by telephone, unless we find that there are facts in your particular case that provide a good reason to schedule your appearance in person, if allowed by the place of confinement, or by video teleconferencing or in person upon your release.

(6) *How witnesses will appear.* Witnesses may appear at a hearing with you in the same manner in which you are scheduled to appear. If they are unable to appear with you in the same manner as you, we will generally direct them to appear by video teleconferencing or by telephone. We will consider directing them to appear in person only when:

(i) Telephone or video teleconferencing equipment is not available to conduct the appearance;

(ii) We determine that use of telephone or video teleconferencing equipment would be less efficient than conducting the appearance in person; or

(iii) We find that there are facts in your particular case that provide a good reason to schedule this individual's appearance in person.

(g) *Objecting to the time of the hearing.*

(1) *General.* If you wish to object to the time of the hearing, you must:

(i) Notify us in writing at the earliest possible opportunity, but not later than 5 days before the date set for the hearing; and

(ii) State the reason(s) for your objection to the time of the hearing and state the time you want the hearing to be held.

(2) If you notify us that you object to the time of the hearing less than 5 days before the date set for the hearing, we will consider this objection only if you show you had good cause for missing the deadline. To determine whether good cause exists for missing the deadline, we use the standards explained in § 404.911.

(h) *Whether good cause exists for changing the time of the hearing.* We will determine whether good cause exists for changing the time of your scheduled hearing. If we find good cause, we will set the time of the new hearing. A finding that good cause exists to reschedule the time of your hearing will generally not change the assignment of the designated adjudicator or how you or any party to the hearing will appear at the hearing, unless we determine a change will promote more efficient administration of the hearing process.

(1) Determining good cause for changing the time of the hearing. We will find good cause to change the time of your hearing if we determine that, based on the evidence:

(i) A serious physical or mental condition or incapacitating injury makes it impossible for you or your representative to travel to the hearing, or a death in the family occurs; or

(ii) Severe weather conditions make it impossible for you or your representative to travel to the hearing.

(2) *Determining good cause in other circumstances.* When we determine whether good cause exists to change the time of your hearing, in circumstances other than those set out in paragraph (h)(1) of this section, we will consider your reason(s) for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to,

the effect on processing other scheduled hearings, delays that may occur in rescheduling your hearing, and whether we previously granted any changes to the time of the hearing.

(3) Examples of such other circumstances that you might give for requesting a change in the time of the hearing include, but are not limited to the following:

(i) You unsuccessfully attempted to obtain a representative and need additional time to secure representation;

(ii) Your representative was appointed within 20 days of the scheduled hearing and needs additional time to prepare for the hearing;

(iii) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(iv) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(v) Transportation is not readily available for you to travel to the hearing; or

(vi) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

■ 3. Revise § 404.929 to read as follows:

§ 404.929 Hearing before an administrative law judge-general.

If you are dissatisfied with one of the determinations or decisions listed in § 404.930, you may request a hearing. The Deputy Commissioner for Hearings Operations, or his or her delegate, will appoint an administrative law judge to conduct the hearing. If circumstances warrant, the Deputy Commissioner for Hearings Operations, or his or her delegate, may assign your case to another administrative law judge. In general, we will schedule you to appear by video teleconferencing or in person. When we determine whether you will appear by video teleconferencing or in person, we consider the factors described in § 404.936(c)(1)(i) through (iii), and in the limited circumstances described in § 404.936(c)(2), we will schedule you to appear by telephone. You may submit new evidence (subject to the provisions of § 404.935), examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she will issue a decision based on the preponderance of the evidence in the hearing record. If you waive your right to appear at the hearing, the administrative law judge will make a decision based on the preponderance of the evidence that is in the file and, subject to the provisions of § 404.935, any new evidence that may have been submitted for consideration.

■ 4. Revise § 404.936 to read as follows:

§ 404.936 Time and place for a hearing before an administrative law judge.

(a) *General.* We set the time and place for any hearing. We may change the time and place, if it is necessary. After sending you reasonable notice of the proposed action, the administrative law judge may adjourn or postpone the hearing or reopen it to receive additional evidence any time before he or she notifies you of a hearing decision.

(b) *Where we hold hearings.* We hold hearings in the 50 States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the United States Virgin Islands. The ''place'' of the hearing is the hearing office or other site(s) at which you and any other parties to the hearing are located when you make your appearance(s) before the administrative law judge by video teleconferencing, in person or, when the circumstances described in paragraph (c)(2) of this section exist, by telephone.

(c) We will generally schedule you or any other party to the hearing to appear either by video teleconferencing or in person.

(1) When we determine whether you will appear by video teleconferencing or in person, we consider the following factors:

(i) The availability of video teleconferencing equipment to conduct the appearance;

(ii) Whether use of video teleconferencing to conduct the appearance would be less efficient than conducting the appearance in person; and

(iii) Any facts in your particular case that provide a good reason to schedule your appearance by video teleconferencing or in person.

(2) Subject to paragraph (c)(3) of this section, we will schedule you or any other party to the hearing to appear by telephone when we find an appearance by video teleconferencing or in person is not possible or other extraordinary circumstances prevent you from appearing by video teleconferencing or in person.

(3) If you are incarcerated and video teleconferencing is not available, we will schedule your appearance by telephone, unless we find that there are facts in your particular case that provide a good reason to schedule your appearance in person, if allowed by the place of confinement, or by video teleconferencing or in person upon your release.

(4) We will generally direct any person we call as a witness, other than you or any other party to the hearing, including a medical expert or a vocational expert, to appear by telephone or by video teleconferencing. Witnesses you call will appear at the hearing pursuant to § 404.950(e). If they are unable to appear with you in the same manner as you, we will generally direct them to appear by video teleconferencing or by telephone. We will consider directing them to appear in person only when:

(i) Telephone or video teleconferencing equipment is not available to conduct the appearance;

(ii) We determine that use of telephone or video teleconferencing equipment would be less efficient than conducting the appearance in person; or

(iii) We find that there are facts in your particular case that provide a good reason to schedule this individual's appearance in person.

(d) *Objecting to the time of the hearing.* (1) If you wish to object to the time of the hearing, you must:

(i) Notify us in writing at the earliest possible opportunity, but not later than 5 days before the date set for the hearing or 30 days after receiving notice of the hearing, whichever is earlier; and

(ii) State the reason(s) for your objection and state the time you want the hearing to be held. If the administrative law judge finds you have good cause, as determined under paragraph (e) of this section, we will change the time of the hearing.

(2) If you notify us that you object to the time of hearing less than 5 days before the date set for the hearing or, if earlier, more than 30 days after receiving notice of the hearing, we will consider this objection only if you show you had good cause for missing the deadline. To determine whether good cause exists for missing this deadline, we use the standards explained in § 404.911.

(e) *Good cause for changing the time.* The administrative law judge will determine whether good cause exists for changing the time of your scheduled hearing. If the administrative law judge finds that good cause exists, we will set the time of the new hearing. A finding that good cause exists to reschedule the time of your hearing will generally not change the assignment of the administrative law judge or how you or another party will appear at the hearing, unless we determine a change will

promote efficiency in our hearing process.

(1) The administrative law judge will find good cause to change the time of your hearing if he or she determines that, based on the evidence:

(i) A serious physical or mental condition or incapacitating injury makes it impossible for you or your representative to travel to the hearing, or a death in the family occurs; or

(ii) Severe weather conditions make it impossible for you or your representative to travel to the hearing.

(2) In determining whether good cause exists in circumstances other than those set out in paragraph (e)(1) of this section, the administrative law judge will consider your reason(s) for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays that might occur in rescheduling your hearing, and whether we previously granted you any changes in the time of your hearing. Examples of such other circumstances that you might give for requesting a change in the time of the hearing include, but are not limited to, the following:

(i) You unsuccessfully attempted to obtain a representative and need additional time to secure representation;

(ii) Your representative was appointed within 30 days of the scheduled hearing and needs additional time to prepare for the hearing;

(iii) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(iv) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(v) Transportation is not readily available for you to travel to the hearing; or

(vi) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

■ 5. Amend § 404.938 by revising paragraphs (b)(3), (b)(5), and (c) and adding paragraph (d) to read as follows:

§ 404.938 Notice of a hearing before an administrative law judge.

* * * * *

(b) * * *

(3) How to request that we change the time of your hearing;

* * *

(5) Whether your appearance or that of any other party or witness is scheduled to be made by video teleconferencing, in person, or, when the circumstances described in § 404.936(c)(2) exist, by telephone. If we have scheduled you to appear by video teleconferencing, the notice of hearing will tell you that the scheduled place for the hearing is a video teleconferencing site and explain what it means to appear at your hearing by video teleconferencing;

* * * * *

(c) *Acknowledging the notice of hearing.* The notice of hearing will ask you to return a form to let us know that you received the notice. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail.

(d) *Amended notice of hearing.* If we need to send you an amended notice of hearing, we will mail or serve the notice at least 20 days before the date of the hearing. Similarly, if we schedule a supplemental hearing, after the initial hearing was continued by the assigned administrative law judge, we will mail or serve a notice of hearing at least 20 days before the date of the hearing.

■ 6. Amend § 404.950 by revising paragraphs (a) and (e) to read as follows:

§ 404.950 Presenting evidence at a hearing before an administrative law judge.

(a) *The right to appear and present evidence.* Any party to a hearing has a right to appear before the administrative law judge, either by video teleconferencing, in person, or, when the conditions in § 404.936(c)(2) exist, by telephone, to present evidence and to state his or her position. A party may also make his or her appearance by means of a designated representative, who may make the appearance by video teleconferencing, in person, or, when the conditions in § 404.936(c)(2) exist, by telephone.

* * * * *

(e) *Witnesses at a hearing.* Witnesses you call may appear at a hearing with you in the same manner in which you are scheduled to appear. If they are unable to appear with you in the same manner as you, they may appear as prescribed in § 404.936(c)(4). Witnesses called by the administrative law judge will appear in the manner prescribed in § 404.936(c)(4). They will testify under oath or affirmation unless the administrative law judge finds an important reason to excuse them from taking an oath or affirmation. The administrative law judge may ask the witness any questions material to the issues and will allow the parties or their designated representatives to do so.

* * * * *

■ 7. Amend § 404.976 by revising paragraph (b) to read as follows:

§ 404.976 Procedures before the Appeals Council on review.

* * * * *

(b) *Oral argument.* You may request to appear before the Appeals Council to present oral argument. The Appeals Council will grant your request if it decides that your case raises an important question of law or policy or that oral argument would help to reach a proper decision. If your request to appear is granted, the Appeals Council will tell you the time and place of the oral argument at least 10 business days before the scheduled date. You will appear before the Appeals Council by video teleconferencing or in person, or, when the circumstances described in § 404.936(c)(2) exist, we may schedule you to appear by telephone. The Appeals Council will determine whether any other person relevant to the proceeding will appear by video teleconferencing, telephone, or in person as based on the circumstances described in § 404.936(c)(4).

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart N—Determinations, Administrative Review Process, and Reopening of Determinations and Decisions

■ 8. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 9. Amend § 416.1414 by revising paragraphs (c), (d), and (e) and adding paragraphs (f), (g), and (h) to read as follows:

§ 416.1414 Disability hearing-general.

* * * * *

(c) *Combined issues.* If a disability hearing is available to you under paragraph (a), and you file a new application for benefits while your request for reconsideration is still pending, we may combine the issues on both claims for the purpose of the disability hearing and issue a combined initial and reconsideration determination which is binding with respect to the common issues on both claims.

(d) *Definition.* For purposes of the provisions regarding disability hearings (§§ 416.1414 through 416.1418) *we, us* or *our* means the Social Security Administration or the State agency.

(e) *Notice of disability hearing.* We will send you a notice of the time and place of your disability hearing at least 20 days before the date of the hearing. The notice of hearing will tell you the scheduled time and place of the hearing and will notify you whether your appearance will be by video teleconference, in person, or by telephone. You may be expected to travel to your disability hearing. (See §§ 416.1499a through 416.1499d regarding reimbursement for travel expenses.)

(f) *Time and place for a disability hearing.* (1) *General.* Either the State agency or the Associate Commissioner for Disability Determinations or his or her delegate, as appropriate, will set the time and place of your disability hearing. We may change the time and place of the hearing, if it is necessary and there is good cause for doing so.

(2) *Where we hold hearings.* The ''place'' of the hearing is the office or other site(s) at which you and any other parties to the hearing are located when you make your appearance(s) before the disability hearing officer by video teleconferencing, in person, or, when the circumstances described in paragraph (f)(4) of this section exist, by telephone.

(3) *When we will schedule your hearing by video teleconferencing or in person.* We will generally schedule you or any other party to the hearing to appear either by video teleconferencing or in person. When we determine whether you will appear by video teleconferencing or in person, we consider the following factors:

(i) The availability of video teleconferencing equipment to conduct the appearance;

(ii) Whether use of video teleconferencing to conduct the appearance would be less efficient than conducting the appearance in person; and

(iii) Any facts in your particular case that provide a good reason to schedule your appearance by video teleconferencing or in person.

(4) *When we will schedule your appearance by telephone.* Subject to paragraph (f)(5), we will schedule you or any other party to the hearing to appear by telephone when we find an appearance by video teleconferencing or in person is not possible or other extraordinary circumstances prevent you from appearing by video teleconferencing or in person.

(5) *Scheduling a hearing when you or any other party to the hearing is incarcerated or otherwise confined.* If you are incarcerated or otherwise confined and video teleconferencing is not available, we will schedule your appearance by telephone, unless we find that there are facts in your particular case that provide a good reason to schedule your appearance in person, if allowed by the place of confinement, or by video teleconferencing or in person upon your release.

(6) *How witnesses will appear.* Witnesses may appear at a hearing with you in the same manner in which you are scheduled to appear. If they are unable to appear with you in the same manner as you, we will generally direct them to appear by video teleconferencing or by telephone. We will consider directing them to appear in person only when:

(i) Telephone or video teleconferencing equipment is not available to conduct the appearance;

(ii) We determine that use of telephone or video teleconferencing equipment would be less efficient than conducting the appearance in person; or

(iii) We find that there are facts in your particular case that provide a good reason to schedule this individual's appearance in person.

(g) *Objecting to the time of the hearing.* (1) *General.* If you wish to object to the time of the hearing, you must:

(i) Notify us in writing at the earliest possible opportunity, but not later than 5 days before the date set for the hearing; and

(ii) State the reason(s) for your objection to the time of the hearing and state the time you want the hearing to be held.

(2) If you notify us that you object to the time of the hearing less than 5 days before the date set for the hearing, we will consider this objection only if you show you had good cause for missing the deadline. To determine whether good cause exists for missing the deadline, we use the standards explained in § 416.1411.

(h) *Whether good cause exists for changing the time of the hearing.* We will determine whether good cause exists for changing the time of your scheduled hearing. If we find good cause, we will set the time of the new hearing. A finding that good cause exists to reschedule the time of your hearing will generally not change the assignment of the designated adjudicator or how you or any other party to the hearing will appear at the hearing, unless we determine a change will promote more efficient administration of the hearing process.

(1) *Determining good cause for changing the time of the hearing.* We will find good cause to change the time of your hearing if we determine that, based on the evidence:

(i) A serious physical or mental condition or incapacitating injury makes it impossible for you or your representative to travel to the hearing, or a death in the family occurs; or

(ii) Severe weather conditions make it impossible for you or your representative to travel to the hearing.

(2) *Determining good cause in other circumstances.* When we determine whether good cause exists to change the time of your hearing, in circumstances other than those set out in paragraph (h)(1) of this section, we will consider your reason(s) for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, delays that may occur in rescheduling your hearing, and whether we previously granted any changes to the time of the hearing. Examples of such other circumstances that you might give for requesting a change in the time of the hearing include, but are not limited to the following:

(i) You unsuccessfully attempted to obtain a representative and need additional time to secure representation;

(ii) Your representative was appointed within 20 days of the scheduled hearing and needs additional time to prepare for the hearing;

(iii) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(iv) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(v) Transportation is not readily available for you to travel to the hearing; or

(vi) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

■ 10. Revise § 416.1429 to read as follows:

§ 416.1429 Hearing before an administrative law judge.

If you are dissatisfied with one of the determinations or decisions listed in § 416.1430, you may request a hearing.

The Deputy Commissioner for Hearings Operations, or his or her delegate, will appoint an administrative law judge to conduct the hearing. If circumstances warrant, the Deputy Commissioner for Hearings Operations, or his or her delegate, may assign your case to another administrative law judge. In general, we will schedule you to appear by video teleconferencing or in person. When we determine whether you will appear by video teleconferencing or in person, we consider the factors described in § 416.1436(c)(1)(i) through (iii), and in the limited circumstances described in § 416.1436(c)(2), we will schedule you to appear by telephone. You may submit new evidence (subject to the provisions of § 416.1435), examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she will issue a decision based on the preponderance of the evidence in the hearing record. If you waive your right to appear at the hearing, the administrative law judge will make a decision based on the preponderance of the evidence that is in the file and, subject to the provisions of § 416.1435, any new evidence that may have been submitted for consideration.

■ 11. Revise § 416.1436 to read as follows:

§ 416.1436 Time and place for a hearing before an administrative law judge.

(a) *General.* We set the time and place for any hearing. We may change the time and place, if it is necessary. After sending you reasonable notice of the proposed action, the administrative law judge may adjourn or postpone the hearing or reopen it to receive additional evidence any time before he or she notifies you of a hearing decision.

(b) *Where we hold hearings.* We hold hearings in the 50 States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the United States Virgin Islands. The ''place'' of the hearing is the hearing office or other site(s) at which you and any other parties to the hearing are located when you make your appearance(s) before the administrative law judge by video teleconferencing, in person or, when the circumstances described in § 416.1436(c)(2) exist, by telephone.

(c) We will generally schedule you or any other party to the hearing to appear either by video teleconferencing or in person.

(1) When we determine whether you will appear by video teleconferencing or in person, we consider the following factors:

(i) The availability of video teleconferencing equipment to conduct the appearance;

(ii) Whether use of video teleconferencing to conduct the appearance would be less efficient than conducting the appearance in person; and

(iii) Any facts in your particular case that provide a good reason to schedule your appearance by video teleconferencing or in person.

(2) Subject to paragraph (c)(3) of this section, we will schedule you or any other party to the hearing to appear by telephone when we find an appearance by video teleconferencing or in person is not possible or other extraordinary circumstances prevent you from appearing by video teleconferencing or in person.

(3) If you are incarcerated and video teleconferencing is not available, we will schedule your appearance by telephone, unless we find that there are facts in your particular case that provide a good reason to schedule your appearance in person, if allowed by the place of confinement, or by video teleconferencing or in person upon your release.

(4) We will generally direct any person we call as a witness, other than you or any other party to the hearing, including a medical expert or a vocational expert, to appear by telephone or by video teleconferencing. Witnesses you call will appear at the hearing pursuant to § 416.1450(e). If they are unable to appear with you in the same manner as you, we will generally direct them to appear by video teleconferencing or by telephone. We will consider directing them to appear in person only when:

(i) Telephone or video teleconferencing equipment is not available to conduct the appearance;

(ii) We determine that use of telephone or video teleconferencing equipment would be less efficient than conducting the appearance in person; or

(iii) We find that there are facts in your particular case that provide a good reason to schedule this individual's appearance in person.

(d) *Objecting to the time of the hearing.* (1) If you wish to object to the time of the hearing, you must:

(i) Notify us in writing at the earliest possible opportunity, but not later than 5 days before the date set for the hearing or 30 days after receiving notice of the hearing, whichever is earlier; and

(ii) State the reason(s) for your objection and state the time you want the hearing to be held. If the administrative law judge finds you have good cause, as determined under paragraph (e) of this section, we will change the time of the hearing.

(2) If you notify us that you object to the time of hearing less than 5 days before the date set for the hearing or, if earlier, more than 30 days after receiving notice of the hearing, we will consider this objection only if you show you had good cause for missing the deadline. To determine whether good cause exists for missing this deadline, we use the standards explained in § 416.1411.

(e) *Good cause for changing the time.* The administrative law judge will determine whether good cause exists for changing the time of your scheduled hearing. If the administrative law judge finds that good cause exists, we will set the time of the new hearing. A finding that good cause exists to reschedule the time of your hearing will generally not change the assignment of the administrative law judge or how you or another party will appear at the hearing, unless we determine a change will promote efficiency in our hearing process.

(1) The administrative law judge will find good cause to change the time of your hearing if he or she determines that, based on the evidence:

(i) A serious physical or mental condition or incapacitating injury makes it impossible for you or your representative to travel to the hearing, or a death in the family occurs; or

(ii) Severe weather conditions make it impossible for you or your representative to travel to the hearing.

(2) In determining whether good cause exists in circumstances other than those set out in paragraph (e)(1) of this section, the administrative law judge will consider your reason(s) for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays that might occur in rescheduling your hearing, and whether we previously granted you any changes in the time of your hearing. Examples of such other circumstances that you might give for requesting a change in the time of the hearing include, but are not limited to, the following:

(i) You unsuccessfully attempted to obtain a representative and need additional time to secure representation;

(ii) Your representative was appointed within 30 days of the scheduled hearing

and needs additional time to prepare for the hearing;

(iii) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(iv) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(v) Transportation is not readily available for you to travel to the hearing; or

(vi) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

■ 12. Amend § 416.1438 by revising paragraphs (b)(3), (b)(5), and (c) and adding paragraph (d) to read as follows:

§ 416.1438 Notice of a hearing before an administrative law judge.

* * * * *

(b) * * *

(3) How to request that we change the time of your hearing;

* * * * *

(5) Whether your appearance or that of any other party or witness is scheduled to be made by video teleconferencing, in person, or, when the circumstances described in § 416.1436(c)(2) exist, by telephone. If we have scheduled you to appear by video teleconferencing, the notice of hearing will tell you that the scheduled place for the hearing is a video teleconferencing site and explain what it means to appear at your hearing by video teleconferencing;

* * * * *

(c) *Acknowledging the notice of hearing.* The notice of hearing will ask you to return a form to let us know that you received the notice. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail.

(d) *Amended notice of hearing.* If we need to send you an amended notice of hearing, we will mail or serve the notice at least 20 days before the date of the hearing. Similarly, if we schedule a supplemental hearing, after the initial hearing was continued by the assigned administrative law judge, we will mail or serve a notice of hearing at least 20 days before the date of the hearing.

■ 13. Amend § 416.1450, by revising paragraphs (a) and (e) to read as follows:

§ 416.1450 Presenting evidence at a hearing before an administrative law judge.

(a) *The right to appear and present evidence.* Any party to a hearing has a right to appear before the administrative law judge, either by video teleconferencing, in person, or, when the conditions in § 416.1436(c)(2) exist, by telephone, to present evidence and to state his or her position. A party may also make his or her appearance by means of a designated representative, who may make the appearance by video teleconferencing, in person, or, when the conditions in § 416.1436(c)(2) exist, by telephone.

* * * * *

(e) *Witnesses at a hearing.* Witnesses you call may appear at a hearing with you in the same manner in which you are scheduled to appear. If they are unable to appear with you in the same manner as you, they may appear as prescribed in § 416.1436(c)(4). Witnesses called by the administrative law judge will appear in the manner prescribed in § 416.1436(c)(4). They will testify under oath or affirmation unless the administrative law judge finds an important reason to excuse them from taking an oath or affirmation. The administrative law judge may ask the witness any questions material to the issues and will allow the parties or their designated representatives to do so.

* * * * *

■ 15. Amend § 416.1476, by revising paragraph (b) to read as follows:

§ 416.1476 Procedures before the Appeals Council on review.

* * * * *

(b) *Oral argument.* You may request to appear before the Appeals Council to present oral argument. The Appeals Council will grant your request if it decides that your case raises an important question of law or policy or that oral argument would help to reach a proper decision. If your request to appear is granted, the Appeals Council will tell you the time and place of the oral argument at least 10 business days before the scheduled date. You will appear before the Appeals Council by video teleconferencing or in person, or, when the circumstances described in § 416.1436(c)(2) exist, we may schedule you to appear by telephone. The Appeals Council will determine whether any other person relevant to the proceeding will appear by video teleconferencing, telephone, or in person as based on the circumstances described in § 416.1436(c)(4).

[FR Doc. 2018–24711 Filed 11–14–18; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50, 312, and 812

[Docket No. FDA–2018–N–2727]

RIN 0910–AH52

Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to amend its regulations to implement a provision of the 21st Century Cures Act (Cures Act). This proposed rule, if finalized, would allow an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The proposed rule, if finalized, would permit an Institutional Review Board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

DATES: Submit either electronic or written comments on this proposed rule by January 14, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions.'')

Written/Paper Submissions

Submit written/paper submissions in the following ways:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–2727 for ''Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Janet Norden, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1127, or Carol Drew, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3505.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

The purpose of this proposed rule is to implement the statutory changes made to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by section 3024 of the Cures Act (Pub. L. 114–255) to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The proposed rule, if finalized, would permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk clinical investigations.

B. Summary of the Major Provisions of the Proposed Rule

The major provisions of the proposed rule would add § 50.22 to part 50 (21 CFR part 50) to allow IRBs responsible for the review, approval, and continuing review of clinical investigations to approve an informed consent procedure that waives or alters certain informed consent elements or that waives the requirement to obtain informed consent for certain minimal risk clinical investigations. In order for an IRB to approve a waiver or alteration of informed consent requirements for minimal risk clinical investigations, the proposed rule would require an IRB to find and document four criteria that are consistent with the ''Federal Policy for the Protection of Human Subjects'' (the Common Rule) (56 FR 28001, June 18, 1991). FDA believes proposed § 50.22 would provide appropriate safeguards to protect the rights, safety, and welfare of the human subjects participating in such clinical investigations. We are also proposing conforming amendments to FDA's regulations, including § 50.20, 21 CFR 312.60, and 21 CFR 812.2.

C. Legal Authority

Sections 505(i)(4) and 520(g)(3) of the FD&C Act (21 U.S.C. 355(i)(4) and 360j(g)(3)), as amended by section 3024 of the Cures Act, in conjunction with FDA's general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as FDA's principal legal authority for this proposed rule.

D. Costs and Benefits

We do not anticipate additional costs associated with this rulemaking. This proposed rule would help enable the conduct of certain minimal risk clinical investigations for which the requirement to obtain informed consent is waived or for which certain elements of informed consent are waived or altered. We expect benefits in the form of healthcare advances from such minimal risk clinical investigations and from harmonization of FDA's informed consent regulations with the Common

Rule's provision for waiver of informed consent for certain minimal risk research. We cannot quantify all of these benefits because of the lack of relevant data available to FDA. The benefits that we are able to quantify are the cost savings to IRBs because the time burdens of reviewing certain minimal risk clinical investigations under differing requirements would be reduced. The estimated cost savings of the proposed rule are approximately $237.6 thousand, with a lower bound of $59.4 thousand and an upper bound of $950.5 thousand. The estimated annualized costs savings of the proposed rule are approximately $27 thousand, with a lower bound of approximately $6,762 and an upper bound of approximately $108.2 thousand, discounted at 3 percent over 10 years. The estimated annualized costs savings of the proposed rule are approximately $26 thousand, with a lower bound of approximately $6,509 and an upper bound of $104.1 thousand, discounted at 7 percent over 10 years.

II. Background and Description of the Proposed Regulation

A. Background

On December 13, 2016, the Cures Act was signed into law, amending certain provisions of the FD&C Act. FDA is proposing to update its regulations to reflect some of those changes that are now in effect. Specifically, section 3024 of the Cures Act amended sections 520(g)(3) and 505(i)(4) of the FD&C Act to provide FDA with the authority to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This proposed rule, if finalized, would implement this statutory change.

Sections 505(i) and 520(g) of the FD&C Act require FDA to publish regulations governing the use in human subjects of drugs and devices in clinical investigations. In 1962, amendments to section 505(i) of the FD&C Act provided that FDA regulations must ensure that informed consent for investigational use of drugs (including biological products) in human beings is obtained except where it is not feasible or it is contrary to the best interests of such human beings. The Medical Device Amendments of 1976 subsequently added section 520(g) to the FD&C Act. Among other requirements, section 520(g)(3)(D) of the FD&C Act directed that FDA regulations governing investigational use of devices require that informed consent be obtained except where the investigator determines in writing that there exists a life-threatening situation involving the human subject of such testing that necessitates the use of such device and it is not feasible to get the consent of the subject and there is not sufficient time to obtain such consent from the subject's representative. Section 520(g)(3)(D) of the FD&C Act further provided that a licensed physician not involved in the research must also concur in this determination, unless immediate use is necessary to save the subject's life and there is not time to get concurrence.

In 1979, FDA proposed revisions to its regulations governing informed consent (44 FR 47713, August 14, 1979). The Agency recognized in the preamble to its proposed rule that the statutory language regarding exceptions from informed consent for investigational drugs differed from that regarding investigational devices. However, the Agency explained that its prior regulations implementing the statutory exception from informed consent for investigational drugs ''carefully limited'' the exception to certain situations that assume ''the patient subject is seriously ill'' and did not differ greatly from the new statutory exceptions from informed consent for devices (see 44 FR 47713 at 47718). When FDA issued final revisions to its informed consent regulations in 1981, it adopted a single set of requirements for informed consent for all FDA-regulated clinical investigations, which reflected the device standard in section 520(g)(3)(D) of the FD&C Act (see 46 FR 8942, January 27, 1981). FDA explained its intent to adopt a single standard that reflected the most current congressional thinking on informed consent (see 44 FR 47713 at 44718; 46 FR 8942 to 8944).

Currently, FDA's regulations governing the protection of human subjects (21 CFR parts 50 and 56) allow exception from the general requirements of informed consent only in life-threatening situations when certain conditions are met (§ 50.23) or when the requirements for emergency research are met (§ 50.24). In all other cases, FDA regulations require that a human subject provide informed consent before participating in a clinical investigation. At this time, FDA's regulations do not allow an exception from the general requirements of informed consent for minimal risk clinical investigations.

In contrast, the Common Rule has included waiver of informed consent provisions for minimal risk research since it was originally issued in 1991 (56 FR 28001). The Common Rule sets forth requirements for the protection of human subjects involved in research that is conducted or supported by the Department of Health and Human Services (HHS) (see 45 CFR 46, Subpart A) and 15 other Federal departments and agencies. The purpose of the Common Rule is to promote uniformity, understanding, and compliance with human subject protections as well as to create a uniform body of regulations across the Federal departments and agencies.[1] The Common Rule standard has permitted an IRB to waive the requirements to obtain informed consent, or to allow changes to, or omission of, some or all elements of informed consent if the IRB finds and documents that: (1) The research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation (45 CFR 46.116(d); 56 FR 28001 at 28017).[2]

FDA amended its regulations in parts 50 and 56 to conform them to the Common Rule in 1991 (56 FR 28001 at 28025) but diverged from the Common Rule's provision for waiver or alteration of informed consent for minimal risk research at 45 CFR 46.116(d). In explaining the reason for this departure, FDA cited sections 505(i) and 520(g)(3)(D) of the FD&C Act[3] and stated that the FD&C Act ''requires informed consent to be obtained from all subjects except in very limited circumstances'' and that the Agency did ''not have the authority under the act to

[1] 80 FR 53931 at 53935, September 8, 2015.

[2] References to the Common Rule in this document are to the 1991 version of the Common Rule, unless otherwise noted. A final rule that revised the 1991 version of the Common Rule adopted an effective and general compliance date of January 19, 2018 (82 FR 7149, January 19, 2017). On January 22, 2018, an interim final rule was published that delayed the effective and general compliance date of the revisions until July 19, 2018 (83 FR 2885). On June 19, 2018, a final rule was published that further delays the general compliance date until January 21, 2019, while allowing the use of three burden-reducing provisions for certain research during the delay period (83 FR 28497). The revised version of the Common Rule, including amendments made by the January 22, 2018 interim final rule and the June 19, 2018 final rule, is referred to in this document as the ''revised Common Rule.''

[3] FDA's proposed rule also cited section 507 of the FD&C Act, which established requirements for the conduct of clinical investigations of antibiotic drugs and provided the same exceptions from the informed consent requirements as those provided under section 505(i). Section 125 of the Food and Drug Administration Modernization Act of 1997 repealed section 507 of the FD&C Act.

waive this requirement'' (53 FR 45671 at 45679, November 10, 1988).

The Common Rule provision recognizes that there may be proposed research that cannot practicably be conducted without a waiver or alteration of informed consent, but the research would contribute valuable medical or scientific knowledge and would present no more than minimal risk to subjects. FDA believes this is also true for some minimal risk FDA-regulated clinical investigations. On March 13, 2014, the Secretary's Advisory Committee on Human Research Protections (SACHRP) considered whether the Common Rule standard for waiver of informed consent for minimal risk research would be appropriate and helpful for FDA-regulated clinical investigations. SACHRP recommended to the Secretary of HHS that FDA adopt the provisions for waiver of informed consent that existed under the Common Rule at that time at 45 CFR 46.116(d). On October 26, 2016, SACHRP reiterated that recommendation to the Secretary.[4]

FDA believes that the Common Rule provision has provided appropriate safeguards to protect the rights, safety, and welfare of human subjects participating in certain minimal risk research for over 25 years. Consistent with SACHRP's recommendations, FDA also believes that this standard is appropriate for FDA-regulated clinical investigations posing no more than minimal risk to human subjects. The Cures Act statutory revision authorizes FDA to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This enables FDA to harmonize with the Common Rule's well-established waiver provision for certain minimal risk research, thereby facilitating investigators' ability to conduct minimal risk clinical investigations that could contribute substantially to the development of products to diagnose or treat diseases or other conditions, without compromising subjects' rights, safety, or welfare. Because some clinical research is subject to both FDA and HHS requirements, harmonization of this waiver provision should also reduce burden on the research community.

The Common Rule was recently revised (82 FR 7149, January 19, 2017), introducing new terminology and regulatory provisions. Although it retains the same criteria for IRB waiver or alteration of informed consent as were included in the 1991 version of the Common Rule, it adds a fifth criterion, *i.e.,* ''if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format'' (new requirement at 45 CFR 46.116(f)(3)(iii)). We are proposing to adopt the four criteria from the 1991 version of the Common Rule. At this time, we are not proposing to adopt the new fifth criterion in the revised Common Rule, which has a general compliance date of January 21, 2019; however, we invite comments on this issue. Section 3023 of the Cures Act requires the Secretary of HHS, to the extent practicable and consistent with other statutory provisions, to harmonize the differences between the HHS human subject regulations and FDA's human subject regulations. FDA will be working with others in HHS to carry out this statutory directive with respect to new terminology and regulatory provisions in the revised Common Rule, such as this new fifth criterion.

Subsequent to the Cures Act amendment to the FD&C Act, FDA issued a guidance document for immediate implementation, entitled ''Institutional Review Board Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects'' (82 FR 34535, July 25, 2017). This guidance informed sponsors, investigators, and IRBs that FDA does not intend to object to an IRB waiving or altering informed consent requirements, as described in the guidance, for certain minimal risk clinical investigations. In addition, the guidance informed sponsors, investigators, and IRBs that FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described in the guidance. FDA intends to withdraw the guidance after regulations to implement section 3024 of the Cures Act become effective.

Obtaining informed consent from those who volunteer to participate in research is a fundamentally important principle of human subject protection. FDA is issuing this proposed rule to permit IRB waiver or alteration of informed consent in limited circumstances, consistent with the Cures Act. Given the variety and complexity of clinical investigations being conducted in today's research environment, FDA is soliciting additional stakeholder input on the types of FDA-regulated minimal risk clinical investigations for which sponsors would anticipate requesting a waiver or alteration of informed consent from the IRB.

B. Description of the Proposed Regulation

FDA proposes to add § 50.22, ''Exception from informed consent requirements for minimal risk clinical investigations'' to part 50. The proposed exception would allow the IRB responsible for the review, approval, and continuing review of the clinical investigation to approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent in § 50.25(a) and (b) of FDA's current regulations, or that waives the requirement to obtain informed consent, provided that the IRB finds and documents that:

- The clinical investigation involves no more than minimal risk to the subjects;
- the waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects;
- the clinical investigation could not practicably be carried out without the waiver or alteration of informed consent; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consistent with the amendments made by section 3024 of the Cures Act, § 50.22(a) would limit the application of a waiver or alteration of informed consent under proposed § 50.22 to clinical investigations that involve no more than minimal risk. FDA regulations and the Common Rule have shared the same definition of ''minimal risk'' since 1991 (see 56 FR 28025, June 18, 1991; § 50.3(k); 45 CFR 46.102(i)).[5]

Proposed § 50.22 also provides for appropriate safeguards to protect the rights, safety, and welfare of human subjects. Proposed § 50.22(b) requires the reviewing IRB to find that the waiver or alteration will not adversely affect the rights and welfare of the subjects. To make this finding, IRBs may consider, for example, whether the waiver or alteration has the potential to negatively affect the subjects' well-being or whether the subject population in

[4] SACHRP's recommendations are available at *https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2014-july-3-letter-attachment-c/index.html* and *https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-november-2-2016-letter/index.html.*

[5] In the revised Common Rule, the definition of ''minimal risk'' is found at 45 CFR 46.102(j).

general would likely object to a waiver or alteration being granted for the research in question. It would not be necessary for an IRB to find that obtaining informed consent would be harmful or contrary to the best interests of subjects in order to satisfy this criterion.

Proposed § 50.22(c) requires the reviewing IRB to find that the clinical investigation could not practicably be carried out without the waiver or alteration. If scientifically sound research can be practicably carried out using only consenting subjects, FDA believes it should be carried out without involving nonconsenting subjects. By practicable, FDA means, for example: (1) That recruitment of consenting subjects does not bias the science and the science is no less rigorous as a result of restricting it to consenting subjects or (2) that the research is not unduly delayed by restricting it to consenting subjects. The emphasis is on situations where it is impracticable to carry out the clinical investigation, as designed, without the waiver or alteration, rather than on situations where it is not feasible to obtain informed consent from human subjects.

Finally, proposed § 50.22(d) requires the reviewing IRB to find that, whenever appropriate, the subjects will be provided with additional pertinent information after participation. For example, an IRB may determine that information that had been previously withheld about the clinical investigation to prevent bias must be provided to subjects following their participation.

If an IRB finds and documents the criteria set forth in proposed § 50.22(a) to (d), the proposed rule would provide for the IRB to approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent in § 50.25(a) and (b), or that waives the requirement to obtain informed consent. This means that an IRB may waive entirely, under proposed § 50.22, the requirement to obtain informed consent, which would constitute a waiver of all elements under § 50.25(a), (b), and (c). However, regarding an alteration to the informed consent document, the proposed rule would not permit an IRB to approve an informed consent document with an omission or alteration of the specific informed consent element set forth in § 50.25(c), which requires that a statement regarding the inclusion of clinical trial information at *https://www.ClinicalTrials.gov* be provided in informed consent documents and processes for applicable clinical trials, as defined in section 402(j)(1)(A) of the Public Health Service Act, 42 U.S.C. 282(j)(1)(A).

FDA revised its informed consent regulations to add § 50.25(c) in response to section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85, September 27, 2007). Section 801 of FDAAA amended section 505(i)(4) of the FD&C Act to direct the Secretary of HHS ''to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.'' Under proposed new § 50.22, if an IRB approved the use of a consent procedure that omitted or altered certain elements in § 50.25(a) and (b), the informed consent document and/or oral presentation provided to subjects would still need to include the statement at § 50.25(c) without alteration. As FDA has previously explained, requiring a uniform statement that cannot be altered helps to ensure that potential clinical trial participants receive a consistent and accurate message that is consistent with the intent of the statutory requirement and are directed to the specific website that contains the clinical trial databank (see 76 FR 256 at 261, January 4, 2011).

Proposed § 50.22 should not be confused with the provision of the current regulations that allows for a waiver of *documentation* of informed consent by an IRB in certain situations; the waiver for documentation of informed consent referenced in § 50.27 and found in § 56.109(c), remains unchanged.

We are also proposing three conforming amendments to §§ 50.20, 312.60, and 812.2 of our current regulations to reflect the proposed exception from informed consent for minimal risk clinical investigations. FDA is proposing to revise the introductory clause of § 50.20, General requirements of informed consent, to include reference to proposed § 50.22 as one of the limited exceptions to the general requirements for informed consent. Thus, the introductory clause to § 50.20 is proposed to read, ''Except as provided in §§ 50.22, 50.23, and 50.24. . . .''

In addition, we are proposing a conforming amendment to the second sentence in § 312.60, General responsibilities of investigators, of our current regulations on investigational new drug applications to reference part 50 generally rather than list each specific exception to the informed consent requirements in part 50. This would simplify the regulatory text and make it clear that the investigator is responsible for obtaining the informed consent of each human subject to whom the drug is administered in accordance with part 50, which includes proposed § 50.22.

The remaining conforming amendment we are proposing in part 812, Investigational Device Exemptions (IDEs), § 812.2(b)(1)(iii), would make it clear that the investigator must obtain informed consent in accordance with part 50, which includes proposed § 50.22. To simplify the current regulatory text, we are proposing to remove the reference to documentation being waived under § 56.109(c), as the relevant section of the regulations in part 50 (*i.e.,* § 50.27) refers investigators to § 56.109(c) and need not be repeated. Thus, the provision of the abbreviated requirements for IDEs in § 812.2(b)(1)(iii) would be simplified to read, ''(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent in accordance with part 50 of this chapter.''

III. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

IV. Legal Authority

Title III, section 3024 of the Cures Act amended sections 520(g)(3) and 505(i)(4) of the FD&C Act to provide FDA with the authority to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This statutory amendment was signed into law and became effective on December 13, 2016. We are proposing these regulations to reflect these statutory changes to the FD&C Act, including appropriate human subject protection safeguards. Thus, sections 520(g)(3) and 505(i)(4) of the FD&C Act, as amended by section 3024 of the Cures Act, in conjunction with FDA's general rulemaking authority in section 701(a) of the FD&C Act, serve as our principal legal authority for this proposed rule.

V. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory

Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that the proposed rule, if finalized, is an Executive Order 13771 deregulatory action and does not require us to identify cost offsets.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would not impose new requirements on any entity and therefore has no associated compliance costs, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

A. Benefits of the Proposed Rule

The proposed rule would amend FDA's current informed consent regulations to harmonize with the 1991 version of the Common Rule's provision for waiver of the requirement to obtain informed consent for certain minimal risk research. We expect benefits in the form of healthcare advances stemming from additional minimal risk clinical investigations that would proceed using a waiver or alteration of informed consent, and from harmonization with the Common Rule's provision for waiver of the requirement to obtain informed consent for certain minimal risk research. The Common Rule provision is currently used by numerous other Federal departments and agencies. Some clinical research is subject to both FDA's regulations and the Common Rule, so harmonization of this specific waiver provision would benefit those entities that conduct, sponsor, or review certain minimal risk clinical investigations by reducing confusion and burden created by the need to comply with differing requirements.

B. Cost Savings of the Proposed Rule

The proposed rule would harmonize FDA's informed consent regulations with the 1991 version of the Common Rule's provision for waiver of the requirement to obtain informed consent for certain minimal risk clinical investigations. As in a previous economic analysis of the 2017 revisions to the Common Rule (Ref. 1), we attempt to quantify the effects of the proposed rule where possible. We conducted a search for active IRBs regulated by both FDA and the Office for Human Research Protections (OHRP) in HHS in the ''Office for Human Research Protections (OHRP) Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in the Last 60 Days'' (Ref. 2). Using this data, we are able to determine whether an IRB is active or inactive, and whether it is regulated by FDA, OHRP, or both. We multiply the number of active IRBs by the percentage of IRBs regulated by both FDA and OHRP to yield an estimate of 2,442 active IRBs that are regulated by both FDA and OHRP (= $3{,}507 \times 0.696$). We expect that some of these IRBs would be affected by the proposed rule, and would experience a reduction in the time burden of determining whether to approve a waiver of the requirement to obtain informed consent for a minimal risk clinical investigation by reviewing it under a harmonized standard.[6] We estimate that 50 percent of affected IRBs would incur time savings from the proposed rule, with a lower bound of 25 percent of affected IRBs and an upper bound of 100 percent of affected IRBs. We estimate that for affected IRBs, cost savings would be incurred in the form of time savings to IRB administrators, IRB chairs, IRB voting members, and IRB administrative staff from evaluating a minimal risk clinical investigation under FDA's and the Common Rule's harmonized regulations for waiving the requirement to obtain informed consent. Based on discussion with FDA subject matter experts (Ref. 3), we estimate that the reduced time burden of the proposed rule is 30 minutes (0.5 hours), with a lower bound of 15 minutes (0.25 hours) and an upper bound of 60 minutes (1 hour).

We draw from Bureau of Labor Statistics data to estimate hourly wage rates for IRB chairs, IRB voting members, and IRB administrative staff in 2016 dollars. Based on an economic analysis of impacts of revisions to the Common Rule (Ref. 1), we use wages for postsecondary education administrators to proxy for IRB administrator wages (Ref. 4), wages for office and administrative support workers to proxy for IRB administrative staff wages (Ref. 5), and wages for postsecondary health teachers to proxy for the wages of IRB chairs and IRB voting members (Ref. 6). We double each hourly wage to account for benefits and overhead, yielding wage rates of $134.50 for IRB administrators (= $\$67.25 \times 2$), $35.94 for IRB administrative staff (= $\$17.97 \times 2$), $109.40 for IRB chairs (= $\$54.70 \times 2$), and $109.40 for IRB voting members (= $\$54.70 \times 2$). We estimate that each of these forms of labor would experience time savings as a result of the proposed rule ranging from 15 to 60 minutes, with a central estimate of 30 minutes. We also estimate that time savings would be incurred by one IRB administrator, one IRB administrative staff, one IRB chair, and one IRB voting member. We multiply the number of active IRBs regulated by the percentage of IRBs affected by the proposed rule, the estimated reduced time burden of the proposed rule, and the sum of each IRB wage rate to yield a total estimated cost savings of approximately $237,631 (= $2{,}442 \times 0.50 \times 0.50 \times$ [$134.50 + $109.40 + $109.40 + $35.94]), with lower bound estimated cost savings of approximately $59,408 (= $2{,}442 \times 0.25 \times 0.25 \times$ [$134.50 + $109.40 + $109.40 + $35.94]) and upper bound estimated cost savings of approximately $950,524 (= $2{,}442 \times 1 \times 1 \times$ [$134.50 + $109.40 + $109.40 + $35.94]). The net present value of the cost savings of the proposed rule is approximately $230.7 thousand, discounted at 3 percent, with a lower bound of approximately $57.7 thousand and an upper bound of approximately

[6] As previously discussed, the revised Common Rule adds a fifth criterion to the waiver or alteration of informed consent requirements (see section II.A). Although FDA is not proposing to adopt the fifth criterion in this rulemaking, for clinical investigations subject to both the Common Rule and FDA regulations, if an IRB finds and documents that research satisfies the criteria for waiver of the requirement to obtain informed consent for minimal risk research under the revised Common Rule, then that research would also meet the standards for waiver of the requirement to obtain informed consent in FDA-regulated clinical investigations described in this proposed rule.

$922.8 thousand. The net present value of the cost savings of the proposed rule are approximately $222.1 thousand, discounted at 7 percent, with a lower bound of approximately $55.5 thousand and an upper bound of approximately $888.3 thousand. The annualized cost savings of the proposed rule are approximately $27 thousand, discounted at 3 percent over 10 years, with a lower bound of approximately $6,762 and an upper bound of approximately $108.2 thousand. The annualized cost savings of the proposed rule are approximately $26 thousand discounted at 7 percent over 10 years, with a lower bound of approximately $6,509 and an upper bound of approximately $104.1 thousand. The estimated cost savings of the proposed rule to IRBs are summarized in table 1.

TABLE 1—COST SAVINGS OF THE PROPOSED RULE TO IRBS

	Low	Middle	High
No. of active IRBs	3,507	3,507	3,507
Percentage of IRBs regulated by FDA and OHRP	69.6%	69.6%	69.6%
No. of active IRBs regulated by FDA and OHRP	2,442	2,442	2,442
Percentage of FDA/OHRP regulated IRBs affected by the proposed rule	25%	50%	100%
Reduced time burden of the proposed rule (hours)	0.25	0.5	1
Hourly wage, IRB administrator	$134.50	$134.50	$134.50
Hourly wage, IRB chair	$109.40	$109.40	$109.40
Hourly wage, IRB voting member	$109.40	$109.40	$109.40
Hourly wage, IRB administrative staff	$35.94	$35.94	$35.94
Total cost savings of the proposed rule	$59,408	$237,631	$950,524
Net present value of the proposed rule (3%)	$57,677	$230,710	$922,839
Net present value of the proposed rule (7%)	$55,521	$222,085	$888,340
Annualized cost savings of the proposed rule (3%, 10 years)	$6,762	$27,046	$108,185
Annualized cost savings of the proposed rule (7%, 10 years)	$6,509	$26,035	$104,141

C. Costs of the Proposed Rule

We do not anticipate additional costs associated with this rulemaking. This proposed rule would help enable the conduct of certain minimal risk clinical investigations for which the requirement to obtain informed consent is waived or for which certain elements of informed consent are waived or altered.

D. Executive Order 13771

Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that the proposed rule, if finalized, is deregulatory under Executive Order 13771 and does not require us to identify cost offsets.

The net present value of the cost savings of the proposed rule are approximately $222.1 thousand, discounted at 7 percent, with a lower bound of approximately $55.5 thousand and an upper bound of approximately $888.3 thousand. The annualized cost savings of the proposed rule are approximately $15,546, discounted at 7 percent on an infinite time horizon, with a lower bound of approximately $3,886 and an upper bound of approximately $62,184. Discounted at 3 percent, the net present value of the cost savings of the proposed rule are approximately $230.7 thousand, with a lower bound of approximately $57.7 thousand and an upper bound of approximately $922.8 thousand. The annualized cost savings of the proposed rule are approximately $6,921, discounted at 3 percent on an infinite time horizon, with a lower bound of approximately $1,730 and an upper bound of approximately $27,685. The estimated net cost savings under Executive Order 13771 are summarized in table 2.

TABLE 2—SUMMARY OF EXECUTIVE ORDER 13771 NET COST SAVINGS

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs						
Present Value of Cost Savings	$222,085	$55,521	$888,340	$230,710	$57,677	$922,839
Present Value of Net Cost Savings	222,085	55,521	888,340	230,710	57,677	922,839
Annualized Costs						
Annualized Cost Savings	15,546	3,886	62,184	6,921	1,730	27,685
Annualized Net Cost Savings	15,546	3,886	62,184	6,921	1,730	27,685

VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). IRB actions related to the waiver or alteration of informed consent requirements are currently approved under OMB control numbers 0910–0014, 0910–0078, 0910–0130, and 0910–0755. Therefore, FDA tentatively concludes the requirements in this document are not subject to additional review by OMB.

VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We

have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Government Publishing Office, ''Federal Policy for the Protection of Human Subjects'', 82 FR 7149 (January 19, 2017), available at: *https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf,* accessed on September 20, 2017.
2. Memorandum to File, FDA summary of data analysis; HHS, ''Office for Human Research Protections (OHRP) Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in Last 60 Days'', prepared by Christian Brown, FDA, September 20, 2017.
3. Memorandum to File, FDA staff meeting on the Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations rulemaking, prepared by Christian Brown, FDA, September 20, 2017, addendum August 20, 2018.
4. Bureau of Labor and Statistics, ''Occupational Employment and Wages, May 2016, 11–9033 Education Administrators, Postsecondary'', available at: *https://www.bls.gov/oes/2016/may/oes119033.htm,* accessed on September 20, 2017.
5. Bureau of Labor and Statistics, ''Occupational Employment and Wages, May 2016, 43–0000 Office and Administrative Support Occupations (Major Group)'', available at: *https://www.bls.gov/oes/2016/may/oes430000.htm,* accessed on September 20, 2017.
6. Bureau of Labor and Statistics, ''May 2016 National Occupational Employment and Wage Estimates, United States'', available at: *https://www.bls.gov/oes/2016/may/oes_nat.htm,* accessed on September 20, 2017.

List of Subjects

21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 50, 312, and 812 be amended as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 2. In § 50.20 revise the first sentence to read as follows:

§ 50.20 General requirements for informed consent.

Except as provided in §§ 50.22, 50.23, and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. * * *

■ 3. Add § 50.22 to subpart B to read as follows:

§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.

The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in § 50.25(a) and (b), or that waives the requirement to obtain informed consent, provided the IRB finds and documents the following:

(a) The clinical investigation involves no more than minimal risk to the subjects;

(b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(c) The clinical investigation could not practicably be carried out without the waiver or alteration; and

(d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 4. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

■ 5. Revise § 312.60 to read as follows:

§ 312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation. An investigator shall obtain the informed consent of each human subject to whom the drug is administered, in accordance with part 50 of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 6. The authority citation for part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360bbb–8b, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 7. Revise § 812.2 (b)(1)(iii) to read as follows:

§ 812.2 Applicability.

* * * * *

(b) * * *

(1) * * *

(iii) Ensures that each investigator participating in an investigation of the

device obtains from each subject under the investigator's care, informed consent in accordance with part 50 of this chapter.

* * * * *

Dated: November 7, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–24822 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 570

RIN 1235–AA22

Expanding Employment, Training, and Apprenticeship Opportunities for 16- and 17-Year-Olds in Health Care Occupations Under the Fair Labor Standards Act, Comment Extension Period

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document extends the period for submitting written comments on the Notice of Proposed Rulemaking (NPRM) entitled ''Expanding Employment, Training, and Apprenticeship Opportunities for 16- and 17-Year-Olds in Health Care Occupations Under the Fair Labor Standards Act.'' The comment period now ends on December 11, 2018. The Department of Labor (Department) is taking this action to provide interested parties additional time to submit comments in response to a request for extension, as some supporting documents for the proposal may not have been originally fully visible in the docket.

DATES: The comment period for the proposed rule published September 27, 2018, at 83 FR 48737, is extended. Comments should be received on or before December 11, 2018.

ADDRESSES: To facilitate the receipt and processing of written comments on this NPRM, the Department encourages interested persons to submit their comments electronically. You may submit comments, identified by Regulatory Information Number (RIN) 1235–AA22, by either of the following methods:

Electronic Comments: Follow the instructions for submitting comments on the Federal eRulemaking Portal *http://www.regulations.gov.*

Mail: Address written submissions to Melissa Smith, Director of the Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: This NPRM is available through the **Federal Register** and the *http://www.regulations.gov* website. You may also access this document via the Wage and Hour Division's (WHD) website at *http://www.dol.gov/whd/.* All comment submissions must include the agency name and Regulatory Information Number (RIN 1235–AA22) for this NPRM. Response to this NPRM is voluntary. The Department requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this NPRM. Submit only one copy of your comment by only one method (*e.g.,* persons submitting comments electronically are encouraged not to submit paper copies). Please be advised that comments received will become a matter of public record and will be posted without change to *http://www.regulations.gov,* including any personal information provided. All comments must be received by 11:59 p.m. on the date indicated for consideration in this NPRM; comments received after the comment period closes will not be considered. Commenters should transmit comments early to ensure timely receipt prior to the close of the comment period. Electronic submission via *http://www.regulations.gov* enables prompt receipt of comments submitted as DOL continues to experience delays in the receipt of mail in our area. For access to the docket to read background documents or comments, go to the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa Smith, Director of the Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210, telephone: (202) 693–0406 (this is not a toll-free number). Copies of this NPRM may be obtained in alternative formats (Large Print, Braille, Audio Tape or Disc), upon request, by calling (202) 693–0675 (this is not a toll-free number). TTY/TDD callers may dial toll-free 1 (877) 889–5627 to obtain information or request materials in alternative formats.

Questions of interpretation and/or enforcement of the agency's regulations may be directed to the nearest WHD district office. Locate the nearest office by calling the WHD's toll-free help line at (866) 4US–WAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD's website at *http://www.dol.gov/whd/america2.htm* for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

On September 27, 2018, the Department published an NPRM and request for comments in the **Federal Register** (83 FR 48737), proposing to revise Hazardous Order Number 7 under the FLSA to allow for 16- or 17-year-olds to operate power-driven patient lifts. The NPRM also requested public comments on the NPRM on or before November 26, 2018. Not all supporting documents in the public docket may have been originally fully visible. That issue has now been addressed, however, and the documents are fully publicly viewable. In light of the above, and out of an abundance of caution, the Department has extended the period for submitting public comment to December 11, 2018.

Bryan L. Jarrett,

Acting Administrator, Wage and Hour Division.

[FR Doc. 2018–24945 Filed 11–14–18; 8:45 am]

BILLING CODE 4510–27–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2018–8]

Noncommercial Use of Pre-1972 Sound Recordings That Are Not Being Commercially Exploited: Extension of Comment Period

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of inquiry; extension of comment period.

SUMMARY: The Copyright Office is extending the deadline for the submission of written comments in response to its October 16, 2018 notice of inquiry regarding the Classics Protection and Access Act, title II of the recently enacted Orrin G. Hatch–Bob Goodlatte Music Modernization Act.

DATES: The initial comment period for the notice of inquiry, published on October 16, 2018, is extended by an additional ten days. Initial comments must be made in writing and must be received in the U.S. Copyright Office no later than 11:59 p.m. Eastern Time on November 26, 2018. Written reply comments must be received no later

than 11:59 p.m. Eastern Time on December 11, 2018.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the regulations.gov system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office's website at *https://www.copyright.gov/rulemaking/pre1972-soundrecordings-noncommercial/.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at *regans@copyright.gov,* Anna Chauvet, Assistant General Counsel, by email at *achau@copyright.gov,* or Jason E. Sloan, Assistant General Counsel, by email at *jslo@copyright.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION: On October 16, 2018, the U.S. Copyright Office issued a notice of inquiry (''NOI'') regarding the Classics Protection and Access Act, title II of the recently enacted Orrin G. Hatch–Bob Goodlatte Music Modernization Act.[1] In connection with the establishment of federal remedies for unauthorized uses of sound recordings fixed before February 15, 1972 (''Pre-1972 Sound Recordings''), Congress established an exception for certain noncommercial uses of Pre-1972 Sound Recordings that are not being commercially exploited. To qualify for this exemption, a user must file a notice of noncommercial use after conducting a good faith, reasonable search to determine whether the Pre-1972 Sound Recording is being commercially exploited, and the rights owner of the sound recording must not object to the use within 90 days. To promulgate the regulations required by the new statute, the Office solicited comments regarding specific steps that a user should take to demonstrate she has made a good faith, reasonable search, as well as the filing requirements for the user to submit a notice of noncommercial use and for a rights owner to submit a notice objecting to such use.[2]

To ensure that members of the public have sufficient time to respond, and to ensure that the Office has the benefit of a complete record, the Office is extending the deadline for the submission of initial written comments to 11:59 p.m. Eastern Time on November 26, 2018. Written reply comments must be received no later than 11:59 p.m. Eastern Time on December 11, 2018. So that the Office is able to meet the statutory deadlines described in the NOI, no further extensions of time will be granted in this rulemaking.

Dated: November 8, 2018.

Catherine Rowland,

Associate Register of Copyrights and Director of Public Information and Education.

[FR Doc. 2018–24848 Filed 11–14–18; 8:45 am]

BILLING CODE 1410–30–P

[1] 83 FR 52176 (Oct. 16, 2018).

[2] *Id.* at 52177–78.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2018–0696; FRL–9986–55–OAR]

RIN 2060–AU33

Adopting Subpart Ba Requirements in Emission Guidelines for Municipal Solid Waste Landfills; Notice of Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public hearing.

SUMMARY: On October 30, 2018, the Environmental Protection Agency (EPA) published in the **Federal Register** a proposed rule titled ''Adopting Subpart Ba Requirements in Emission Guidelines for Municipal Solid Waste Landfills.'' The EPA is announcing that it will hold a public hearing on the proposed action and extend the comment period. The hearing will provide interested parties the opportunity to present data, views, or arguments concerning the proposed action. The comment period on the proposed action will be extended to January 3, 2019.

DATES: The EPA will hold a public hearing on November 27, 2018, in Washington, DC. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

Comments: The EPA must receive comments on this proposed action no later than January 3, 2019.

ADDRESSES: The hearing will be held at the EPA WJC East Building, 1201 Constitution Avenue NW, Room #1117A & B, Washington, DC 20004. The hearing will convene at 9:00 a.m. local time and will conclude at 5:00 p.m. local time. There will be a lunch break from 12:00 p.m. to 1:00 p.m. The EPA will end the hearing 2 hours after the last registered speaker has concluded their comments.

Because this hearing is being held at a U.S. government facility, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. Please note that the REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. For purposes of the REAL ID Act, the EPA will accept government-issued IDs, including driver's licenses from the District of Columbia and all states and territories. Acceptable alternative forms of identification include: Federal employee badges, passports, enhanced driver's licenses, and military identification cards. For additional information for the status of your state regarding REAL ID, go to: *https://www.dhs.gov/real-id-frequently-asked-questions.* Any objects brought into the building need to fit through the security screening system, such as a purse, laptop bag, or small backpack. Demonstrations will not be allowed on federal property for security reasons.

FOR FURTHER INFORMATION CONTACT: The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/forms/public-hearing-proposal-adopt-subpart-ba-requirements* or contact Virginia Hunt at (919) 541–0832 to register to speak at the hearing. The last day to pre-register to speak at the hearing will be November 21, 2018. By November 26, 2018, the EPA will post at *https://www.epa.gov/stationary-sources-air-pollution/forms/public-hearing-proposal-adopt-subpart-ba-requirements* a general agenda for the hearing that will list pre-registered speakers in approximate order. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk. The EPA will make every effort to accommodate all speakers who arrive and register, although preferences on speaking times may not be able to be fulfilled.

SUPPLEMENTARY INFORMATION:

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) or in hard copy form.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing. Commenters should notify Virginia Hunt if there are special needs related to providing comments at the hearing. Verbatim transcripts of the hearing and written statements will be included in the docket for the rulemaking.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/forms/public-hearing-proposal-adopt-subpart-ba-requirements.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact Virginia Hunt at (919) 541–0832 or *hunt.virginia@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

The EPA will not provide audiovisual equipment for presentations unless we receive special requests in advance. Commenters should notify Virginia Hunt when they pre-register to speak that they will need specific equipment. If you require the service of a translator or special accommodations such as audio description, please pre-register for the hearing and describe your needs by November 21, 2018. We may not be able to arrange accommodations without advanced notice.

Dated: November 9, 2018.

Panagiotis Tsirigotis,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2018–24964 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 192

[Docket No. PHMSA–2018–0073]

Pipeline Safety: Guidance on the Extension of the 7-year Integrity Management Reassessment Interval by 6 Months

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Request for comments.

SUMMARY: PHMSA is publishing this document to seek public comments on frequently asked questions (FAQs) developed to provide guidance on what constitutes sufficient justification for an operator to request a 6-month extension to a gas pipeline's 7-year integrity management reassessment interval. This guidance, which consists of one revised and two new FAQs, will implement authority granted by Congress in Section 5(e) of the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (2011 Act).

DATES: Interested persons are invited to submit comments on or before December 17, 2018.

ADDRESSES: Comments should reference Docket No. PHMSA–2018–0073 and may be submitted in the following ways:

E-gov website: http://www.regulations.gov. This site allows the public to enter comments on any **Federal Register** document issued by any agency.

Fax: (202) 493–2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of the DOT's West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Monday through Friday between 9 a.m. and 5 p.m. Eastern Standard Time (EST), except Federal holidays.

Instructions: Identify the docket number, PHMSA–2018–0073, at the beginning of your comments. Please note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Anyone may search the electronic form of comments received for PHMSA dockets. You may review the DOT's complete Privacy Act Statement, 65 FR 19476, which was published in the **Federal Register** on April 11, 2000.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* at any time. You may also visit Room W12–140 on the ground level of the DOT's West Building, located at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Monday through Friday between 9 a.m. and 5 p.m. EST, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a stamped, self-addressed postcard with the following statement: ''Comments on PHMSA–2018–0073.'' The docket clerk will date stamp the postcard prior to returning it to you via the mail. Please note that, due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that you consider an alternative method (internet, fax, or professional delivery service) for submitting comments to the docket and ensuring their timely delivery to the DOT.

Note: Privacy Act Statement: the DOT may solicit comments from the public regarding certain general notices. The DOT posts these comments without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS). This document can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT:

General: Ms. Nancy White by telephone at 202–366–1419, or email at *nancy.white@dot.gov.*

Technical: Mr. Kenneth Lee by telephone at 202–366–2694, or email at *kenneth.lee@dot.gov.*

SUPPLEMENTARY INFORMATION: Congress made several amendments to the pipeline safety statutes in the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (the 2011 Act). The Secretary of Transportation (the Secretary) has delegated to PHMSA the responsibility for implementing the changes resulting from the 2011 Act. Section 5, ''Integrity Management,'' paragraph (e), of the 2011 Act made a technical correction to the Federal pipeline safety statutes regarding the performance of integrity management assessments. As part of an operator's integrity management program, operators must assess pipelines in high-consequence areas for defects and anomalies at a minimum of once every 7 years. The technical correction clarified that the Secretary may extend such deadlines by an additional 6 months if the operator submits written notice to the Secretary with sufficient

justification of the need for the extension.

To implement this authority, PHMSA is issuing guidance on what constitutes sufficient justification to extend a gas pipeline operator's 7-year integrity management reassessment interval by up to 6 months if the operator submits written notice. PHMSA invites interested individuals to participate by reviewing the FAQs provided below and submitting written comments, data, or other information. Please include any comments on potential safety and environmental impacts that may result from issuance of the FAQs. Before finalizing the FAQs, PHMSA will evaluate all comments received on or before the comment closing date. PHMSA will consider all relevant comments we receive prior to the deadline when making changes to the final FAQs. Comments received after the closing date will be evaluated to the extent practicable.

Once finalized, PHMSA's FAQs will be posted on PHMSA's public website at *https://primis.phmsa.dot.gov/gasimp/faqs.htm:*

Guidance on the Extension of the 7-year Integrity Management Reassessment Interval by 6 Months (FAQs):

• *NEW* FAQ–281. How do I extend the assessment schedule beyond 7 years?

Notify PHMSA, in accordance with 49 CFR 192.949, of the need for an extension, which may not exceed 6 months. The notification must be made 180 days prior to end of the 7-year assessment date and include sufficient information to justify the extension.

• *NEW* FAQ–282. What constitutes sufficient information to justify extension of the assessment interval?

Documentation is required to comply with 49 CFR 192.943 and include:

—An explanation as to why the deadline could not be met and how it will not compromise safety, and

—Identification of any additional actions necessary to ensure public safety during the extension time period.

• *REVISED* FAQ–207. Table 3 of ASME/ANSI B31.8S indicates that reassessment intervals must be 5 years for some instances in which test pressure was higher than would be required by subpart J. If I conduct my assessments in accordance with Subpart J, must I reassess more frequently than once every 7 years?

Section 192.939(a)(1) specifies requirements for establishing reassessment intervals. Two options are allowed: (i) Basing the interval on identified threats, assessment results, data integration, and risk analysis, or (ii) using the intervals specified in Table 3 of ASME/ANSI B31.8S. An operator using the former option (§ 192.939(a)(1)(i)) could establish intervals longer than those in Table 3. The intervals that can be established by either method are limited to the maximum intervals in the table in § 192.939.

Pressure tests used as integrity management assessments must meet the requirements of Subpart J, including required test pressures. Higher test pressures must be used to justify extended reassessment intervals (§ 192.937(c)(2)). As used here ''extended reassessment intervals'' refers to any interval longer than 7 years as required by §§ 192.937(a) and 192.939(a) and (b).

Operators conducting assessments by pressure testing and who use test pressures meeting Subpart J requirements may establish a reassessment interval of 7 years, unless their analysis under § 192.939(a)(i) indicates a need for a shorter interval. This is true even if Table 3 would lead to a shorter interval.

Operators who use Table 3 test pressures may establish reassessment intervals in accordance with Table 3 up to the maximums listed in the table in § 192.939, again unless their analysis under § 192.939(a)(i) indicates a need for a shorter interval. Operators who establish intervals longer than 7 years must conduct a confirmatory direct assessment within the 7-year period. (For segments operating at less than 30% specified maximum yield strength, a low-stress reassessment per § 192.941 may be conducted in lieu of confirmatory direct assessment—see § 192.939(b)(1)).

PHMSA may extend the 7-year interval for an additional 6 months if the operator submits written notice that includes sufficient justification regarding the need for an extension (Reference FAQ–281 and 282).

Issued in Washington, DC, on November 7, 2018, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2018–24774 Filed 11–14–18; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 180906820–8820–01]

RIN 0648–BI48

Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries; 2019 Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes 2019 specifications for the summer flounder and black sea bass fisheries and maintains previously established 2019 specifications for the scup fishery. Additionally, this action proposes to reopen the February 2018 black sea bass recreational fishery and to adjust to the current commercial incidental possession limit for scup. The implementing regulations for the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan require us to publish specifications for the upcoming fishing year for each of these species and to provide an opportunity for public comment. This action is intended to inform the public of the proposed specifications and management measures for the start of the 2019 fishing year for these three species.

DATES: Comments must be received on or before November 30, 2018.

ADDRESSES: An environmental assessment (EA) was prepared for this action that describes the proposed measures and other considered alternatives, and provides an analysis of the impacts of the proposed measures and alternatives. Copies of the Summer Flounder, Scup, and Black Sea Bass 2019 Specifications, including the EA, are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *http://www.mafmc.org/s/SFSBSB_2019_specs_EA.pdf.*

You may submit comments on this document, identified by NOAA–NMFS–2018–0110, by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0110,*

2. Click the ''Comment Now!'' icon, complete the required fields, and

3. Enter or attach your comments.

—OR—

Mail: Submit written comments to Michael Pentony, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA, 01930. Mark the outside of the envelope, ''Comments on the Proposed Rule for the Summer Flounder, Scup, and Black Sea Bass 2019 Specifications.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Emily Gilbert, Fishery Policy Analyst, (978) 281–9244.

SUPPLEMENTARY INFORMATION:

General Background

The Mid-Atlantic Fishery Management Council (Council) and the Atlantic States Marine Fisheries Commission (Commission) cooperatively manage the summer flounder, scup, and black sea bass fisheries. The Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) and its implementing regulations outline the Council's process for establishing specifications. Specifications in these fisheries include various catch and landing subdivisions, such as the commercial and recreational sector annual catch limits (ACL), annual catch targets (ACT), and sector-specific landing limits (*i.e.,* the commercial fishery quota and recreational harvest limit), as well as management measures, as needed, that are designed to ensure these catch limits will not be exceeded. Annual specifications may be established for three year periods, and, in interim years, specifications are reviewed by the Council to ensure previously established multi-year specifications remain appropriate. The FMP also contains formulas to divide the specification catch limits into commercial and recreational fishery allocations, state-by-state quotas, and quota periods, depending on the species in question. Rulemaking for measures used to manage the recreational fisheries (minimum fish sizes, open seasons, and bag limits) for these three species occurs separately, and typically takes place in the spring of each year.

This action proposes 2019 specifications for summer flounder and black sea bass. The previously approved 2019 scup specifications (82 FR 60682; December 22, 2017) remain unchanged from the current two year specifications and are maintained through this action. The Council's Science and Statistical Committee (SSC) and Summer Flounder, Scup, and Black Sea Bass Monitoring Committee met in July 2018 to develop specification recommendations, including new acceptable biological catch limits (ABC) for summer flounder and black sea bass. The Council and the Commission's Summer Flounder, Scup, and Black Sea Bass Management Board (Board) met jointly August 14–15, 2018, to consider the SSC and Monitoring Committee's recommendations, receive public comments on those recommendations, and to formalize recommendations to the NMFS for catch limit specifications and commercial management measures. Recreational fishery management measures will be developed in early 2019. A summer flounder benchmark assessment, which will incorporate updated Marine Recreational Information Program (MRIP) data, is expected to be completed by early 2019. Operational assessments for black sea bass and scup that will also incorporate updated MRIP information will be completed in spring 2019. Because of this, the Council and Board have only recommended specifications for 2019. As explained below, the Council and Board are considering the specifications here as interim measures and will likely develop mid-year changes to the summer flounder specifications, if not also black sea bass, to address the updated assessment information, if necessary.

Proposed 2019 Summer Flounder Specifications

In June, the Northeast Fisheries Science Center (Center) provided the Council with a summer flounder data update. The data update provided a projection for stock biomass for 2019. Most state and Federal survey indices of abundance, with the exception of Massachusetts and Delaware, remain below their most recent peaks (generally 2009–2012) in the update. Recruitment indices in 2017 were highly variable. Based on the best available scientific information, the summer flounder stock is subject to overfishing but is not overfished. After reviewing the update, the SSC and Monitoring Committee recommended an interim ABC of 15.41 million lb (6,990 mt).

At the joint August meeting, the Council and Board made recommendations for interim summer flounder specifications for the start of the 2019 fishing year (Table 1). Compared to 2018, the proposed interim 2019 ABC is a 16-percent increase. The results from the benchmark stock assessment are expected to be available in early 2019 following peer review in November 2018. The Council and Board intend to consider revising the 2019 summer flounder specifications at a joint meeting in February 2019 taking into account the benchmark stock assessment. If revisions are recommended at this meeting, we anticipate updated catch limits could be in place by early May 2019.

TABLE 1—CURRENT 2018 AND PROPOSED 2019 SUMMER FLOUNDER SPECIFICATIONS

	2018 (current)		2019		Difference (%)
	million lb	mt	million lb	mt	
Overfishing Limits (OFL)	18.69	8,476	20.60	9,344	10
ABC	13.23	5,999	15.41	6,990	16
Commercial ACL	7.70	3,491	9.18	4,164	19
Commercial ACT	7.70	3,491	9.18	4,164	19
Projected Commercial Discards	1.07	485	1.47	667	2
Commercial Quota	6.63	3,006	7.72	3,502	16
Recreational ACL	5.53	2,508	6.22	2,821	12

TABLE 1—CURRENT 2018 AND PROPOSED 2019 SUMMER FLOUNDER SPECIFICATIONS—Continued

	2018 (current)		2019		Difference (%)
	million lb	mt	million lb	mt	
Recreational ACT	5.53	2,508	6.22	2,821	12
Projected Recreational Discards	1.11	504	1.08	490	−3
Recreational Harvest Limit	4.42	2,004	5.15	2,336	16

2019 Summer Flounder Commercial Non-Landing Accountability Measure

Our final 2017 catch accounting shows that the 2017 commercial fishery exceeded its ACL by 21 percent and the 2017 ABC was exceeded by 7 percent, due to higher than expected discards in the commercial fishery. Currently, the regulations require a pound-for-pound accountability measure (AM) that is applied to the commercial ACT when the ACL has been exceeded and the overage is caused by higher discards than those estimated prior to the fishing year. A final rule for a framework adjustment (Framework 13) that would modify this AM published on October 25, 2018 (83 FR 53825), and will be effective on November 26, 2018. That action adjusts this non-landings based AM to help account for the variability in commercial discard estimates and provide additional flexibility based on stock status and the biological consequences, if any, of estimated discard overages. In terms of impacts of the 2017 discard overage for 2019, the AM as modified by the pending framework would result in a scaled payback against the commercial fishery's ACT, based on the amount of the overage and the status of the summer flounder stock, using the most recent biological reference points.

Based on the 2016 assessment update, this scaled payback would be 1.04 million lb (472 mt). This overage, when applied to the proposed 2019 commercial ACT of 9.18 million lb (3,502 mt), would result in a commercial quota of 6.67 million lb (3,030 mt), after subtracting the 2019 projected estimated discards. The resulting quota is less than one percent higher than the 2018 quota.

Proposed 2019 Commercial State Quota Shares

Table 2 presents the proposed state summer flounder allocations for 2019 using the commercial state quota allocations described in the FMP. Any commercial quota adjustments to account for commercial landings overages will be published in the final specification rule prior to the start of the respective fishing year.

TABLE 2—2019 PROPOSED INITIAL SUMMER FLOUNDER STATE COMMERCIAL QUOTAS

State	FMP Percent share	2019 Initial quota		2019 Initial quota, including AM accounting for 2017 non-landings overages (using AM as modified by Framework 13)	
		lb	kg	lb	kg
ME	0.04756	3,672	1,665	3,172	1,439
NH	0.00046	36	16	31	14
MA	6.82046	526,540	238,834	454,925	206,350
RI	15.68298	1,210,726	549,176	1,046,055	474,482
CT	2.25708	174,247	79,037	150,547	68,287
NY	7.64699	590,348	267,777	510,054	231,357
NJ	16.72499	1,291,169	585,665	1,115,557	506,008
DE	0.01779	1,373	623	1,187	538
MD	2.0391	157,419	71,404	136,008	61,692
VA	21.31676	1,645,654	746,456	1,421,828	644,930
NC	27.44584	2,118,819	961,080	1,830,638	830,363
Total	100	7,720,000	3,501,733	6,670,000	3,025,461

Note: Kilograms are as converted from lb and do not sum to the converted total due to rounding. Rounding of quotas results in totals slightly exceeding 100 percent.

The Council and Board recommended no adjustment to the commercial minimum fish size (14-inch (35.6 cm) total length), gear requirements, and possession limits. The Council and Board will develop recreational management measures (*i.e.,* minimum fish sizes, open seasons, and bag limits) for summer flounder this fall and NMFS rulemaking will occur in early spring of 2019.

Proposed 2019 Black Sea Bass Specifications

At the August meeting, the Council and Board made recommendations for the 2019 black sea bass specifications, but for reasons outlined below, we propose maintaining status quo measures currently in place for 2018.

In June 2018, the Center provided the Council with a black sea bass data update, including updated catch, landings, and survey indices through 2017. Black sea bass biomass continues to be high and the 2015 year class appears to be above average in both the northern and southern surveys. Updated stock status information and biomass projections incorporating data on the 2015 year class are not available, but will be once the operational assessment is completed in April 2019.

The SSC recommended a 2019 ABC of 7.97 million lb (3,615 mt), which was based on biomass projections from the 2016 benchmark stock assessment. This ABC would be an 11-percent reduction

compared to the 2018 ABC. This declining pattern of ABCs reflects the population responding to fishing at maximum sustainable yield and the decrease of the large 2011 year class, but does not incorporate the information on the 2015 year class. Based on this ABC recommendation, the Council and Board recommended the 2019 specifications outlined in Table 3.

Following the Council and Board meeting, the Center performed a sensitivity analysis of the 2019 projection derived from the 2016 benchmark stock assessment. As previously described, that projection did not include the 2015 year class because those fish were too small to be widely captured in the surveys at the time of the 2016 assessment. This sensitivity analysis used various recruitment scenarios applied to the original projection and compared them to the most recent survey indices. The objective of this analysis was to see if that projection would have supported different specifications for 2019 had we been able to incorporate what we know now about the strength of the 2015 year class. The results suggest that the 2015 year class would only have to be about 50 percent above average to allow for 2019 catch limits to be the same as what they were in 2018. Based on a comparison between the Center's 2018 spring survey results and average recruitment from 2003–2018, the 2015 year class appears to be well more than 50 percent above average. Based on this information, we propose maintaining status quo black sea bass specifications for 2019 (Table 3).

TABLE 3—PROPOSED 2019 BLACK SEA BASS SPECIFICATIONS

[In millions of lb]

	Proposed *NMFS Recommendation (Status Quo 2018)*		*Council and Board Recommendation*	
	million lb	mt	million lb	mt
OFL	10.29	4,667	9.18	4,164
ABC	8.94	4,055	7.97	3,615
Commercial ACL	4.35	1,974	3.88	1,760
Commercial ACT	4.35	1,974	3.88	1,760
Projected Commercial Discards	0.83	377	0.74	336
Commercial Quota	3.52	1,596	3.14	1,424
Recreational ACL	4.59	2,083	4.10	1,860
Recreational ACT	4.59	2,083	4.10	1,860
Projected Recreational Discards	0.93	422	0.83	376
Recreational Harvest Limit	3.66	1,661	3.27	1,483

Maintaining status quo would allow for stability in the black sea bass commercial and recreational fisheries while we wait for the results of the MRIP operational assessment to be completed in April 2019. Once that information is available, the Council and Board may recommend adjusting black sea bass measures mid-year.

The Council and Board recommended no adjustment to the commercial minimum fish size (11-inch (27.9 cm) total length), gear requirements, and possession limits.

Recreational Black Sea Bass Wave 1 Fishery

This action also proposes reopening the black sea bass recreational fishery for the month of February (during MRIP Wave 1). The current Federal black sea bass recreational management measures (*i.e.,* a 12.5-inch (31.8-cm) minimum size and a possession limit of 15 fish) would apply to the fishery for this limited winter season. The intent of this action is to allow for some recreational fishing access during a portion of Wave 1 in 2019.

There are currently no MRIP survey estimates collected for Wave 1, but catch from this time period must be accounted for, and count against the recreational harvest limit. Similar to last year, to account for the harvest during this 28-day season, the Council and Board recommended a catch estimate of 100,000 lb (45.3 mt). States that decide to participate in the Wave 1 fishery must account for this catch when developing their management measures for the remainder of the fishing year. Only two states participated in the 2018 February recreational fishery. The estimated catch was nominal. Measures for the rest of the 2019 recreational fishery will be developed through the winter for implementation in spring 2019.

2019 Scup Specifications

The scup fishery is currently operating under multi-year specifications projected through 2019. The Council received a data update indicating that biomass continues to be high, and the 2015 year class appears to be above average. In response, the Council and Board made no adjustments to the previously implemented multi-year specifications set in August 2017. This action reaffirms the Council's and Board's previous recommendation for scup 2019 specifications. Those specifications result in the same commercial quota and recreational harvest limit as implemented in 2018 (Table 4).

TABLE 4—SCUP SPECIFICATIONS FOR 2019

	million lb	mt
OFL	41.03	18,612
ABC	36.43	16,525
Commercial ACL	28.42	12,890
Commercial ACT	28.42	12,890
Commercial Discards	4.43	2,011
Commercial Quota	23.98	10,879
Recreational ACL	8.01	3,636
Recreational ACT	8.01	3,636

TABLE 4—SCUP SPECIFICATIONS FOR 2019—Continued

	million lb	mt
Recreational Discards	0.65	293
Recreational Harvest Limit	7.37	3,342

The 2019 scup commercial quota is divided into three commercial fishery quota periods, as outlined in Table 5.

TABLE 5—COMMERCIAL SCUP QUOTA ALLOCATIONS FOR 2019 BY QUOTA PERIOD

Quota period	Percent share	2019 Initial quota	
		lb	mt
Winter I	45.11	10,820,000	4,908
Summer	38.95	9,340,986	4,237
Winter II	15.94	3,822,816	1,734
Total	100.0	23,983,802	10,879

Note: Metric tons are as converted from lb and may not necessarily total due to rounding.

The current quota period possession limits are not changed by this action, and are outlined in Table 6. The Winter I possession limit will drop to 1,000 lb (454 kg) upon attainment of 80 percent of that period's allocation. If the Winter I quota is not fully harvested, the remaining quota is transferred to Winter II. The Winter II possession limit may be adjusted (in association with a transfer of unused Winter I quota to the Winter II period) via notice in the **Federal Register**. The regulations specify that the Winter II possession limit increases consistent with the increase in the quota, as described in Table 7.

TABLE 6—COMMERCIAL SCUP POSSESSION LIMITS BY QUOTA PERIOD

Quota period	Percent share	Federal possession limits (per trip)	
		lb	kg
Winter I	45.11	50,000	22,680
Summer	38.95	N/A	N/A
Winter II	15.94	12,000	5,443
Total	100.0	N/A	N/A

TABLE 7—POTENTIAL INCREASE IN WINTER II POSSESSION LIMITS BASED ON THE AMOUNT OF UNUSED SCUP ROLLED OVER FROM WINTER I TO WINTER II

Initial Winter II possession limit		Rollover from Winter I to Winter II		Increase in Initial Winter II possession limit		Final Winter II possession limit after rollover from Winter I to Winter II	
lb	kg	lb	kg	lb	kg	lb	kg
12,000 ..	5,443	0–499,999	0–226,796	0	0	12,000	5,443
12,000 ..	5,443	500,000–999,999	226,796–453,592	1,500	680	13,500	6,123
12,000 ..	5,443	1,000,000–1,499,999	453,592–680,388	3,000	1,361	15,000	6,804
12,000 ..	5,443	1,500,000–1,999,999	680,389–907,184	4,500	2,041	16,500	7,484
12,000 ..	5,443	*2,000,000–2,500,000	907,185–1,133,981	6,000	2,722	18,000	8,165

*This process of increasing the possession limit in 1,500 lb (680 kg) increments would continue past 2,500,000 lb (1,122,981 kg), but we end here for the purpose of this example.

Adjustment to the Commercial Scup Gear-Based Possession Limit Thresholds

This action proposes adjustments to the gear-based incidental possession limit for the commercial fishery. The incidental possession limit applies to vessels with commercial moratorium scup permits fishing with nets with diamond mesh smaller than 5 inches (12.7 cm) in diameter. The incidental possession limit is currently 1,000 lb (454 kg) during October 1-April 30 and 200 lb (91 kg) during May 1-September 30. The action would add another threshold period from April 15-June 15 to allow for higher retention in the small-mesh squid fishery that operates during that time and occasionally catches larger amounts of scup than the current limits allow to be landed (Table 8). During that time, vessels with scup moratorium permits using small mesh

could land up to 2,000 lb (907 kg) of scup.

Table 8. Proposed adjustment to the scup incidental possession limit

	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec
Current	1,000 lb (454 kg)				200 lb (91 kg)					1,000 lb (454 kg)		
Proposed	1,000 lb (454 kg)			2,000 lb (907kg)		200 lb (91 kg)				1,000 lb (454 kg)		

The Council and Board made no adjustments to the current commercial minimum fish size (9-inch (22.9-cm) total length) and winter quota period directed-fishery possession limits.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The Mid-Atlantic Fishery Management Council conducted an evaluation of the potential socioeconomic impacts of the proposed measures in conjunction with an environmental assessment. According to the commercial ownership database, 771 affiliate firms landed summer flounder and/or black sea bass during the 2015–2017 period, with 762 of those business affiliates categorized as small businesses and nine categorized as large businesses. Summer flounder and black sea bass represented approximately 4 percent of the average receipts of the small entities and 1 percent for large entities considered over this time period.

The ownership data for the for-hire fleet indicate that there were 869 for-hire affiliate firms with summer flounder and/or black sea bass permits generating revenues from recreationally fishing, all of which are categorized as small businesses. Although it is not possible to derive what proportion of the overall revenues came from specific fishing activities, given the popularity of these three species as recreational targets it is likely that revenues generated from these species are important for some, if not all, of these firms.

For the summer flounder fishery, the proposed measures would increase both the 2019 commercial quota and the 2019 recreational harvest limit. Even though there will be an AM applied to the commercial summer flounder fishery, the resulting commercial quota will still be a slight increase from 2018. For the black sea bass fishery, the proposed measures would result in a 2019 commercial quota and a 2019 recreational harvest limit that are identical to what was in place for 2018. As a result, this action is not expected to adversely impact revenues for vessels that fish for summer flounder and black sea bass commercially. The increase in the summer flounder recreational harvest limit does not directly impact the party/charter fishery. Future regulatory action may be needed to adjust current summer flounder, black sea bass, and scup recreational management measures (*i.e.,* bag limits, seasons, and minimum sizes), and consideration of the impact of those potential future measures on small entities engaged in the for-hire fishery will be evaluated at that time, should such a regulatory action become necessary.

Because this rule will not have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis is not required and none has been prepared. There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: November 9, 2018.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.125, paragraphs (a)(1) and (a)(5) are revised to read as follows:

§ 648.125 Scup gear restrictions.

(a) * * * (1) *Minimum mesh size.* No owner or operator of an otter trawl vessel that is issued a scup moratorium permit may possess more than 1,000 lb (454 kg) of scup from October 1 through April 14, more than 2,000 lb (907 kg) from April 15 through June 15, or more than 200 lb (91 kg) of scup from June 16 through September 30, unless fishing with nets that have a minimum mesh size of 5.0-inch (12.7-cm) diamond mesh, applied throughout the codend for at least 75 continuous meshes forward of the terminus of the net, and all other nets are stowed and not available for immediate use as defined in § 648.2.

* * * * *

(5) *Stowage of nets.* The owner or operator of an otter trawl vessel retaining 1,000 lb (454 kg) or more of scup from October 1 through April 14, 2,000 lb (907 kg) or more of scup from April 15 through June 15, or 200 lb (90.7 kg) or more of scup from June 16 through September 30, and subject to the minimum mesh requirements in paragraph (a)(1) of this section, and the owner or operator of a midwater trawl or other trawl vessel subject to the minimum size requirement in § 648.126, may not have available for immediate use any net, or any piece of net, not meeting the minimum mesh size requirement, or mesh that is rigged in a

manner that is inconsistent with the minimum mesh size. A net that is stowed and not available for immediate use as defined in § 648.2, and that can be shown not to have been in recent use, is considered to be not available for immediate use.

* * * * *

■ 3. Section 648.146 is revised to read as follows:

§ 648.146 Black sea bass recreational fishing season.

Vessels that are not eligible for a moratorium permit under § 648.4(a)(7), and fishermen subject to the possession limit specified in § 648.145(a), may only possess black sea bass from February 1 through February 28, May 15 through December 31, unless this time period is adjusted pursuant to the procedures in § 648.142.

[FR Doc. 2018–24946 Filed 11–14–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151124999–8985–01]

RIN 0648–BF57

Magnuson-Stevens Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Approval of New Gear Under Small-Mesh Fisheries Accountability Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: We propose to approve new selective trawl gear for use in several non-groundfish fisheries when subject to the Georges Bank yellowtail flounder accountability measure. The proposed selective gear would reduce bycatch of groundfish species, while allowing the target fisheries to continue operating when selective trawl gear is required. Approving this selective trawl gear would provide the fishing industry with more flexibility because there are limited selective trawl gears currently approved for use. We also propose to disapprove the use of this gear in the southern windowpane accountability measure areas.

DATES: Written comments must be received on or before December 17, 2018.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2018–0119, by either of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0119*;

2. Click the ''Comment Now!'' icon and complete the required fields; and

3. Enter or attach your comments.

• *Mail:* Submit written comments to Michael Pentony, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on the Proposed Rule for Selective Gear.''

Instructions: All comments received that were timely and properly submitted are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by us.

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Management Specialist, phone: (978) 281–9116; email: *Emily.Keiley@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Northeast Multispecies Fishery Management Plan (FMP) requires the use of selective trawl gear in certain times and areas. The FMP specifies the list of selective trawl gear that meet the required selectivity standards. The FMP also authorizes NMFS to approve additional selective gear, at the request of the New England Fishery Management Council, if the gear meets the regulatory requirements for new selective gear. The regulations (§ 648.85(b)(6)(iv)(J)(*2*)(*i*)) require that new selective gear must either: Demonstrate a statistically significant reduction in catch of at least 50 percent, by weight, on a trip-by-trip basis, of each regulated species stock of concern, or, catch of stocks of concern must be less than 5 percent of the total catch of regulated groundfish (by weight, on a trip-by-trip basis). The Council submitted two requests to add the large-mesh belly panel to the list of approved selective gears: (1) For the Georges Bank yellowtail accountability measure (AM); and (2) for the southern windowpane AM.

The small-mesh trawl fishery (*e.g.,* whiting and squid) has a sub-annual catch limit (sub-ACL) and AM for Georges Bank yellowtail flounder. If catch exceeds the sub-ACL, the AM requires small-mesh trawl vessels to use selective trawl gear that reduces flatfish catch in certain areas for the subsequent fishing year.

Southern windowpane flounder is allocated to three fishery components: Groundfish; scallops; and, other non-groundfish fisheries. The other (non-groundfish) component is primarily the scup, fluke, squid, and whiting fisheries. If the AM for the other (non-groundfish) component is triggered, vessels fishing with any trawl gear with a codend mesh size greater than, or equal to 5 in (12.7 cm), are required to use one of the approved selective trawl gears to reduce flatfish bycatch in certain areas in Southern New England in a subsequent year.

The selective trawl gears approved for use under these AMs are: Haddock separator trawl; Ruhle trawl; and rope separator trawl. When we adopted the AMs for the non-groundfish fisheries, many industry members expressed concern that the selective trawl gears currently approved for use were not suitable for their fisheries. To address this concern, Cornell University conducted a series of studies to test the effectiveness of a new selective gear, the large-mesh belly panel, in several non-groundfish fisheries. The experimental gear included a large-mesh panel to replace the first bottom belly of the trawl net that allows flatfish such as windowpane and yellowtail flounder to escape.

Cornell University conducted two studies in 2014 to investigate using a large-mesh belly panel in a small-mesh trawl net typical of those used in the squid and whiting fisheries on Georges Bank. Both experiments demonstrated a statistically significant reduction in catch of more than 50 percent of Georges Bank yellowtail flounder on a trip-by-trip basis, as required by regulations, without a significant reduction in squid and whiting catch. These studies also demonstrated that the large-mesh belly panel reduced catch, by more than 50 percent per trip, of stocks that are overfished or subject to overfishing.

Cornell University conducted an additional study in 2015 to investigate using a large-mesh belly panel in a trawl net typical of those used in the scup fishery in southern New England

waters. The experiment demonstrated a statistically significant reduction in southern windowpane flounder catch of more than 50 percent, without a significant reduction in catch of legal-sized scup. Catch in the large-mesh belly panel gear was compared to catch in the standard net, and three regulated stocks of concern were caught in significant numbers in the standard net. The percent reduction by trip, and the mean percent reduction, for each species is presented in Table 1; trips that do not meet the 50 percent reduction standard are highlighted in gray. Catches, on average, of yellowtail and winter flounder were only reduced by 48 percent when the large-mesh belly panel was used.

Table 1: Percent decrease in catch, of species of concern, in the large-mesh belly panel compared to standard trawl gear in southern New England waters.

Trip ID	Stocks of Concern, Percent Decrease		
	Windowpane Flounder	Yellowtail Flounder	Winter Flounder
1	38%	60%	49%
2	53%	35%	45%
3	56%	55%	33%
4	58%	43%	65%
Mean	**51%**	**48%**	**48%**

Proposed Action

Based on the results of the studies described above (copies available from NMFS at the mailing address listed under **ADDRESSES**), we have preliminarily determined that the large-mesh belly panel meets the necessary gear performance standards for use in the Georges Bank yellowtail AM area, and we are proposing to approve the use of this gear in that area. The large-mesh belly panel would be added to the list of three existing selective gears currently authorized for use in the Georges Bank yellowtail AM area. We have also preliminarily determined that the large-mesh belly panel does not meet the gear standard in the southern windowpane AM area, and we are proposing to disapprove its use in that area.

This action would define the large-mesh belly panel in the regulations in § 648.80. The proposed gear specifications included in this rule are based on the experimental gear used in the Cornell studies. The experimental selective gear was a 4-seam 3-bridal otter trawl, modified to include a large-mesh panel to replace the first bottom belly that allows escapement of flatfish. The large-mesh panel was made from 5 mm (3⁄16 in) poly webbing and the mesh size was approximately 32 in (81.3 cm) knot-center to knot-center diamond mesh. The panel was two meshes deep and was sewn into the standard mesh of the first bottom belly using a ''saw-toothing'' technique. This resulted in an effective area for fish escapement of three full 32-in (81.3-cm) meshes, or an opening in the belly of the net that is approximately 8 ft (2.4 m) deep from front to back. The large-mesh belly panel was attached approximately 1 ft (30.5 cm) behind the footrope and extended widthwise across the entire belly of the net (from gore to gore). Because it is important that the large-mesh belly panel gear definition balance the conservation requirements and adaptability of the gear modifications across multiple fisheries, we are requesting specific comments on this gear configuration.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the National Marine Fisheries Service (NMFS) Assistant Administrator has made a preliminary determination that this proposed rule is consistent with Framework 51, other provisions of the Magnuson-Stevens Act, and other applicable law. In making the final determination, we will consider the data, views, and comments received during the public comment period.

This proposed rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866.

This proposed rule does not contain policies with Federalism or takings implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual determination for this determination is as follows.

The Council requested that we approve a new selective trawl gear (the large-mesh belly panel) for use in several non-groundfish fisheries to reduce groundfish bycatch. For some stocks, non-groundfish fisheries have an AM that requires the use of selective trawl gear when the ACL has been exceeded. Most of the approved selective trawls are not designed for use in these fisheries, and the large-mesh belly panel would provide these fisheries a better alternative than what is currently available. The requirement to use selective trawl gear was adopted in 2013. This rule would provide vessels an alternative selective gear for meeting that requirement, which would provide additional fishing opportunities, increase operational flexibility, and improve economic efficiency. This action is necessary to allow the fisheries to more effectively harvest its optimum yield, while continuing to reduce bycatch of windowpane and yellowtail flounder. This action seeks to fulfill the purpose and need while meeting the overarching goals and objectives of the Northeast Multispecies FMP.

For purposes of the Regulatory Flexibility Act, NMFS established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (*see* 50 CFR 200.2). A business

primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. The determination of whether the entity is large or small is based on the average annual revenue for the most recent 3 years for which data are available (in this case, from 2014 through 2016).

The small-mesh exempted fishery allows vessels to harvest species in designated areas using mesh sizes smaller than the minimum mesh size required by Regulated Mesh Area regulations. To participate in the small-mesh multispecies exempted fishery, vessels must possess either a limited access multispecies permit (categories A, C, D, E, or F) or an open access multispecies permit (category K). Limited access multispecies permit holders can target small-mesh multispecies with different possession limit requirements depending on fishing region and mesh size used. Open access, Category K permit holders may fish for small-mesh multispecies when participating in an exempted fishing program. Therefore, entities holding one or more multispecies permits (permit type A, C–F, K) are the entities that have the potential to be directly impacted by this action. According to the commercial database, there were 853 distinct ownership entities, based on entities' participation during the 2014–2016 time-period, that could potentially target small-mesh multispecies. This includes entities that could not be classified into a business type because they did not earn revenue from landing and selling fish in 2014–2016 and thus are considered to be small. Of the 853 total firms, 844 are categorized as small business entities and 9 are categorized as large businesses. While 853 commercial entities have the potential to be impacted by the proposed action, not all of these entities actively land small-mesh multispecies for commercial sale. There are 406 distinct entities that commercially sold small-mesh multispecies from 2014–2016 and may be directly affected by the proposed action. Of those, 404 are categorized as small businesses.

The measures proposed are expected to have a positive economic effect on small entities. It could increase catch of target stocks, in a scenario when fishing would otherwise be prohibited. Providing increased fishing opportunities should increase landings and profits. This action is not expected to have a significant or substantial effect on small entities. The effects on the regulated small entities identified in this analysis are expected to be positive relative to the no action alternative, in which this new selective trawl gear would not be added to the list of approved selective gears. Under the proposed action, small entities would not be placed at a competitive disadvantage relative to large entities, and the regulations would not reduce the profit for any small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement will be submitted to OMB for approval. Public reporting burden for the selection of the gear code is estimated to average one minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS at the **ADDRESSES** above, and by email to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: November 9, 2018.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.84, add paragraph (f) to read as follows:

§ 648.84 Gear-marking requirements and gear restrictions.

* * * * *

(f) *Large-mesh belly panel trawl.* A large-mesh belly panel trawl is defined as a four-seam bottom trawl net (*i.e.,* a net with a top and bottom panel and two side panels) modified to include a large-mesh panel to replace the first bottom belly, as further specified in paragraphs (f)(1) and (2) of this section.

(1) *Mesh size.* The minimum mesh size applied throughout the body of the trawl, as well as the codend mesh size, must be consistent with mesh size requirements specified in § 648.80. If a vessel is fishing in an exemption area or an exempted fishery, it must comply with all of the requirements and conditions of the exemption.

(2) *Large-mesh belly panel.* The large-mesh belly panel must have a minimum mesh size of 30 in (76.2 cm) measured using the standard defined in § 648.80(f)(2). The width of the panel must extend the full width of the bottom panel (*i.e.,* from one bottom gore to the other bottom gore). The depth must be at least 90 in (228.6 cm) and at least 3 meshes deep (2 meshes deep with a 15-in (38.1-cm) sewing seam on top and bottom). No more than six meshes of the small-mesh net may be left behind the sweep, before the large-mesh panel is sewn in.

■ 3. In § 648.90, revise paragraph (a)(5)(v), to read as follows:

§ 648.90 NE multispecies assessment, framework procedures, and specifications, and flexible area action system.

(a) * * *

(5) * * *

(v) *AM if the small-mesh fisheries GB yellowtail flounder sub-ACL is exceeded.* If NMFS determines that the sub-ACL of GB yellowtail flounder allocated to the small-mesh fisheries, pursuant to paragraph (a)(4)(iii)(G) of this section, is exceeded, NMFS shall implement the AM specified in this paragraph consistent with the Administrative Procedures Act. The AM requires that small-mesh fisheries vessels, as defined in paragraph (a)(4)(iii)(G)(*1*) of this section, use one of the following approved selective trawl gear in the GB yellowtail flounder stock area, as defined at § 648.85(b)(6)(v)(H): A haddock separator trawl, as specified

in § 648.85(a)(3)(iii)(A); a Ruhle trawl, as specified in § 648.85(b)(6)(iv)(J)(*3*); a rope separator trawl, as specified in § 648.84(e); a large-mesh belly panel trawl, as specified in § 648.84(f); or any other gear approved consistent with the process defined in § 648.85(b)(6). If reliable information is available, the AM shall be implemented in the fishing year immediately following the year in which the overage occurred only if there is sufficient time to do so in a manner consistent with the Administrative Procedures Act. Otherwise, the AM shall be implemented in the second fishing year after the fishing year in which the overage occurred. For example, if NMFS determined after the start of Year 2 that the small-mesh fisheries sub-ACL for GB yellowtail flounder was exceeded in Year 1, the applicable AM would be implemented at the start of Year 3. If updated catch information becomes available subsequent to the implementation of an AM that indicates that an overage of the small-mesh fisheries sub-ACL did not occur, NMFS shall rescind the AM, consistent with the Administrative Procedure Act.

* * * * *

[FR Doc. 2018–24975 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 83, No. 221
Thursday, November 15, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data related to what types of technologies are used on farms during a specified reference period. This clearance will allow NASS to conduct surveys in a timely manner for the cooperating institutions providing funding for the surveys.

DATES: Comments on this notice must be received by January 14, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* 855–838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 202–720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at 202–690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Farm Technology Survey.

OMB Control Number: 0535–NEW.

Type of Request: Intent to seek approval to conduct a new information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare, and issue state and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture; and also to conduct the Census of Agriculture.

The Farm Technology Survey will collect information from farmers regarding what types of technologies are used during a specified reference period. These technologies will include both physical and non-physical types such as tablets, applications, automatic sensors, etc. The collected data will be used by State Departments of Agriculture and Land Grant Universities to determine the need for providing assistance to farmers and ranchers to fulfill their technology needs, indicated by the data. These surveys will be conducted through cooperative agreements with State Departments of Agriculture and/or universities; with the cooperators providing the funding.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for this information collection is based on similar surveys with expected response time of 15 minutes. The estimated sample size will be approximately 2,000. The frequency of data collection for each survey is annual. The estimated number of responses per respondent is 1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data. NASS will conduct the survey initially by mail with phone follow-up for non-response.

Respondents: Farmers and ranchers.

Estimated Number of Respondents: Approximately 2,000 annually.

Frequency of Responses: On occasion.

Estimated Total Burden on Respondents: Approximately 600 hours annually. This will include burden for both the initial mailing and phone follow-up to non-respondents, as well as publicity and instruction materials mailed out with questionnaires.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, October 31, 2018.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2018–24918 Filed 11–14–18; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Generic Clearance for Survey Research Studies. Burden hours and number of contacts will be increased to accommodate the proposed testing for the upcoming three year period.

DATES: Comments on this notice must be received by January 14, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0248, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance to Conduct Survey Research Studies.

OMB Control Number: 0535–0248.

Type of Request: To revise and extend a currently approved information collection for a period of three years.

Abstract: The National Agricultural Statistics Service (NASS) of the United States Department of Agriculture (USDA) will request approval from the Office of Management and Budget (OMB) for a generic clearance that will allow NASS to rigorously develop, test, and evaluate its survey instruments and methodologies. The primary objectives of the National Agricultural Statistics Service are to prepare and issue State and national estimates of crop production, livestock production, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture. This request is part of an on-going initiative to improve NASS surveys, as recommended by both its own guidelines and those of OMB.

In the last decade, state-of-the art techniques have been increasingly instituted by NASS and other Federal agencies and are now routinely used to improve the quality and timeliness of survey data and analyses, while simultaneously reducing respondents' cognitive workload and burden. The purpose of this generic clearance is to allow NASS to continue to adopt and use these state-of-the-art techniques to improve its current data collections efforts. These tests will also be used to aid in the development of new surveys.

NASS envisions using a variety of survey improvement techniques, as appropriate to the individual project under investigation. These include focus groups, cognitive and usability laboratory and field techniques, exploratory interviews, behavior coding, respondent debriefing, pilot surveys, and split-panel tests. After obtaining participants' permission, NASS plans to audio-record some cognitive interviews and usability interviews, in order to allow for more complete and accurate summaries of these qualitative interviews. This is a standard procedure for cognitive interviews and usability interviews at many other survey organizations, including Federal agencies. The consent form would be used for audio recording some cognitive interviews and usability interviews for research purposes. For these types of interviews, there will be no collection of Personally Identifiable Information (PII) or any identifying information about the operator or operation.

In addition to the testing techniques listed above NASS will be including parallel testing with this renewal request. NASS is investigating methodologies using additional sources of farm operators (including web scraping). These methodologies will be tested against the NASS's current multi-frame methodology.

Following standard OMB requirements NASS will submit a change request to OMB individually for each survey improvement project it undertakes under this generic clearance and provide OMB with a copy of the questionnaire (if one is used), and all other materials describing the project.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and Office of Management and Budget regulations at 5 CFR part 1320. Participation in all surveys and studies conducted under this approval will be voluntary.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for these collections of information is estimated to average from 15 minutes to 1.5 hours per respondent, dependant upon the survey and the technique used to test for that particular survey. The overall average is estimated to be 0.45 hours per response.

Respondents: Farmers, ranchers, farm managers, farm contractors, agri-businesses, and households.

Estimated Number of Respondents: 50,000.

Frequency of Responses: On occasion.

Estimated Total Annual Burden: 22,000 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 1, 2018.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2018–24917 Filed 11–14–18; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Revision of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Proposed collection; comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's intention to request an extension for a currently approved information collection.

DATES: Comments on this notice must be received by January 14, 2019 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Thomas Dickson, Rural Development Innovation Center—Regulatory Team, U.S. Department of Agriculture, 1400 Independence Avenue SW, STOP 1522, Washington, DC 20250, Telephone: 202–690–4492, email: Thomas *Dickson@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program (Section 9003)

OMB Number: 0570–0065.

Expiration Date of Approval: March 31, 2019.

Type of Request: Revision of a currently approved information collection.

Abstract: The purpose of this information collection is to obtain information necessary to evaluate loan applications to determine the eligibility of the applicant and the project for the program and to qualitatively assess the project's technical and financial merit to determine which projects should be funded.

Estimate of Burden: The following annual estimates are based on an average volume of activity which includes; 10 Phase 1 applications, 8 Phase 2 applications, and 1 new loan guarantees. Phase 1 applications are evaluated by the Agency to determine whether the Borrower is eligible, the proposed loan is for an eligible purpose, there is reasonable assurance of repayment ability, there is sufficient Collateral and equity, and the proposed loan complies with all applicable statutes and regulations. Phase 2 applications are required for Phase I applicants who score favorable and are invited to submit a Phase 2 application. The Agency anticipates the number of respondents to fluctuate based on funding levels.

Respondents: Respondents for this data are lending institutions and for-profit businesses but also include individuals and corporations. The annual estimates below are for both subparts associated with this rule.

Estimated Number of Respondents: 11.

Estimated Number of Responses per Respondent: 17.7.

Estimated Number of Responses: 195.

Estimated Total Annual Burden on Respondents: 3,631 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Rural Business-Cooperative Service, including whether the information will have practical utility; (b) the accuracy of the Rural Business-Cooperative Service's estimate of the burden of the proposed collection of information including validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Thomas Dickson, Rural Development Innovation Center—Regulatory Team, U.S. Department of Agriculture, Rural Development, STOP 1522, 1400 Independence Avenue SW, Washington, DC 20250–1522.

Copies of this information collection can be obtained from Kimble Brown, Rural Development Innovation Center, Regulations Team, at (202) 692–0043 or email: *Kimble.Brown@wdc.usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: November 1, 2018.

Bette B. Brand,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2018–24929 Filed 11–14–18; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Solicitation of Applications for Inviting Applications for the Rural Economic Development Loan and Grant Programs for Fiscal Year 2019

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This notice is to invite applications for loans and grants under the Rural Economic Development Loan and Grant (REDLG) Programs for fiscal year (FY) 2019, subject to the availability of funding. This notice is being issued in order to allow applicants sufficient time to leverage financing, prepare and submit their applications, and give the Agency time to process applications within FY 2019. Successful applications will be selected by the Agency for funding and subsequently awarded to the extent that funding may ultimately be made available through appropriations. An announcement on the website at *http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas* will identify the amount received in the appropriations.

All applicants are responsible for any expenses incurred in developing their applications.

DATES: See under **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Submit applications in paper format to the USDA Rural Development State Office for the State where the Project is located. A list of the USDA Rural Development State Office contacts can be found at: *http://www.rd.usda.gov/contact-us/state-offices.*

FOR FURTHER INFORMATION CONTACT: Cindy Mason at (202) 690–1433, *cindy.mason@wdc.usda.gov,* and Sami Zarour at (202) 720–9549, *sami.zarour@wdc.usda.gov,* Specialty Programs Division, Business Programs, Rural Business-Cooperative Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, MS 3226, Room 4204–South, Washington, DC 20250–3226, or call 202–720–1400. For further information on this notice, please contact the USDA Rural Development State Office in the State in which the applicant's headquarters is located.

SUPPLEMENTARY INFORMATION: The Agency encourages applications that will support recommendations made in the Rural Prosperity Task Force report to help improve life in rural America,

www.usda.gov/ruralprosperity. Applicants are encouraged to consider projects that provide measurable results in helping rural communities build robust and sustainable economies through strategic investments in infrastructure, partnerships, and innovation.

Key strategies include:

- Achieving e-Connectivity for Rural America
- Developing the Rural Economy
- Harnessing Technological Innovation
- Supporting a Rural Workforce
- Improving Quality of Life

Overview

Solicitation Opportunity Type: Rural Economic Development Loans and Grants.

Announcement Type: Initial Solicitation Announcement.

Catalog of Federal Domestic Assistance Number: 10.854.

Dates: The deadline for completed applications to be received in the USDA Rural Development State Office no later than 4:30 p.m. (local time) are: Second Quarter, December 31, 2018; Third Quarter, March 31, 2019 and Fourth Quarter, June 30, 2019.

A. Program Description

1. *Purpose of the Program.* The purpose of the program is to promote rural economic development and job creation projects.

2. *Statutory Authority.* These Programs are authorized under 7 U.S.C. 940c and 7 CFR part 4280, subpart A. Assistance provided to Rural areas, as defined, under this program may include business startup costs, business expansion, business incubators, Technical assistance feasibility studies, Advanced telecommunications services and computer networks for medical, educational, and job training services, and Community Facilities Projects for economic development.

Awards under the REDLG Programs will be made on a competitive basis using specific selection criteria contained in 7 CFR part 4280, subpart A. Information required to be in the application package includes Standard Form (SF) 424, ''Application for Federal Assistance;'' a Resolution of the Board of Directors; AD–1047, ''Debarment/ Suspension Certification;'' AD–1049 ''Certification Regarding Drug-Free Workplace Requirements;'' SF LLL, Restrictions on Lobbying; RD 400–1, ''Equal Opportunity Agreement;'' RD 400–4, ''Assurance Agreement;'' Assurance Statement for the Uniform Act; Seismic Certification (if construction); and paperwork required in accordance with 7 CFR part 1970, ''Environmental Policies and Procedures.'' If the proposal involves new construction; large increases in employment; hazardous waste; a change in use, size, capacity, purpose, or location from an original facility; or is publicly controversial, the following is required: Environmental documentation in accordance with 7 CFR part 1970;'' RUS Form 7, ''Financial and Statistical Report;'' RUS Form 7a, ''Investments, Loan Guarantees, and Loans,'' or similar information; and written narrative of Project description. Applications will be tentatively scored by the State Offices and submitted to the National Office for review.

3. *Definition of Terms.* The definitions applicable to this notice are published at 7 CFR 4280.3.

4. *Application Awards.* The Agency will review, evaluate, and score applications received in response to this notice based on the provisions found in 7 CFR part 4280, subpart A, and as indicated in this notice. However, the Agency advises all interested parties that the applicant bears the burden in preparing and submitting an application in response to this notice whether or not funding is appropriated for these Programs in FY 2019.

B. Federal Award Information

Type of Awards: Loans and Grants.

Fiscal Year Funds: FY 2019.

Available Funds: Anyone interested in submitting an application for funding under these Programs are encouraged to consult the Rural Development Notices of Solicitation of Applications website at *http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas* for funding information.

Maximum Award: The Agency anticipates the following maximum amounts per award: Loans—$2,000,000; Grants—$300,000.

Award Dates: Second Quarter, February 28, 2019; Third Quarter, May 31, 2019; and Fourth Quarter, August 31, 2019.

Performance Period: October 1, 2019, through September 30, 2020.

Renewal or Supplemental Awards: None.

C. Eligibility Information

1. Eligible Applicants

Loans and grants may be made to any entity that is identified by USDA Rural Development as an eligible borrower under the Rural Electrification Act of 1936, as amended (Act). In accordance with 7 CFR 4280.13, applicants that are not delinquent on any Federal debt or otherwise disqualified from participation in these Programs are eligible to apply. An applicant must be eligible under 7 U.S.C. 940c. Notwithstanding any other provision of law, any former Rural Utilities Service borrower that has repaid or prepaid an insured, direct, or guaranteed loan under the Act, or any not-for-profit utility that is eligible to receive an insured or direct loan under such Act shall be eligible for assistance under section 313(b)(2)(B) of such Act in the same manner as a borrower under such Act. All other restrictions in this notice will apply.

The Agency requires the following information to make an eligibility determination. These applications must include, but are not limited to, the following:

(a) An original and one copy of SF 424, ''Application for Federal Assistance (for non-construction);''

(b) Copies of applicant's organizational documents showing the applicant's legal existence and authority to perform the activities under the Grant;

(c) A proposed scope of work, including a description of the proposed Project, details of the proposed activities to be accomplished and timeframes for completion of each task, the number of months duration of the Project, and the estimated time it will take from grant approval to beginning of Project implementation;

(d) A written narrative that includes, at a minimum, the following items:

(i) An explanation of why the Project is needed, the benefits of the proposed Project, and how the Project meets the Grant eligible purposes;

(ii) Area to be served, identifying each governmental unit, *i.e.,* tribe, town, county, etc., to be affected by the Project;

(iii) Description of how the Project will coordinate economic development activities with other economic development activities within the Project area;

(iv) Businesses to be assisted, if appropriate, and economic development to be accomplished;

(v) An explanation of how the proposed Project will result in newly created, increased, or supported jobs in the area and the number of projected new and supported jobs within the next 3 years;

(vi) A description of the applicant's demonstrated capability and experience in providing the proposed Project assistance, including experience of key staff members and persons who will be providing the proposed Project activities and managing the Project;

(vii) The method and rationale used to select the areas and businesses that will receive the service;

(viii) A brief description of how the work will be performed, including whether organizational staff or consultants or contractors will be used; and

(ix) Other information the Agency may request to assist it in making a grant award determination.

(e) The last 3 years of financial information to show the applicant's financial capacity to carry out the proposed work. If the applicant is less than 3 years old, at a minimum, the information should include all balance sheet(s), income statement(s), and cash flow statement(s). A current audited report is required if available;

(f) Documentation regarding the availability and amount of other funds to be used in conjunction with the funds from REDLG; and

(g) A budget which includes salaries, fringe benefits, consultant costs, indirect costs, and other appropriate direct costs for the Project.

2. Cost Sharing or Matching

For loans, either the Ultimate Recipient or the Intermediary must provide supplemental funds for the Project equal to at least 20 percent of the loan to the Intermediary. For grants, the Intermediary must establish a Revolving Loan Fund (or Fund) and contribute an amount equal to at least 20 percent of the Grant. The supplemental contribution must come from Intermediary's funds which may not be from other Federal Grants, unless permitted by law.

3. Other

Applications will only be accepted for projects that promote rural economic development and job creation.

There are no ''responsiveness'' or ''threshold'' eligibility criteria for these loans and grants. There is no limit on the number of applications an applicant may submit under this announcement. In addition to the forms listed under the program description, Form AD 3030 ''Representations Regulation Felony Conviction and Tax Delinquent Status for Corporate Applicants,'' must be completed in the affirmative.

None of the funds made available by this or any other Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

None of the funds made available by this or any other Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

4. Completeness Eligibility

Applications will not be considered for funding if they do not provide sufficient information to determine eligibility or are missing required elements.

D. Application and Submission Information

1. Address To Request Application Package

For further information, entities wishing to apply for assistance should contact the USDA Rural Development State Office provided in the **ADDRESSES** section of this notice to obtain copies of the application package.

Prior to official submission of grant applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made by June 15, 2019. Technical assistance is not meant to be an analysis or assessment of the quality of the materials submitted, a substitute for agency review of completed applications, nor a determination of eligibility, if such determination requires in-depth analysis. The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

Applications must be submitted in paper format. Applications submitted to a Rural Development State Office must be received by the closing date and local time deadline.

All applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number which can be obtained at no cost via a toll-free request line at (866) 705–5711 or at *http://fedgov.dnb.com/webform.* Each applicant (unless the applicant is an individual or Federal awarding agency that is excepted from the requirements under 2 CFR 25.110(b) or (c) or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to: (i) Be registered in the System for Award Management (SAM) before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. The Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

Please note that applicants must locate the downloadable application package for this program by the Catalog of Federal Domestic Assistance Number or FedGrants Funding Opportunity Number, which can be found at *http://www.grants.gov.*

2. Content and Form of Application Submission

An application must contain all of the required elements. Each selection priority criterion outlined in 7 CFR 4280.42(b) must be addressed in the application. Failure to address any of the criterion will result in a zero-point score for that criterion and will impact the overall evaluation of the application. Copies of 7 CFR part 4280, subpart A, will be provided to any interested applicant making a request to a Rural Development State Office. An original copy of the application must be filed with the Rural Development State Office for the State where the Intermediary is located.

The applicant documentation and forms needed for a complete application are located in the Program Description

section of this notice, and 7 CFR part 4280, subpart A. There are no specific formats required per this notice, and applicants may request forms and addresses from the **ADDRESSES** section of this notice.

(a) There are no specific limitations on the number of pages or other formatting requirements other than those described in the Program Description section.

(b) There are no specific limitations on the number of pages, font size and type face, margins, paper size, number of copies, and the sequence or assembly requirements.

(c) The component pieces of this application should contain original signatures on the original application.

3. Submission Dates and Times

(a) Application Deadline Dates: No later than 4:30 p.m. (local time) on:

Second Quarter, December 31, 2018; Third Quarter, March 31, 2019; and Fourth Quarter, June 30, 2019.

Explanation of Dates: Applications must be in the USDA Rural Development State Office by the dates and times as indicated above. If the due date falls on a Saturday, Sunday, or Federal holiday, the application is due the next business day.

(b) The deadline date means that the completed application package must be received in the USDA Rural Development State Office by the deadline date and time established above. All application documents identified in this notice are required.

(c) If completed applications are not received by the deadline established above, the application will neither be reviewed nor considered under any circumstances.

(d) The Agency will determine the application receipt date based on the actual date postmarked.

(e) If the grantee has a previously approved indirect cost rate, it is permissible, otherwise, the applicant may elect to charge the 10 percent indirect cost permitted under 2 CFR 200.414(f). Due to the time required to evaluate Indirect Cost Rates, it is likely that all funds will be awarded by the time the Indirect Cost Rate is determined. No foreign travel is permitted. Pre-Federal award costs will only be permitted with prior written approval by the Agency.

(f) Applicants must submit applications in hard copy format as previously indicated in the Application and Submission Information section of this notice. If the applicant wishes to hand deliver its application, the addresses for these deliveries can be located in the **ADDRESSES** section of this notice.

(g) If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

E. Application Review Information

1. Criteria

All eligible and complete applications will be evaluated and scored based on the selection criteria and weights contained in 7 CFR part 4280, subpart A. Failure to address any one of the criteria by the application deadline will result in the application being determined ineligible, and the application will not be considered for funding.

2. Review and Selection Process

The State Offices will review applications to determine if they are eligible for assistance based on requirements contained in 7 CFR part 4280, subpart A. If determined eligible, your application will be submitted to the National Office. Funding of projects is subject to the Intermediary's satisfactory submission of the additional items required by that subpart and the USDA Rural Development Letter of Conditions. The Agency reserves the right to award additional discretionary points under 7 CFR 4280.43.

In order to distribute funds among the greatest number of projects possible, applications will be reviewed, prioritized, and funded by ranking each State's highest scoring Project in highest to lowest score order. The highest scoring Project from each State will be considered that State's Priority One Project. Priority One projects will be ranked according to score from highest to lowest. The second highest scoring Project from each State will be considered the State's Priority Two Project. Priority Two projects will be ranked according to score from highest to lowest and so forth until all projects have been scored and ranked in priority order. All Priority One projects will be funded before any Priority Two projects and so forth until funds are depleted, so as to ensure broad geographic distribution of funding.

F. Federal Award Administration Information

1. *Federal Award Notices.* Successful applicants will receive notification for funding from the Rural Development State Office. Applicants must comply with all applicable statutes and regulations before the loan/grant award can be approved. Provided the application and eligibility requirements have not changed, an application not selected will be reconsidered in three subsequent quarterly funding competitions for a total of four competitions. If an application is withdrawn, it can be resubmitted and will be evaluated as a new application.

2. *Administrative and National Policy Requirements.* Additional requirements that apply to intermediaries or grantees selected for these Programs can be found in 7 CFR part 4280, subpart A. Awards are subject to USDA grant regulations at 2 CFR Chapter IV which incorporated the Office of Management and Budget (OMB) regulations 2 CFR 200.

All successful applicants will be notified by letter which will include a Letter of Conditions, and a Letter of Intent to Meet Conditions. This letter is not an authorization to begin performance. If the applicant wishes to consider beginning performance prior to the loan or grant being officially closed, all pre-award costs must be approved in writing and in advance by the Agency. The loan or grant will be considered officially awarded when all conditions in the Letter of Conditions have been met and the Agency obligates the funding for the Project.

Additional requirements that apply to intermediaries or grantees selected for these Programs can be found in 7 CFR 4280, subpart A; the Grants and Agreements regulations of the U.S. Department of Agriculture codified in 2 CFR 400.1 to 400.2 and 2 CFR part 415 to 422, and successor regulations to these parts.

In addition, all recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive compensation (see 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) reporting requirements (see 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)).

The following additional requirements apply to intermediaries or grantees selected for these Programs:

(a) Form RD 4280–2 ''Rural Business-Cooperative Service Financial Assistance Agreement.''

(b) Letter of Conditions.

(c) Form RD 1940–1, ''Request for Obligation of Funds.''

(d) Form RD 1942–46, ''Letter of Intent to Meet Conditions.''

(e) Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters-Primary Covered Transactions.''

(f) Form AD–1048 ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions.''

(g) Form AD–1049, ''Certification Regarding a Drug-Free Workplace Requirement (Grants).''

(h) Form AD–3031, ''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.'' Must be signed by corporate applicants who receive an award under this notice.

(i) Form RD 400–4, ''Assurance Agreement.'' Each prospective recipient must sign Form RD 400–4, ''Assurance Agreement,'' which assures USDA that the recipient is in compliance with Title VI of the Civil Rights Act of 1964, 7 CFR part 15, and other Agency regulations. That no person will be discriminated against based on race, color, or national origin, in regard to any program or activity for which the recipient receives Federal financial assistance. That nondiscrimination statements are in advertisements and brochures.

Collect and maintain data provided by Ultimate Recipients on race, sex, and national origin and ensure Ultimate Recipients collect and maintain this data. Race and ethnicity data will be collected in accordance with OMB **Federal Register** notice, ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity'' (62 FR 58782), October 30, 1997. Sex data will be collected in accordance with Title IX of the Education Amendments of 1972. These items should not be submitted with the application but should be available upon request by the Agency.

The applicant and the Ultimate Recipient must comply with Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, Age Discrimination Act of 1975, Executive Order 12250, Executive Order 13166 Limited English Proficiency (LEP), and 7 CFR part 1901, subpart E.

(j) SF LLL, ''Disclosure of Lobbying Activities,'' if applicable.

(k) Use Form SF 270, ''Request for Advance or Reimbursement.''

3. Reporting

(a) A Financial Status Report and a Project performance activity report will be required of all grantees on a quarterly basis until initial funds are expended and yearly thereafter, if applicable, based on the Federal fiscal year. The grantee will complete the Project within the total time available to it in accordance with the Scope of Work and any necessary modifications thereof prepared by the grantee and approved by the Agency. A final Project performance report will be required with the final Financial Status Report. The final report may serve as the last quarterly report. The final report must provide complete information regarding the jobs created and supported as a result of the Grant if applicable. Grantees must continuously monitor performance to ensure that time schedules are being met, projected work by time periods is being accomplished, and other performance objectives are being achieved. Grantees must submit an original of each report to the Agency no later than 30 days after the end of the quarter. The Project performance reports must include, but not be limited to, the following:

(1) A comparison of actual accomplishments to the objectives established for that period;

(2) Problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall Project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular Project work elements doing established time periods. This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation; and

(3) Objectives and timetable established for the next reporting period.

(4) Any special reporting requirements, such as jobs supported and created, businesses assisted, or economic development which results in improvements in median household incomes, and any other specific requirements, should be placed in the reporting section of the Letter of Conditions.

(5) Within 90 days after the conclusion of the Project, the Intermediary will provide a final Project evaluation report. The last quarterly payment will be withheld until the final report is received and approved by the Agency. Even though the Intermediary may request reimbursement on a monthly basis, the last 3 months of reimbursements will be withheld until a final report, Project performance, and financial status report are received and approved by the Agency.

(b) In addition to any reports required by 2 CFR part 200 and 2 CFR 400.1 to 400.2 and 2 CFR part 415 to 422, the Intermediary or grantee must provide reports as required by 7 CFR part 4280, subpart A.

G. Federal Awarding Agency Contact(s)

For general questions about this announcement, please contact your USDA Rural Development State Office provided in the **ADDRESSES** section of this notice.

H. Civil Rights Requirements

All grants made under this notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973, Title VIII of the Civil Rights Act of 1968, Title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

I. Other Information

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirement contained in this notice is approved by OMB under OMB Control Number 0570–0070.

Federal Funding Accountability and Transparency Act

All applicants, in accordance with 2 CFR part 25, must have a DUNS number, which can be obtained at no cost via a toll-free request line at (866) 705–5711 or online at *http://fedgov.dnb.com/webform.* Similarly, all applicants must be registered in SAM prior to submitting an application. Applicants may register for the SAM at *http://www.sam.gov.* All recipients of Federal financial grant assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170.

Nondiscrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its agencies, offices, and employees, and institutions participating in or administering USDA Programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET

Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Dated: November 7, 2018.

Bette B. Brand,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2018–24938 Filed 11–14–18; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Rural Broadband Access Loans and Loan Guarantees Program

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Solicitation of Applications (NOSA).

SUMMARY: The Rural Utilities Service (RUS), an Agency of the United States Department of Agriculture (USDA), announces that it is accepting applications for fiscal year (FY) 2019 for the Rural Broadband Access Loans and Loan Guarantees Program (the Broadband Program). RUS will publish the amount of funding received through the final appropriations act on its website at *https://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas.*

RUS is accepting applications on a rolling basis throughout FY 2019. This will give RUS the ability to request additional information and modifications to a submitted application whenever necessary.

Applications will be processed on a first come, first served basis. Every 90 days, RUS will conduct an evaluation of the submitted applications. During the evaluation period, applications will be ranked based on the percentage of unserved households that the applicant proposes to serve. RUS will conduct at least two evaluation periods for FY 2019. Because the Agency will receive applications throughout the fiscal year, subsequent evaluation periods can alter the ranking of applications.

In addition to announcing its acceptance of FY 2019 applications, RUS revises the minimum and maximum amounts for broadband loans for the fiscal year.

DATES: Applications under this NOSA will be accepted immediately through September 30, 2019. RUS will process loan applications as they are received.

Applications can only be submitted online through the RD Apply website at *https://www.rd.usda.gov/programs-services/rd-apply* through September 30, 2019.

FOR FURTHER INFORMATION CONTACT: Shawn Arner, Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service, Room 2844, STOP 1597, 1400 Independence Avenue SW, Washington, DC 20250–1597; telephone: (202) 720–0800, or email: *shawn.arner@usda.gov.*

SUPPLEMENTARY INFORMATION:

General Information

The Rural Broadband Access Loan and Loan Guarantee Program (the Broadband Program) is authorized by the Rural Electrification Act (7 U.S.C. 901 *et seq.*), as amended by the Agricultural Act of 2014 (Pub. L. 113–79), also referred to as the 2014 Farm Bill.

During FY 2019, loans will be made available for the construction, improvement, and acquisition of facilities and equipment that will provide service at the Broadband Lending Speed in eligible rural areas. Applications are subject to the requirements of 7 CFR part 1738. No funding for Guaranteed Loans is available in FY 2019 and the agency will not be considering applications for this type of funding.

The Agency encourages applications that will support recommendations made in the Rural Prosperity Task Force report to help improve life in rural America which can be found at *www.usda.gov/ruralprosperity.* Applicants are encouraged to consider projects that provide measurable results in helping rural communities build robust and sustainable economies through strategic investments in infrastructure, partnerships and innovation. Key strategies include:

- Achieving e-Connectivity for Rural America
- Developing the Rural Economy
- Harnessing Technological Innovation
- Supporting a Rural Workforce
- Improving Quality of Life

Application Assistance

RUS offers pre-application assistance, in which National Office staff and the assigned General Field Representative review the draft application, provide detailed comments, and identify areas where an application is not meeting eligibility requirements for funding. The online application system allows RUS staff to assist an applicant with every part of an application as it is being developed. Once the application is formally submitted, the online system will timestamp the submitted version and establish the application's place in the processing queue.

Based on the order in which the applications are received, RUS will review the application for completeness. The applicant may be asked for additional information to clarify aspects of an otherwise complete application or to assist the Agency in the underwriting process. If the application is determined to be complete, RUS will review the package for eligibility and technical and financial feasibility, in accordance with 7 CFR part 1738. If an application is ultimately found to be incomplete or inadequate, a detailed explanation will be provided to the applicant.

To further assist in the preparation of applications, an application guide is available online at: *https://www.rd.usda.gov/programs-services/farm-bill-broadband-loans-loan-guarantees.* An application guide may also be requested from the RUS contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Application Requirements: All requirements for submission of an application under the Broadband Program are subject to 7 CFR part 1738.

Application Materials/Submission: Applications must be submitted through the Agency's online application system located at *https://www.rd.usda.gov/programs-services/rd-apply.* All materials required for completing an application are included in the online system.

Minimum and Maximum Loan Amounts

Loans under this authority will not be made for less than $100,000. The maximum loan amount that will be considered for FY 2019 is $25,000,000.

Required Definitions for Broadband Program Regulation

The regulation for the Broadband Program requires that certain definitions affecting eligibility be revised and published from time to time by the Agency in the **Federal Register**. For the purposes of this NOSA, the Agency is revising the definitions of *Broadband Service* and *Broadband Lending Speed.*

Broadband Service is determined to exist if customers can access a minimum rate-of-data transmission of 25 megabits downstream and 3 megabits upstream for both mobile and fixed service. This rate is used to determine whether an area is eligible for funding.

Broadband Lending Speed is the minimum rate-of-data transmission that applicants must propose to offer the customer. The Broadband Lending Speed is 25 megabits downstream and 3 megabits upstream for both mobile and fixed service.

Priority for Approving Loan Applications

Applications for FY 2019 will be accepted from the publication date of this NOSA through September 30, 2019. Although review of applications will begin as they are submitted, all applications will be evaluated and ranked every 90 days based on the percentage of unserved households in the proposed funded service area. Subject to available funding, eligible applications that propose to serve a higher percentage of unserved households will receive funding offers before other eligible applications that propose to serve a lower percentage of unserved households. The amount available will be published on the Agency web page once all budgetary allocations have been completed.

Loan offers are limited to the funds available at the time of the Agency's decision to approve an application.

Applications will not be accepted after September 30, 2019, until a new application opportunity has been opened with the publication of an additional NOSA in the **Federal Register**.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements associated with Broadband loans, as covered in this NOSA, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0572–0130.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, the USDA, its agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339 (English) or (800) 845–6136 (Spanish).

Individuals who wish to file a Program Discrimination Complaint must complete the USDA Program Discrimination Complaint Form (PDF). To file a program discrimination complaint, you may obtain a complaint form by sending an email to *Cr-info@ascr.usda.gov* or calling (866) 632–9992 to request the form. A letter may also be written containing all of the information requested in the form.

Send the completed complaint form or letter by mail to the U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410, or email at *program.intake@usda.gov.* Additional information can be found online at *https://www.ascr.usda.gov/filing-program-discrimination-complaint-usda-customer.*

USDA is an equal opportunity provider, employer, and lender.

Dated: October 24, 2018.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2018–24860 Filed 11–14–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Florida Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Florida Advisory Committee (Committee) will hold a meeting on Monday, December 3, 2018, at 1:00 p.m. (EST) for the purpose discussing civil rights concerns in the state.

DATES: The meeting will be held on Monday, December 3, 2018, at 1:00 p.m. (EST).

Public Call Information: Dial: 877–260–1479, Conference ID: 5812789.

FOR FURTHER INFORMATION CONTACT: Jeff Hinton, DFO, at *jhinton@usccr.gov*

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the toll-free call-in number dial: 877–260–1479, Conference ID: 5812789. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Written comments may be mailed to the Regional Program Unit Office, U.S. Commission on Civil Rights, 230 S Dearborn St., Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or may be emailed to the Regional Director, Jeff Hinton at *jhinton@usccr.gov.* Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Florida Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Program Unit at the above email or street address.

Agenda

Welcome and Introductions

Discussion: Civil Rights Issues in Florida

Public Comment

Adjournment

Dated: November 8, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–24876 Filed 11–14–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the North Dakota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the North Dakota Advisory Committee to the Commission will by teleconference at 12:00 p.m. (CST) on Wednesday, December 5, 2018. The purpose of the meeting is for project and briefing planning.

DATES: Wednesday, December 5, 2018, at 12:00 p.m. MDT.

Public Call-In Information: Conference call-in number: 1–877–260–1479 and conference call 9602962.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor, at *ebohor@usccr.gov* or by phone at 303–866–1040.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–877–260–1479 and conference call 9602962. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 1–877–260–1479 and conference call 9602962.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1040, or emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://gsageo.force.com/FACA/apex/FACAPublicCommittee?id=a10t0000001gzl9AAA;* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone numbers, email or street address.

Agenda: Wednesday, December 5, 2018, 12:00 p.m. (CST).

- Rollcall and Welcome
- Project Planning
- Briefing Planning
- Open Comment
- Adjourn

Dated: November 9, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–24901 Filed 11–14–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Institute of Standards and Technology (NIST).

Title: National Voluntary Laboratory Accreditation Program (NVLAP) Information Collection System.

OMB Control Number: 0693–0003.

Form Number(s): None.

Type of Request: Regular submission (revision and extension of a currently approved information collection).

Number of Respondents: 750.

Average Hours per Response: 3 hours.

Burden Hours: 2,250.

Needs and Uses: This information is collected from all testing and calibration laboratories that apply for National Voluntary Laboratory Accreditation Program (NVLAP) accreditation. It is used by NVLAP to assess laboratory conformance with applicable criteria as defined in 15 CFR part 285, Section 285.14. The information provides a service to customers in business and industry, including regulatory agencies and purchasing authorities that are seeking competent laboratories to perform testing and calibration services. An accredited laboratory's contact information and scope of accreditation are provided on NVLAP's website (*http://www.nist.gov/nvlap*).

Affected Public: Business or other for-profit organizations, not-for-profit institutions, and Federal, State or Local government.

Frequency: Annually.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–24959 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2075]

Reorganization of Foreign-Trade Zone 283; (Expansion of Service Area) Under Alternative Site Framework; West Tennessee Area

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or

adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Northwest Tennessee Regional Port Authority, grantee of Foreign-Trade Zone 283, submitted an application to the Board (FTZ Docket B–19–2018, docketed March 19, 2018) for authority to expand the service area of the zone to include Crockett County as well as portions of Weakley, Henry, Carroll and Henderson Counties, Tennessee, as described in the application, adjacent to the Memphis Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (83 FR 12563, March 22, 2018) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 283 to expand the service area under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Dated: November 8, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2018–24937 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–71–2018]

Foreign-Trade Zone (FTZ) 230—Greensboro, North Carolina; Notification of Proposed Production Activity; Patheon Softgels; (Pharmaceutical Products); High Point, North Carolina

The Piedmont Triad Partnership, grantee of FTZ 230, submitted a notification of proposed production activity to the FTZ Board on behalf of Patheon Softgels (Patheon), located in High Point, North Carolina. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 7, 2018.

Patheon already has authority to produce certain prescription pharmaceutical products and soft gelatin capsules within Subzone 230C. The current request would add a finished product and a foreign status material/component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status material/component and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Patheon from customs duty payments on the foreign-status material/component used in export production. On its domestic sales, for the foreign-status material/component noted below and in the existing scope of authority, Patheon would be able to choose the duty rate during customs entry procedures that applies to gelatin encapsulated mono methyl fumarate capsule (duty-free). Patheon would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The material/component sourced from abroad is Mono Methyl Fumarate (duty rate 6.5%). The request indicates the material/component is subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 26, 2018.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov* or (202) 482–1963.

Dated: November 9, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018–24933 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2073]

Reorganization of Foreign-Trade Zone 81 Under Alternative Site Framework; Portsmouth, New Hampshire

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Pease Development Authority, grantee of Foreign-Trade Zone 81, submitted an application to the Board (FTZ Docket B–6–2018, docketed on January 30, 2018 and amended on August 1, 2018) for authority to reorganize under the ASF with a service area of the Counties of Rockingham, Strafford, Carroll (partial), Belknap (partial), Cheshire, Hillsborough, Merrimack (partial), Sullivan and Grafton (partial), New Hampshire, in and adjacent to the Portsmouth Customs and Border Protection port of entry, FTZ 81's existing Sites 1, 2, 4 and 5 would be categorized as magnet sites and existing Site 6 would be categorized as a usage-driven site;

Whereas, notice inviting public comment was given in the **Federal Register** (83 FR 4896–4897, February 2, 2018) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby orders:

The amended application to reorganize FTZ 81 under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, to an ASF sunset provision for magnet sites that would terminate authority for Sites 1, 2, 4 and 5 if not activated within five years from the month of approval, and to an ASF sunset provision for usage-driven sites that would terminate authority for Site 6 if no foreign-status merchandise is admitted for a *bona fide* customs purpose within three years from the month of approval.

Dated: November 8, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2018–24936 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2072]

Reorganization of Foreign-Trade Zone 9 Under Alternative Site Framework; Honolulu, Hawaii

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the State of Hawaii, grantee of Foreign-Trade Zone 9, submitted an application to the Board (FTZ Docket B–40–2018, docketed June 18, 2018) for authority to reorganize under the ASF with a service area of the City and County of Honolulu, County of Hawaii, County of Kauai, and County of Maui, Hawaii, in and adjacent to the Hilo and Kona (Hawaii), Kahului and Kihei (Maui), Honolulu (Oahu) and Nawiliwili-Port Allen (Kauai) U.S. Customs and Border Protection ports of entry, FTZ 9's existing Sites 2, 3, 4, 5 and 9 would be categorized as magnet sites and existing Sites 1, 6, 7 and 8 would be categorized as usage-driven sites;

Whereas, notice inviting public comment was given in the **Federal Register** (83 FR 29541–29542, June 25, 2018) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 9 under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, to an ASF sunset provision for magnet sites that would terminate authority for Sites 2, 3, 4 and 9 if not activated within five years from the month of approval and to an ASF sunset provision for usage-driven sites that would terminate authority for Sites 1, 6, 7 and 8 if no foreign-status merchandise is admitted to the sites for a *bona fide* customs purpose within three years from the month of approval.

Dated: November 8, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2018–24935 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–46–2018)

Foreign-Trade Zone (FTZ) 41—Milwaukee, Wisconsin; Authorization of Production Activity; CNH Industrial America LLC; (Tractors, Component Parts, and Axle Subassemblies); Sturtevant, Wisconsin

On July 11, 2018, CNH Industrial America LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 41I, in Sturtevant, Wisconsin.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 33918, July 18, 2018). On November 8, 2018, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: November 8, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018–24932 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2074]

Production Authority Not Approved; Gildan Yarns, LLC; Foreign-Trade Zone 57; (Cotton and Cotton/Polyester Yarns); Salisbury, North Carolina

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Charlotte Regional Partnership, Inc., grantee of FTZ 57, has requested production authority on behalf of Gildan Yarns, LLC, for its facility located in Salisbury, North Carolina (B–43–2017, docketed June 16, 2017);

Whereas, notice inviting public comment has been given in the **Federal Register** (82 FR 28628–28629, June 23, 2017) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations have not been satisfied;

Now, therefore, the Board hereby does not approve the application requesting production authority under zone procedures within FTZ 57 at the facility

of Gildan Yarns, LLC, located in Salisbury, North Carolina, as described in the application and **Federal Register** notice.

Dated: November 8, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2018–24934 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with September anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with September anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 30 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce has found that determinations concerning whether particular companies should be ''collapsed'' (*e.g.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*e.g.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[2] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(v) set a deadline for

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[2] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[4] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to Commerce no later than 30 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews:

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than September 30, 2019.

Antidumping duty proceedings	Period to be reviewed
Brazil: Emulsion Styrene Butadiene Rubber A–351–849	2/24/17–8/31/18
Arlanxeo Brasil S.A.	
India: Certain Lined Paper Products A–533–843	9/1/17–8/31/18
Cellpage Ventures Private Limited.	
Goldenpalm Manufacturers PVT Limited.	
Kokuyo Riddhi Paper Products Private Limited.	
Lodha Offset Limited.	
Lotus Global Private Limited.	
Magic International Pvt. Ltd.	
Marisa International.	
Navneet Education Ltd.	
PB Bafna Ventures Private Limited.	
Pioneer Stationery Private Limited.	
SAB International.	
SGM Paper Products.	
Super Impex.	
India: Oil Country Tubular Goods A–533–857	9/1/17–8/31/18
GVN Fuels, Ltd.	
Mexico: Emulsion Styrene-Butadiene Rubber A–201–848	2/24/17–8/31/18

[3] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[4] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

Antidumping duty proceedings	Period to be reviewed
Negromex, S.A. de C.V.	
Mexico: Heavy Walled Rectangular Weld Carbon Steel Pipes and Tubes A–201–847	9/1/17–8/31/18
Arco Metal, S.A. de C.V.	
Forza Steel, S.A. de C.V.	
Industrias Monterrey, S.A. de C.V.	
Maquilacero, S.A. de C.V.	
Perfiles y Herrajes LM, S.A. de C.V.	
Productos Laminados de Monterrey, S.A. de C.V.	
PYTCO, S.A. de C.V.	
Regiomontana de Perfiles y Tubos, S.A. de C.V.	
Ternium S.A. de C.V.	
Tuberia Nacional, S.A. de C.V.	
Tuberias Procarsa S.A. de C.V.	
Poland: Emulsion Styrene Butadiene Rubber A–455–805	2/24/17–8/31/18
Synthos Dwory 7 Spolka Z Orgraniczona Odpowiedzialnoscia Spolka Jawna (SP.ZO.O.S.J.).	
Republic of Korea: Cold-Rolled Steel Flat Products A–580–881	9/1/17–8/31/18
Hyundai Steel Company.	
POSCO.	
Dongbu Steel Co., Ltd.	
Dongbu Steel Incheon Steel Co., Ltd.	
Republic of Korea: Emulsion Styrene Butadience Rubber A–580–890	2/24/17–8/31/18
LG Chem, Ltd.	
Daewoo International Corporatin.	
Kumho Petrochemical Co. Ltd.	
Sungsan International Co., Ltd.	
WE International Co., Ltd.	
Kukje Trading Corp.	
Hyundai Glovis Co., Ltd.	
Republic of Korea: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes A–580–880	9/1/17–8/31/18
Ahshin Pipe & Tube Company.	
Bookook Steel Co., Ltd.	
Dong-A Steel Company.	
Dongbu Steel Co., Ltd.	
Ganungol Industries Co. Ltd.	
Hanjin Steel Pipe.	
HiSteel Co., Ltd.	
Husteel Co., Ltd.	
Hyosung Corporation.	
Hyundai Steel Co.	
Hyundai Steel Pipe Company.	
K Steel Co. Ltd.	
Kukje Steel Co., Ltd.	
Miju Steel Manufacturing Co., Ltd.	
NEXTEEL Co., Ltd.	
POSCO DAEWOO.	
Sam Kang Industrial Co., Ltd.	
Sam Kang Industries Co., Ltd.	
Samson Controls Ltd., Co.	
SeAH Steel Corporation.	
Yujin Steel Industry Co. Ltd.	
Republic of Korea: Oil Country Tubular Goods A–580–870	9/1/17–8/31/18
AJU Besteel Co., Ltd.	
BDP International.	
Daewoo America.	
Daewoo International Corporation.	
Dong Yang Steel Pipe.	
Dong-A Steel Co. Ltd.	
Dongbu Incheon Steel.	
DSEC.	
Emdtebruecker Eisenwerk and Company.	
Hansol Metal.	
Husteel Co., Ltd.	
Hyundai Steel Company.	
Hyundai RB.	
ILJIN Steel Corporation.	
Jim And Freight Co., Ltd.	
Kia Steel Co. Ltd.	
KSP Steel Company.	
Kukje Steel.	
Kumkang Kind Co., Ltd.	
Kurvers.	

Antidumping duty proceedings	Period to be reviewed
NEXTEEL Co., Ltd.	
POSCO Daewoo America.	
POSCO Daewoo Corporation.	
Samsung.	
Samsung C and T Corporation.	
SeAH Besteel Corporation.	
SeAH Steel Corporation.	
Steel Canada.	
Sumintomo Corporation.	
TGS Pipe.	
Yonghyun Base Materials.	
ZEECO Asia.	
Socialist Republic of Vietnam: Oil Country Tubular Goods A–552–817	9/1/17–8/31/18
SeAH Steel Vina Corporation.	
Pusan Pipe America.	
Romania: Carbon and Alloy Seamless Standard Line and Pressure Pipe (Under 4½ Inches) [5] A–485–805	8/1/17–7/31/18
SC TMK-Artrom S.A.	
Taiwan: Narrow Woven Ribbons With Woven Selvedge A–583–844	9/1/17–8/31/18
Banduoo Ltd.	
Fujian Rongshu Industry Co., Ltd.	
Maple Ribbon Co., Ltd.	
Roung Shu Industry Corporation.	
Xiamen Yi-He Textile Co., Ltd.	
The People's Republic of China: Certain Magnesia Carbon Bricks A–570–954	9/1/17–8/31/18
Fedmet Resources Corporation.	
Fengchi Imp. and Exp. Co., Ltd.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City.	
Fengchi Mining Co., Ltd. of Haicheng City.	
Fengchi Refractories Co., of Haicheng City.	
Liaoning Zhongmei High Temperature Material Co., Ltd.	
Liaoning Zhongmei Holding Co., Ltd.	
RHI Refractories Liaoning Co., Ltd.	
Shenglong Refractories Co., Ltd.	
Yingkou Heping Samwha Minerals, Co., Ltd.	
Yingkou Heping Sanhua Materials Co., Ltd.	
The People's Republic of China: Certain New Pneumatic Off-the-Road Tires A–570–912	9/1/17–8/31/18
Laizhou Xiongying Rubber Industry Co., Ltd.	
Qingdao Honghua Tyre Factory.	
Qingdao Jinhaoyang International Co., Ltd.	
Triangle Tyre Co., Ltd.	
Weihai Zhongwei Rubber Co., Ltd.	
The People's Republic of China: Certain Steel Nails [6] A–570–909	8/1/17–7/31/18
Air It on Inc.	
A-Jax Enterprises Ltd.	
A-Jax International Co. Ltd.	
Anhui Amigo Imp.& Exp. Co. Ltd.	
Anhui Tea Imp. & Exp. Co. Ltd.	
Anjing Caiquing Hardware Co., Ltd.	
Asiahan Industrial Trading Ltd.*.	
Astrotech Steels Pvt. Ltd.	
Baoding Jieboshun Trading Co., Ltd.*.	
Beijing Catic Industry Ltd.	
Beijing Jinheung Co., Ltd.*.	
Beijing Qin-Li Jeff Trading Co., Ltd.	
Beijing Qin-Li Metal Industries Co., Ltd.*.	
Bodi Corporation.	
Cana (Rizhou) Hardward Co. Ltd.	
Cangzhou Nandagang Guotai Hardware Products Co., Ltd.*.	
Cangzhou Xinqiao Int'l Trade Co. Ltd.	
Certified Products Taiwan Inc.	
Changzhou Kya Trading Co. Ltd.	
Chanse Mechatronics Scientech Development (Jiangsu) Inc.*.	
Chia Pao Metal Co. Ltd.	
China Dinghao Co. Ltd.	
China Staple Enterprise Co. Ltd.	
Chinapack Ningbo Imp. & Exp. Co. Ltd.	
Chite Enterprise Co. Ltd.	
Chonyi International Co. Ltd.*.	
Crelux Int'l Co. Ltd.	
Daejin Steel Co. Ltd.	
Dezhou Hualude Hardware Products Co. Ltd.	
Dingzhou Baota Metal Products Co. Ltd.	

Antidumping duty proceedings	Period to be reviewed
Dong E Fuqiang Metal Products Co. Ltd.	
Dream Rising Co., Ltd.	
Eco-Friendly Floor Ltd.	
Ejen Brother Limited.	
Everglow Inc.	
Everleading International Inc.	
Faithful Engineering Products Co. Ltd.	
Fastening Care.	
Fastgrow International Co. Inc.	
Foshan Hosontool Development Hardware Co. Ltd.	
GD CP International Ltd.	
GDCP International Co., Ltd.	
Geeky Wires Limited.	
Glori-Industry Hong Kong Inc.	
Guangdong Meite Mechanical Co. Ltd.	
Guangdong TC Meite Intelligent Tools Co., Ltd.	
Hangzhou Orient Industry Co., Ltd.	
Hebei Canzhou New Century Foreign Trade Co. Ltd.	
Hebei Jindun Trade Co., Ltd.	
Hebei Minghao Imp. & Exp. Co. Ltd.*.	
Hebei Minmetals Co., Ltd.	
Hengtuo Metal Products Co. Ltd.	
Home Value Co., Ltd.*.	
Hongkong Shengshi Metal Products Co., Ltd.*.	
Hongyi (HK) Hardware Products Co. Ltd.	
Huaiyang County Yinfeng Plastic Factory.	
Hualude International Development Co. Ltd.	
Huanghua Haixin Hardware Products Co., Ltd.*.	
Huanghua Yingjin Hardware Products.	
Inmax Industries Sdn. Bhd.	
ITW Construction Products.	
Jade Shuttle Enterprise Co. Ltd.	
Jiang Men City Yu Xing Furniture Limited Company.	
Jiangsu General Science Technology Co. Ltd.	
Jiangsu Holly Corporation.	
Jiangsu Huaiyin Guex Tools.	
Jiangsu Inter-China Group Corp.	
Jiangu Soho Honry Imp. and Exp. Co. Ltd.	
Jiaxing TSR Hardware Inc.	
Jinhai Hardware Co. Ltd.	
Jinsco International Corp.	
Jinsheung Steel Corporation.	
Koram Inc.	
Korea Wire Co. Ltd.	
Liang's Ind. Corp.	
Liaocheng Minghui Hardware Products.	
Linyi FlyingArrow Imp. & Exp. Co Ltd.	
M&M Industries Co., Ltd.	
Maanshan Lilai International Trade Co. Ltd.*.	
Max Co., Ltd.	
Milkway Chemical Supply Chain Service Co., Ltd.	
Mingguang Abundant Hardware Products Co. Ltd.	
Mingguang Ruifeng Hardware Products Co. Ltd.	
Modern Factory For Metal Products.	
Nailtech Co. Ltd.	
Nanjing Caiquing Hardware Co. Ltd.	
Nanjing Nuochun Hardware Co. Ltd.	
Nanjing Tianxingtong Electronic Technology Co. Ltd.*.	
Nanjing Tianyu International Co. Ltd.*.	
Nanjing Toua Hardware & Tools Co. Ltd.*.	
Nanjing Yuechang Hardware Co., Ltd.	
Nanjing Zeejoe International Trade.	
Nantong Intlevel Trade Co., Ltd.	
Natuzzi China Limited.	
Nielsen Bainbridge LLC.	
Ningbo Adv. Tools Co. Ltd.	
Ningbo Angelar Trading Co., Ltd.	
Ningbo Fine Hardware Production Co. Ltd.	
Ningbo Freewill Imp. & Exp Co., Ltd.	
Ningbo Langyi Metal Products Co., Ltd.*.	
Ningbo Sunrise International Ltd.	
Ningbo WePartner Imp. & Exp. Co., Ltd.	
Overseas Distribution Services Inc.	
Overseas International Steel Industry.	

Antidumping duty proceedings	Period to be reviewed
Paslode Fasteners Co. Ltd.	
Patek Tool Co. Ltd.	
President Industrial Inc.	
Promising Way (Hong Kong) Ltd.	
Qingda Jisco Co. Ltd.	
Qingdao Ant Hardware Manufacturing Co. Ltd.	
Qingdao D&L Hardware Co. Ltd.	
Qingdao Gold Dragon Co. Ltd.	
Qingdao Hongyuan Nail Industry Co. Ltd.	
Qingdao JCD Machinery Co., Ltd.	
Qingdao Meijialucky Industry and Co.	
Qingdao MST Industry and Commerce Co. Ltd.	
Qingdao Powerful Machinery Co., Ltd.*.	
Qingdao Top Metal Industrial Co., Ltd.*.	
Qingdao Top Steel Industrial Co. Ltd.	
Qingdao Uni-Trend International.	
Quzhou Monsoon Hardware Co. Ltd.	
Region Industries Co. Ltd.	
Region System Sdn. Bhd.	
Rise Time Industrial Ltd.	
Romp Coil Nail Industries Inc.	
R-Time Group Inc.	
Ruifeng Hardware Products Co., Ltd.	
SDC International Australia Pty. Ltd.	
Senco Asia Manufacturing Ltd.	
Shandong Dinglong Imp. & Exp. Co., Ltd.	
Shandong Liaocheng Minghua Metal Pvt. Ltd.	
Shandong Liaocheng Minghua Metal Pvt. Ltd.	
Shandong Oriental Cherry Hardware Group Co. Ltd.	
Shandong Oriental Cherry Hardware Import & Export Co. Ltd.	
Shandong Qingyun Hongyi Hardware Co. Ltd.	
Shanghai Cedargreen Imp. & Exp. Co., Ltd.	
Shanghai Curvet Hardware Products Co. Ltd.	
Shanghai Curvet Hardware, Co., Ltd.*.	
Shanghai Haoray International Trade Co. Ltd.	
Shanghai Jade Shuttle Hardware Tools Co. Ltd.	
Shanghai Seti Enterprise Int'l Co. Ltd.	
Shanghai Sutek Industries Co., Ltd.	
Shanghai Yiren Machinery Co., Ltd.	
Shanghai Yueda Fasteners Co., Ltd.	
Shanghai Yueda Nails Co. Ltd.	
Shanghai Yueda Nails Co. Ltd.	
Shanghai Zoonlion Industrial Co., Ltd.	
Shanxi Easyfix Trade Co. Ltd.	
Shanxi Hairui Trade Co. Ltd.	
Shanxi Pioneer Hardware Industrial Co. Ltd.	
Shanxi Tianli Industries Co. Ltd.	
Shanxi Xinjintai Hardware Co., Ltd.	
Shaoxing Chengye Metal Producing Co. Ltd.	
Shenzhen Xinjintai Hardware Co. Ltd.	
S-Mart (Tianjin) Technology Development Co. Ltd.*.	
Stanley Black & Decker, Inc.	
Sueyi International Ltd.	
Sumec Machinery and Electric Co., Ltd.*.	
Suntec Industries Co. Ltd.	
Suzhou Xingya Nail Co. Ltd.	
Taizhou Dajiang Ind. Co. Ltd.	
Test-Rite International Co., Ltd.*.	
The Stanley Works (Langfang) Fastening Systems Co., Ltd.	
Theps International.	
Tianji Hweschun Fasteners Manufacturing Co. Ltd.	
Tianjin Baisheng Metal Products Co. Ltd.	
Tianjin Bluekin Indusries Ltd.	
Tianjin Coways Metal Products Co. Ltd.	
Tianjin Dagang Jingang Nail Factory.	
Tianjin Evangel Imp. & Exp. Co. Ltd.	
Tianjin Fulida Supply Co. Ltd.	
Tianjin Huixingshangmao Co. Ltd.	
Tianjin Jin Xin Sheng Long Metal Products Co. Ltd.	
Tianjin Jinchi Metal Products Co. Ltd.	
Tianjin Jinghai County Hongli Industry and Business Co. Ltd.	
Tianjin Jinghai Yicheng Metal Pvt.	
Tianjin Jinlin Pharmaceutical Factory.	
Tianjin Jinmao Imp. & Exp. Corp. Ltd.	

Antidumping duty proceedings	Period to be reviewed
Tianjin Lianda Group Co. Ltd.	
Tianjin Liweitian Metal Technology*.	
Tianjin Tianhua Environmental Plastics Co. Ltd.	
Tianjin Universal Machinery Imp. & Exp.	
Tianjin Yong Sheng Towel Mill.	
Tianjin Yongye Furniture Co. Ltd.	
Tianjin Zhonglian Metals Ware Co. Ltd.	
Tianjin Zhonglian Times Technology.	
Tianjin Zhongsheng Garment Co. Ltd.	
Tinjin Liweitian Metal Technology.	
Tinjin Tiaolai Import & Export Company Ltd.	
Tsugaru Enterprise Co., Ltd.	
Unicorn Fasteners Co. Ltd.	
Verko Incorporated.	
Win Fasteners Manufactory (Thailand) Co. Ltd.	
Wire Products Manufacturing Co., Ltd.	
Wulian Zhanpeng Metals Co. Ltd.	
Xi'An Metals and Minerals Imp. & Exp. Co. Ltd.	
Xiamen Zhaotai Industrial Corp.	
Yongchang Metal Product Co.	
Youngwoo Fasteners Co., Ltd.	
Yuyao Dingfeng Engineering Co. Ltd.	
Zhanghaiding Hardware Co., Ltd.	
Zhangjiagang Lianfeng Metals Products Co. Ltd.	
Zhangjiagang Longxiang Industries Co. Ltd.	
Zhaoqing Harvest Nails Co. Ltd.	
Zhejiang Best Nail Industry Co. Ltd.	
Zhejiang Jihengkang (JHK) Door Ind. Co. Ltd.	
Zhejiang Saiteng New Building Materials Co., Ltd.*.	
Zhejiang Yiwu Yongzhou Imp. & Exp. Co. Ltd.	
Zhong Shan Daheng Metal Products Co. Ltd.	
Zhong Shan Shen Neng Metals Products Co. Ltd.	
Zhucheng Jinming Metal Products Co. Ltd.	
Zhucheng Runfang Paper Co. Ltd.	
The People's Republic of China: Freshwater Crawfish Tailmeat A–570–848	9/1/17–8/31/18
Anhui Luan Hongyuan Foodstuffs Co., Ltd.	
China Kingdom (Beijing) Import & Export Co., Ltd.	
Deyan Aquatic Products and Food Co., Ltd.	
Hubei Nature Agriculture Industry Co., Ltd.	
Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd.	
Hubei Yuesheng Aquatic Products Co., Ltd.	
Jingzhou Tianhe Aquatic Products Co., Ltd.	
Kunshan Xinrui Trading Co., Ltd.	
Nanjing Gemsen International Co., Ltd.	
Nanjing Yinxiangchen International Trade Co., Ltd.	
Shanghai Ocean Flavor International Trading Co., Ltd.	
Weishan Hongda Aquatic Food Co., Ltd.	
Xiping Opeck Food Co., Ltd.	
Xuzhou Jinjiang Foodstuffs Co., Ltd.	
Yangcheng Hi-King Agriculture Developing Co., Ltd.	
The People's Republic of China: Hydrofluorocarbon Blends[7] A–570–028	8/1/17–7/31/18
Daikin Fluorochemicals (China) Co., Ltd.	
Zhejiang Sanmei Chemical Industry Co., Ltd.	
Weitron International Refrigeration Equipment (Kunshan) Co., Ltd.	
Turkey: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes A–489–824	9/1/17–8/31/18
Agir Haddecilik A.S.	
Cinar Boru Profil San Ve Tic Stl.	
MTS Lojistik ve Tasimacilik Hizmetleri TIC A.S. Istanbul.	
Noksel Celik Boru Sanayi A.	
Ozedemir Boru Profil San. ve Tic. Ltd. Sti.	
Turkey: Oil Country Tubular Goods A–489–816	9/1/17–8/31/18
Cayirova Boru San A.S.	
Çayirova Boru Sanayi ve Ticaret A.Ş. and Yücel Boru Ithalat-Ihracat ve.	
Pazarlama A.Ş. (collectively Yücel).	
HG Tubulars Canada Ltd.	
Toscelik Single Entity (The Toscelik Single Entity comprises the following companies: Toscelik Profil ve Sac Endustrici A.S and its affiliates Tosyali Dis Ticaret A.S., Tosyali Demir Celik A.S., Tosyali Holding A.S., Toscelik Granul San A.S., Tosyali Elektrik Enerjsi Toptan Satis, Tosyali Elek Enerjsi Uretim A.S., and Toscelik Spiral Boru Uretim San A.S.).	
Yucelboru Ihracat, Ithalat.	
United Kingdom: Cold-Rolled Steel Flat Products A–412–824	9/1/17–8/31/18
Caparo Precision Strip, Ltd./Liberty Performance Steels, Ltd.[8].	

Antidumping duty proceedings	Period to be reviewed
Countervailing Duty Proceedings	
India: Lined Paper Products C–533–844	1/1/17–12/31/17
Goldenpalm Manufacturers PVT Limited.	
Republic of Korea: Certain Cold-Rolled Steel Flat Products C–580–882	1/1/17–12/31/17
Dongbu Steel Co., Ltd.	
Hyundai Steel Company.	
POSCO.	
Dongbu Incheon Steel Co., Ltd.	
Dongbu Steel Incheon Steel Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Euro Line Global Co., Ltd.	
Hanawell Co., Ltd.	
Hankum Co., Ltd.	
Hyuk San Profile Co., Ltd.	
Hyundai Steel Co., Ltd.	
Nauri Logistics Co., Ltd.	
Taihan Electric Wire Co., Ltd.	
Union Steel Co., Ltd.	
The People's Republic of China: Certain Magnesia Carbon Bricks C–570–955	1/1/17–12/31/17
Fedmet Resources Corporation.	
Fengchi Imp. and Exp. Co., Ltd.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City.	
Fengchi Mining Co., Ltd. of Haicheng City.	
Fengchi Refractories Co., of Haicheng City.	
Liaoning Zhongmei High Temperature Material Co., Ltd.	
Liaoning Zhongmei Holding Co., Ltd.	
RHI Refractories Liaoning Co., Ltd.	
Shenglong Refractories Co., Ltd.	
Yingkou Heping Samwha Minerals, Co., Ltd.	
Yingkou Heping Sanhua Materials Co., Ltd.	
The People's Republic of China: Certain New Pneumatic Off-the-Road Tires C–570–913	1/1/17–12/31/17
Laizhou Xiongying Rubber Industry Co., Ltd.	
Qingdao Jinhaoyang International Co., Ltd.	
Triangle Tyre Co., Ltd.	
Weihai Zhongwei Rubber Co., Ltd.	
The People's Republic of China: Certain Passenger Vehicle and Light Truck Tires[9] C–570–017	1/1/17–12/31/17
Qingzhou Detai International Trading Co., Ltd.	
The People's Republic of China: Narrow Woven Ribbons with Woven Selvedge C–570–953	1/1/17–12/31/17
Yama Ribbons and Bows Co., Ltd.	
Turkey: Heavy-Walled Rectangular Welded Carbon Steel Pipes and Tubes C–489–825	1/1/17–12/31/17
Agir Haddecilik A.S.	
Cinar Boru Profil San Ve Tic Stl.	
MTS Lojistik ve Tasimacilik Hizmetleri TIC A.S. Istanbul.	
Noksel Celik Boru Sanayi A.	
Ozdemir Boru Profil San. Ve Tic. Ltd. Sti.	
Turkey: Oil Country Tubular Goods C–489–817	1/1/17–12/31/17
Borusan Mannesamann Boru Sanayi ve Ticaret A.S.	
Borusan Istikbal Ticaret T.A.S.	

[5] The name of the company listed above was misspelled in the initiation notice that published on October 4, 2018 (83 FR 50077). The correct spelling of the company name is listed in this notice.

[6] In the initiation notice that published on October 4, 2018 (83 FR 50077), Commerce inadvertently made several errors with respect to the initiation of this review. This notice serves as a correction to the October initiation notice. Specifically, the companies with an ''*'' after their names were left off the list in the October notice. Moreover, the following companies that were listed in the October 4, 2018 notice are not under review: Hangzhou Spring Washer Co. Ltd., Home International Development Co. Ltd., and Tianjin Huixishangmao Co. Ltd. In addition, we hereby correct the names of the following companies: Shanxi Hairui Trade Co. Ltd., Shenzhen Xinjintai Hardware Co. Ltd., and Unicorn Fasteners Co. Ltd.

[7] In the initiation notice that published on October 4, 2018 (83 FR 50077), Commerce inadvertently misspelled the company names listed above. The correct spelling of the company names is listed in this notice. In addition, we inadvertently initiated an administrative review for Weitron, Inc., the affiliated U.S. reseller of Weitron International Refrigeration Equipment (Kunshan) Co., Ltd. *See* Weitron International Refrigeration Equipment (Kunshan) Co., Ltd.'s Letter, ''Request for Administrative Review of the Antidumping Duty Order on Hydrofluorocarbon Blends and Components Thereof from the People's Republic of China (A–570–028),'' dated August 31, 2017, showing that Weitron, Inc. is the U.S. affiliated reseller of this Chinese exporter.

[8] We have previously determined that Liberty Performance Steels Ltd. is the successor-in-interest to Caparo Precision Strip, Ltd.

[9] The name of the company listed above was misspelled in the initiation notice that published on October 4, 2018 (83 FR 50077). The correct spelling of this company name is listed in this notice.

Suspension Agreements

None

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment.

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information.[10] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty or countervailing duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[11] Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable revised certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under part 351 expires, or as otherwise specified by the Secretary. *See* 19 CFR 351.302. In general, an extension request will be considered untimely if it is filed after the time limit established under part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning U.S. Customs and Border Protection data; and (5) quantity and value questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Please review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: November 8, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–24943 Filed 11–14–18; 8:45 am]

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[10] *See* section 782(b) of the Act.

[11] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–085]

Certain Quartz Surface Products From the People's Republic of China: Preliminary Affirmative Determination of Critical Circumstances, in Part, in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that critical circumstances exist with respect to imports of certain quartz surface products (quartz surface products) from certain producers and

exporters from the People's Republic of China (China).

DATES: Applicable November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Darla Brown, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–1791.

SUPPLEMENTARY INFORMATION:

Background

On April 17, 2018, Commerce received a countervailing duty (CVD) petition concerning imports of quartz surface products from China filed in proper form on behalf of the petitioner, Cambria Company LLC.[1] On May 16, 2018, we initiated this investigation,[2] and on September 21, 2018, we published an affirmative *Preliminary Determination*.[3]

Commerce selected Fasa Industrial Corporation, Limited (Fasa Industrial), Foshan Yixin Stone Co., Ltd. (Foshan Yixin), and Foshan Hero Stone Co., Ltd. (Hero Stone) as the individually-examined respondents in this investigation. With respect to Hero Stone and Fasa Industrial, in the *Preliminary Determination* we based the subsidy rates for these respondents on adverse facts available (AFA), in accordance with section 776(a) and (b) of the Tariff Act of 1930, as amended (the Act).[4]

On October 9, 2018, the petitioner alleged that critical circumstances exist with respect to imports of quartz surface products from China, pursuant to section 703(e)(1) of the Act and 19 CFR 351.206.[5]

In accordance with 19 CFR 351.206(c)(1), if the petitioner submits an allegation of critical circumstances 30 days or more before the scheduled date of the final determination,[6] Commerce will make a preliminary finding whether there is a reasonable basis to believe or suspect that critical circumstances exist. Commerce will issue its preliminary finding of critical circumstances within 30 days after the petitioner submits the allegation.[7]

Period of Investigation (POI)

The POI is January 1, 2017, through December 31, 2017.

Critical Circumstances Allegation

The petitioner alleged a massive increase of imports of certain quartz surface products from China and provided monthly import data for the period January 2017 through August 2018.[8] The petitioner states that a comparison of total imports, by quantity, for the period February 2018 through April 2018, to the period May 2018 through July 2018, shows that imports of quartz surface products from China increased by 81 percent,[9] which is considered ''massive'' under 19 CFR 351.206(h)(2). The petitioner also alleges that there is a reasonable basis to believe that there are subsidies in this investigation which are inconsistent with the Subsidies and Countervailing Measures Agreement (SCM Agreement).[10]

Critical Circumstances Analysis

Section 703(e)(1) of the Act provides that Commerce will preliminarily determine that critical circumstances exist if there is a reasonable basis to believe or suspect that: (A) The alleged countervailable subsidy is inconsistent with the SCM Agreement; [11] and (B) there have been massive imports of the subject merchandise over a relatively short period.

In determining whether there are ''massive imports'' over a ''relatively short period,'' pursuant to section 703(e)(1)(B) of the Act and 19 CFR 351.206(h) and (i), Commerce normally compares the import volumes of the subject merchandise for at least three months immediately preceding the filing of the petition (*i.e.,* the base period) to a comparable period of at least three months following the filing of the petition (*i.e.,* the comparison period). However, the regulations also provide that if Commerce finds that importers, or exporters or producers, had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely, Commerce may consider a period of not less than three months from the earlier time.[12] Imports must increase by at least 15 percent during the comparison period to be considered massive.[13]

Foshan Yixin

In the *Preliminary Determination,* we found that Foshan Yixin did not receive any countervailable subsidies during the POI that are inconsistent with the SCM Agreement.[14] Accordingly, because the requirement under section 703(e)(1)(A) of the Act has not been met, we preliminarily determine that critical circumstances do not exist with respect to Foshan Yixin.

Fasa Industrial and Hero Stone

As explained in our *Preliminary Determination,* we applied total adverse facts available (AFA) to Fasa Industrial and Hero Stone, pursuant to section 776(b) of the Act. In applying total AFA to these two companies, we preliminarily determined that both Fasa Industrial and Hero Stone benefited from countervailable subsidies under the ''Export Assistance Grants'' program.[15] Although we did not make a preliminary finding as to whether the ''Export Assistance Grants'' program was inconsistent with the SCM Agreement in the *Preliminary Determination,* we now preliminarily find, pursuant to section 776(b) of the Act, that there is a reasonable basis to believe or suspect that the program, as alleged in the Petition and supported by information reasonably available to the petitioner, is export contingent within the meaning of section 771(5A)(B) of the Act and, thus, inconsistent with the SCM Agreement.[16] We preliminarily found this program to have a program-specific rate of 0.58 percent.[17] We are making the inconsistency determination

[1] *See* ''Petitions for the Imposition of Antidumping and Countervailing Duties: Certain Quartz Surface Products from the People's Republic of China,'' dated April 17, 2018 (Petition).

[2] *See Certain Quartz Surface Products from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 83 FR 22618 (May 16, 2018) (*Initiation Notice*), and accompanying Initiation Checklist.

[3] *See Certain Quartz Surface Products from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Determination,* 83 FR 47881 (September 21, 2018) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[4] *See Preliminary Determination* PDM at Use of Facts Otherwise Available and Adverse Inferences.

[5] *See* Letter from the petitioner, ''Certain Quartz Surface Products from the People's Republic of China: Amendment to Petition for the Imposition of Antidumping and Countervailing Duties to Allege Existence of Critical Circumstances,'' dated October 9, 2018 (Critical Circumstances Allegation).

[6] The final determination for this CVD investigation is currently due no later than January 28, 2019.

[7] *See* 19 CFR 351.206(c)(2)(ii).

[8] *See* Amended Critical Circumstances Allegation at Exhibit 1.

[9] *See* Critical Circumstances Allegation at 2.

[10] *Id.* at 5–6.

[11] Commerce limits its critical circumstances findings to those subsidies contingent upon export performance or use of domestic over imported goods (*i.e.,* those prohibited under Article 3 of the SCM Agreement). *See e.g., Final Affirmative Countervailing Duty Determination and Final Negative Critical Circumstances Determination: Carbon and Certain Alloy Steel Wire from Germany,* 67 FR 55808, 55809–10 (August 30, 2002) (*Steel Wire from Germany*).

[12] *See* 19 CFR 351.206(i).

[13] *See* 19 CFR 351.206(h)(2).

[14] *See Preliminary Determination* PDM at Analysis of Programs.

[15] *Id.* at 11.

[16] *See* Countervailing Duty Investigation Initiation Checklist: Certain Quartz Surface Products from the People's Republic of China, dated May 7, 2018.

[17] *See Preliminary Determination* PDM at Appendix.

with regard to this program, which had the lowest rate in the *Preliminary Determination* among the programs alleged to be inconsistent with the SCM Agreement. In so doing, we intend to limit the corresponding offset to the dumping margin (if one is found) in the companion antidumping duty investigation, which best fulfills our statutory mandate ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully,'' [18] and induce future cooperation by companies in investigations where the petitioners allege the existence of programs potentially inconsistent with the SCM Agreement.

Because we preliminarily find that the ''Export Assistance Grants'' program is export contingent, we preliminarily find that the criterion under section 703(e)(1)(A) of the Act has been met. In addition, for the purposes of the ''massive imports'' analysis, we preliminarily determine, pursuant to section 776(b) of the Act, that Fasa Industrial and Hero Stone shipped quartz surface products in ''massive'' quantities during the comparison period, thereby fulfilling the criteria under section 703(e)(1)(B) of the Act.[19] As a result, we preliminarily determine that critical circumstances exist with regard to Fasa Industrial and Hero Stone.

All Other Companies

We based the all-others rate applied in the *Preliminary Determination* on the rate preliminarily calculated for Foshan Yixin. As noted above, we preliminarily found that Foshan Yixin did not use any countervailable subsidies inconsistent with the SCM Agreement. As a result, we also preliminarily determine that all other exporters of subject merchandise from China not selected as mandatory respondents did not use countervailable subsidies inconsistent with the SCM Agreement, and thus preliminarily find that critical circumstances do not exist with respect to the companies covered by the all-others rate.

Final Determination

We will make a final determination concerning critical circumstances in the final determination of this investigation, which is currently scheduled for January 28, 2019.

[18] Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Doc. 103–316, Vol. 1 (1994) at 870, *reprinted in* 1994 U.S.C.C.A.N. 4040, 4199.

[19] *See* Critical Circumstances Allegation at Exhibit 1.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[20] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[21]

Electronically filed documents must be received successfully in their entirety by 5:00 p.m. Eastern Time on the due dates established above.[22]

Suspension of Liquidation

In accordance with section 703(e)(2)(A) of the Act, for Fasa Industrial and Hero Stone, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of any unliquidated entries of subject merchandise from the China entered, or withdrawn from warehouse for consumption, on or after June 23, 2018, which is 90 days prior to the date of publication of the *Preliminary Determination* in the **Federal Register**. For such entries, CBP shall require a cash deposit equal to the estimated preliminary subsidy rates established for Fasa Industrial and Hero Stone in the *Preliminary Determination.* This suspension of liquidation will remain in effect until further notice.

ITC Notification

In accordance with section 703(f) of the Act, we will notify the ITC of this preliminary determination of critical circumstances.

This determination is issued and published pursuant to sections 703(f) and 777(i)(1) of the Act.

Dated: November 8, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–24941 Filed 11–14–18; 8:45 am]

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[20] *See* 19 CFR 351.309(d)(1).

[21] *See* 19 CFR 351.309(c)(2) and (d)(2).

[22] *See* 19 CFR 351.303(b)(1).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–073]

Antidumping Duty Investigation of Common Alloy Aluminum Sheet From the People's Republic of China: Affirmative Final Determination of Sales at Less-Than-Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that common alloy aluminum sheet (common alloy sheet) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less-than-fair value (LTFV) for the period of investigation (POI) April 1, 2017, through September 30, 2017.

DATES: Applicable November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Scott Hoefke or Julie Geiger, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–4947 and (202) 482–2057, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 6, 2018, Commerce published in the **Federal Register** the *Preliminary Determination* and invited interested parties to comment.[1] On August 8, 2018, Commerce published in the **Federal Register** the *Amended Preliminary Determination*.[2] A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum that is dated concurrently with this determination and hereby adopted by this notice.[3]

[1] *See Antidumping Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value, Preliminary Affirmative Determination of Critical Circumstance, and Postponement of Final Determination,* 83 FR 29088 (June 22, 2018) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] *See Common Alloy Aluminum Sheet from the People's Republic of China: Amended Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 83 FR 39056 (August 8, 2018) (*Amended Preliminary Determination*).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Investigation of Common Alloy

Continued

The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed Issues and Decision Memorandum and the electronic version are identical in content.

Scope Comments

We invited parties to comment on Commerce's Scope Comments Preliminary Decision Memorandum.[4] Commerce has reviewed the briefs submitted by interested parties, considered the arguments therein, and has made no changes to the scope of the investigation. For further discussion, *see* Commerce's Scope Comments Final Decision Memorandum.[5]

Methodology

Commerce conducted this investigation in accordance with section 731 of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

Scope of the Investigation

The merchandise covered by this investigation is common alloy sheet from China. For a complete description of the scope of this investigation, *see* Appendix I.

Verification

As provided in section 782(i) of the Act, in July, we conducted verification of the questionnaire responses submitted by Henan Mingtai Industrial Co., Ltd. and Zhengzhou Mingtai (collectively, Mingtai). We issued verification reports on August 28, 2018.[6] We used standard verification procedures, including an examination of relevant accounting and financial records, and original source documents provided by Mingtai.

Period of Investigation

The POI is April 1, 2017, through September 30, 2017.

Analysis of Comments Received

The issues raised in the case and rebuttal briefs that were submitted by parties are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice at Appendix II.

Final Affirmative Determination, in Part, of Critical Circumstances

In the *Preliminary Determination,* we found that critical circumstances exist for to Nanjie Resources Co., Limited (Nanjie), Yong Jie New Material Co., Ltd. (Yong Jie New Material), and Zhejiang Yongjie Aluminum Co., Ltd. (Yongjie Aluminum) (collectively, Yongjie Companies); Zhejiang GKO Aluminium Stock Co., Ltd. (GKO Aluminium); the companies eligible for a separate rate; and the China-wide entity.[7] After analyzing comments received from interested parties regarding our preliminary critical circumstances determinations, we continue to find that, in accordance with section 735(a)(3) of the Act and 19 CFR 351.206, critical circumstances exist with respect to Nanjie, the Yongjie Companies, GKO Aluminium, the companies eligible for a separate rate, and the China-wide entity.[8]

Use of Adverse Facts Available (AFA)

For the final determination we continue to rely upon facts otherwise available, with adverse inferences (AFA), for the China-wide entity, the Yongjie Companies, and GKO Aluminium, pursuant to sections 776(a) and (b) of the Act.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, and minor corrections presented at verification, we made certain changes to Mingtai's margin calculation since the *Preliminary Determination.* For Mingtai, we calculated U.S. price and normal value using the same methodology stated in the *Preliminary Determination,* except as follows:

- We revised the surrogate value for Mingtai's argon factor of production using data from Bulgaria instead of South Africa.
- We revised the surrogate value for Mingtai's prompt aluminum scrap factor of production.
- We revised Mingtai's normal value calculation by: (1) Disallowing a claimed by-product offset; and (2) treating run-around aluminum scrap as a direct material input, not as a by-product.

China-Wide Entity

For the final determination, we continue to find that the China-wide entity, which includes certain Chinese exporters and/or producers that did not respond to Commerce's requests for information, including mandatory respondents GKO Aluminium and the Yongjie Companies, failed to provide necessary information, failed to provide information in a timely manner, and significantly impeded this proceeding by not submitting the requested information. We also continue to find that the China-wide entity failed to cooperate to the best of its ability. As a result, we continue to rely on AFA in determining the rate for the China-wide entity and, as AFA, we select the highest rate listed in the initiation of the investigation (*i.e.,* 59.72 percent), which is greater than the revised weighted-average dumping margin of Mingtai (*i.e.,* 49.85 percent).[9]

Combination Rates

Consistent with *Preliminary Determination* [10] and Policy Bulletin 05.1,[11] Commerce calculated combination rates for the respondents that are eligible for a separate rate in this investigation.

Final Determination

The final weighted-average antidumping margins are as follows:

Aluminum Sheet from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See* Memorandum, ''Common Alloy Aluminum Sheet from the People's Republic of China: Scope Comments Preliminary Decision Memorandum,'' dated June 15, 2018.

[5] *See* Memorandum, ''Common Alloy Aluminum Sheet from the People's Republic of China: Scope Comments Final Decision Memorandum,'' dated concurrently with this memorandum.

[6] *See* Commerce Memoranda, ''Verification of the Questionnaire Responses of Henan Mingtai Al Industrial Co., ltd. and Zhengzhou Mingtai Industry Co., Ltd. in the Less-Than-Fair-Value Investigation of Common Alloy Aluminum Sheet from the People's Republic of China,'' dated August 28, 2018.

[7] *See Preliminary Determination,* 83 FR at 29089.

[8] *See* Issues and Decision Memorandum, at Comment 2.

[9] *See* Issues and Decision Memorandum, at 5–7.

[10] *See Preliminary Determination,* 83 FR at 29089–29090.

[11] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

Exporter	Producer	Weighted-average margin (percent)	Cash deposit adjusted for subsidy offset (percent)
Henan Mingtai Al Industrial Co., Ltd./Zhengzhou Mingtai Industry Co., Ltd.	Henan Mingtai Al Industrial Co., Ltd./Zhengzhou Mingtai Industry Co., Ltd.	49.85	49.85
Alcha International Holdings Limited	Jiangsu Alcha Aluminium Co., Ltd	49.85	49.85
Alumax Composite Material (Jiangyin) Co., Ltd	Chalco Ruimin Co., Ltd	49.85	49.85
Granges Aluminum (Shanghai) Co., Ltd	Granges Aluminum (Shanghai) Co., Ltd	49.85	49.85
Henan Founder Beyond Industry Co., Ltd	Henan Xintai Aluminum Industry Co., Ltd	49.85	49.85
Huafon Nikkei Aluminium Corporation	Huafon Nikkei Aluminium Corporation	49.85	49.85
Jiangsu Lidao New Material Co., Ltd	Henan Jinyang Luyue Co., Ltd	49.85	49.85
Jiangsu Lidao New Material Co., Ltd	Jiangsu Zhong He Aluminum Co., Ltd	49.85	49.85
Jiangyin Litai Ornamental Materials Co., Ltd	Jiangyin Litai Ornamental Materials Co., Ltd	49.85	49.85
Jiangyin New Alumax Composite Material Co. Ltd	Chalco Ruimin Co., Ltd	49.85	49.85
Shandong Fuhai Industrial Co., Ltd	Shandong Fuhai Industrial Co., Ltd	49.85	49.85
Tianjin Zhongwang Aluminium Co., Ltd	Tianjin Zhongwang Aluminium Co., Ltd	49.85	49.85
Xiamen Xiashun Aluminum Foil Co., Ltd	Xiamen Xiashun Aluminum Foil Co., Ltd	49.85	49.85
Yantai Jintai International Trade Co., Ltd	Shandong Nanshan Aluminium Co., Ltd	49.85	49.85
Yinbang Clad Material Co., Ltd	Yinbang Clad Material Co., Ltd	49.85	49.85
Zhengzhou Silverstone Limited	Henan Zhongyuan Aluminum Co., Ltd	49.85	49.85
Zhengzhou Silverstone Limited	Luoyang Xinlong Aluminum Co., Ltd	49.85	49.85
Zhengzhou Silverstone Limited	Shanghai Dongshuo Metal Trade Co., Ltd	49.85	49.85
Zhengzhou Silverstone Limited	Zhengzhou Mingtai Industry Co., Ltd	49.85	49.85
China-Wide Entity [12]		59.72	59.72

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, for this final determination, we will direct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of common alloy sheet from China, as described in Appendix I of this notice, which are entered, or withdrawn from warehouse, for consumption on or after June 6, 2018, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.* Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above as follows: (1) For the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Chinese producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or the China-wide entity) that supplied that third country exporter. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of common alloy sheet, no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated and all cash deposits posted will be refunded. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Suspension of Liquidation'' section.

Notification Regarding Administrative Protective Orders

This notice will serve as a reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Return or Destruction of Proprietary Information

In the event the ITC issues a final negative injury determination, this notice serves as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply

[12] The China-wide entity also includes the following companies that filed separate rate applications: Nanjie Resources Co., Limited, Yong Jie New Material Co., Ltd., and Zhejiang Yongjie Aluminum Co., Ltd., Zhejiang GKO Aluminium Stock Co., Ltd.; Alnan Aluminium Inc.; Chalco Ruimin Co., Ltd.; CHALCO–SWA Cold Rolling Co., Ltd.; Luoyang Wanji Aluminium Processing Co., Ltd.; and Wanji Global (Singapore) PTE. LTD.

with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act and 19 CFR 351.210(c).

Dated: November 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is aluminum common alloy sheet (common alloy sheet), which is a flat-rolled aluminum product having a thickness of 6.3 mm or less, but greater than 0.2 mm, in coils or cut-to-length, regardless of width. Common alloy sheet within the scope of this investigation includes both not clad aluminum sheet, as well as multi-alloy, clad aluminum sheet. With respect to not clad aluminum sheet, common alloy sheet is manufactured from a 1XXX-, 3XXX-, or 5XXX-series alloy as designated by the Aluminum Association. With respect to multi-alloy, clad aluminum sheet, common alloy sheet is produced from a 3XXX-series core, to which cladding layers are applied to either one or both sides of the core.

Common alloy sheet may be made to ASTM specification B209–14, but can also be made to other specifications. Regardless of specification, however, all common alloy sheet meeting the scope description is included in the scope. Subject merchandise includes common alloy sheet that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the common alloy sheet.

Excluded from the scope of this investigation is aluminum can stock, which is suitable for use in the manufacture of aluminum beverage cans, lids of such cans, or tabs used to open such cans. Aluminum can stock is produced to gauges that range from 0.200 mm to 0.292 mm, and has an H–19, H–41, H–48, or H–391 temper. In addition, aluminum can stock has a lubricant applied to the flat surfaces of the can stock to facilitate its movement through machines used in the manufacture of beverage cans. Aluminum can stock is properly classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7606.12.3045 and 7606.12.3055.

Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set for the above.

Common alloy sheet is currently classifiable under HTSUS subheadings 7606.11.3060, 7606.11.6000, 7606.12.3090, 7606.12.6000, 7606.91.3090, 7606.91.6080, 7606.92.3090, and 7606.92.6080. Further, merchandise that falls within the scope of this investigation may also be entered into the United States under HTSUS subheadings 7606.11.3030, 7606.12.3030, 7606.91.3060, 7606.91.6040, 7606.92.3060, 7606.92.6040, 7607.11.9090. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2018–24869 Filed 11–14–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 10–4A001]

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended Export Trade Certificate of Review to Alaska Longline Cod Commission (''ALCC''), Application No. 10–4A001.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an amended Export Trade Certificate of Review to ALCC on November 7, 2018.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325 (2018). OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

ALCC's Export Trade Certificate of Review has been amended to:

1. Add the following companies as new Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

a. Alaskan Leader Vessel LLC, Lynden, WA
b. Bristol Leader Fisheries LLC, Lynden, WA
c. Bering Leader Fisheries LLC, Lynden, WA
d. Northern Leader Fisheries LLC, Lynden, WA
e. Prowler Fisheries, LLC, Seattle, WA

2. Delete the following companies as Members of the Certificate:

a. Pathfinder Fisheries LLC, Seattle, WA
b. Bering Select Seafoods Company, Seattle, WA
c. Glacier Bay Fisheries LLC

3. Change/correct the name or location of the following Members of the Certificate:

a. Alaskan Leader Fisheries, Inc., Lynden, WA changes to Alaskan Leader Fisheries LLC, Lynden, WA
b. Coastal Villages Longline, LLC changes to Coastal Villages Longline LLC, Anchorage, AK
c. Romanzoff Fishing Company, Seattle, WA changes to Romanzof Fishing Company, L.L.C., Seattle, WA
d. Tatoosh Seafoods LLC, Seattle, WA changes to Tatoosh Seafoods, LLC, Edmonds, WA
e. Beauty Bay Washington, LLC, Seattle, WA changes to Beauty Bay Washington, LLC, Edmonds, WA

f. Blue North Fisheries, Inc, Seattle, WA changes to Blue North Fisheries, Inc., Seattle, WA

g. Clipper Group, Ltd, Seattle, WA changes to Clipper Group, Ltd., Seattle, WA

h. Liberator Fisheries, LLC, Seattle, WA changes to Liberator Fisheries LLC, Seattle, WA

i. Siberian Sea Fisheries, LLC, Seattle, WA changes to Siberian Sea Fisheries LLC, Seattle, WA

ALCC's Membership, as amended, is below: Alaskan Leader Fisheries LLC, Lynden, Washington; Alaskan Leader Seafoods LLC, Lynden, Washington; Alaskan Leader Vessel LLC, Lynden, Washington; Bristol Leader Fisheries LLC, Lynden, Washington; Bering Leader Fisheries LLC, Lynden, Washington; Northern Leader Fisheries LLC, Lynden, Washington; Gulf Mist, Inc., Everett, Washington; Deep Sea Fisheries, Inc., Everett, Washington; Aleutian Spray Fisheries, Inc., Seattle, Washington; Liberator Fisheries LLC, Seattle, Washington; Siberian Sea Fisheries LLC, Seattle, Washington; Akulurak LLC, Seattle, Washington; Romanzof Fishing Company, L.L.C., Seattle, Washington; Beauty Bay Washington, LLC, Edmonds, Washington; Tatoosh Seafoods, LLC, Edmonds, Washington; Blue North Fisheries, Inc., Seattle, Washington; Blue North Trading Company, LLC, Seattle, Washington; Clipper Group, Ltd., Seattle, Washington; Clipper Seafoods, Ltd., Seattle, Washington (a wholly-owned subsidiary of Clipper Group, Ltd.); Shelford's Boat, Ltd., Mill Creek, Washington; Siu Alaska Corporation, Anchorage, Alaska; Coastal Villages Longline LLC, Anchorage, Alaska; and Prowler Fisheries, LLC, Seattle, Washington.

The effective date of the amended Certificate is August 9, 2018, the date on which ALCC's application to amend was deemed submitted.

Dated: November 8, 2018.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2018–24947 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Preliminary Affirmative Determination of Circumvention

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Diamond Tools Technology (Thailand) Co., Ltd. (Diamond Tools) is circumventing the antidumping duty order on diamond sawblades and parts thereof (diamond sawblades) from the People's Republic of China (China).

DATES: Applicable November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun, AD/CVD Operations Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5760.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2017, in response to a request from Diamond Sawblades Manufacturers' Coalition (the petitioner), Commerce published the initiation of the anti-circumvention inquiry to determine whether certain imports of diamond sawblades comprised of cores and segments produced in China and joined into diamond sawblades in, and exported from, Thailand by Diamond Tools are circumventing the antidumping duty order on diamond sawblades from China.[1]

Scope of the Order

The merchandise subject to the order is diamond sawblades. The diamond sawblades subject to the order are currently classifiable under subheadings 8202 to 8206 of the Harmonized Tariff Schedule of the United States (HTSUS), and may also enter under subheading 6804.21.00. The HTSUS subheadings are provided for convenience and customs purposes. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.[2] The written description is dispositive.

Scope of the Anti-Circumvention Inquiry

We initiated this anti-circumvention inquiry to cover diamond sawblades produced in Thailand by Diamond Tools with cores and segments produced in China and subsequently exported from Thailand to the United States.[3] During the conduct of this anti-circumvention inquiry, Diamond Tools reported that, in addition to diamond sawblades produced in Thailand with cores and segments produced in China, it also produced diamond sawblades with either Chinese cores and Thai segments or Thai cores and Chinese segments.[4] Based on the additional information we received from Diamond Tools, and as further discussed in the Preliminary Analysis Memorandum,[5] we are also examining whether diamond sawblades produced in Thailand by Diamond Tools with either cores or segments produced in China are circumventing the order.

Methodology

Commerce is conducting this anti-circumvention inquiry in accordance with section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h). Because China is a non-market economy country within the meaning of section 771(18) of the Act, Commerce relied on surrogate values to value the purchases of Chinese cores and Chinese segments, as discussed in section 773(c) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a

[1] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Initiation of Anti-Circumvention Inquiry,* 82 FR 57709 (December 7, 2017) (*Initiation Notice*).

[2] *See* the Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Decision Memorandum for Preliminary Affirmative Determination of Circumvention,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum) at 2–3.

[3] *See Initiation Notice,* 82 FR at 57710 (''This anti-circumvention inquiry covers diamond sawblades exported from Thailand to the United States that are produced by Diamond Tools from cores and segments of {China} origin.'').

[4] *See, e.g.,* Diamond Tools' original response dated January 18, 2018, at 4.

[5] *See* the Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Preliminary Analysis Memorandum for Diamond Tools Technology (Thailand) Co., Ltd.'' dated concurrently with this memorandum (Preliminary Analysis Memorandum) for more information containing Diamond Tools' business proprietary information.

complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Preliminary Determination

As detailed in the Preliminary Decision Memorandum, Commerce preliminarily determines that diamond sawblades produced by Diamond Tools in Thailand using cores and/or segments from China and exported from Thailand to the United States are circumventing the antidumping duty order on diamond sawblades from China. We therefore preliminarily determine that it is appropriate to include this merchandise within the antidumping duty order on diamond sawblades from China and to instruct U.S. Customs and Border Protection (CBP) to suspend entries of merchandise produced using Chinese cores and/or Chinese segments by Diamond Tools in Thailand and exported to the United States.

Suspension of Liquidation

As stated above, Commerce has made a preliminary affirmative finding of circumvention of the antidumping duty order on diamond sawblades from China for diamond sawblades assembled or completed using Chinese cores and/or Chinese segments as inputs by Diamond Tools in Thailand and exported to the United States. This preliminary circumvention finding applies to diamond sawblades assembled or completed using Chinese cores and/or Chinese segments as inputs by Diamond Tools in Thailand. In accordance with section 19 CFR 351.225(l)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of diamond sawblades produced (*i.e.,* assembled or completed) using Chinese cores and/or Chinese segments by Diamond Tools in Thailand that were entered, or withdrawn from warehouse, for consumption on or after December 1, 2017, the date of initiation of this anti-circumvention inquiry. The suspension of liquidation instructions will remain in effect until further notice. For the reasons stated in the Preliminary Analysis Memorandum, which contains Diamond Tools' business proprietary information,[6] Commerce will instruct CBP to require antidumping duty cash deposits equal to the rate established for the China-wide entity, *i.e.,* 82.05 percent,[7] for entries of such merchandise produced by Diamond Tools.

Diamond sawblades assembled or completed in Thailand using both non-Chinese origin cores and non-Chinese origin segments are not subject to this anti-circumvention inquiry. However, for the reasons stated in the Preliminary Analysis Memorandum, Commerce finds that Diamond Tools is not currently able to identify diamond sawblades produced with non-Chinese origin cores and non-Chinese origin segments.[8] Therefore, Commerce will not implement a certification process at this preliminary stage, and we will require cash deposits on all entries of diamond sawblades produced by Diamond Tools in Thailand. We invite parties to comment on this issue in their case briefs.

Public Comment

Commerce intends to disclose the analysis used in these preliminary findings within five days of publication of this notice. Interested parties are invited to comment on the preliminary determination of this anti-circumvention inquiry. Pursuant to 19 CFR 351.309(b)(2), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may not be filed later than five days after the time limit for filing case briefs.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case or rebuttal briefs in this anti-circumvention inquiry are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Any interested party who wishes to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days after the day of publication of this notice pursuant to 19 CFR 351.310(c). A request should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues to be discussed. If a request for a hearing is made, then Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. Issues raised in the hearing will be limited to those raised in case and rebuttal briefs.

International Trade Commission Notification

Consistent with section 781(e) of the Act, Commerce will notify the International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to this anti-circumvention inquiry within the antidumping duty order on diamond sawblades from China. Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the subject merchandise. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Final Determination

According to section 781(f) of the Act, Commerce shall, to the maximum extent practicable, make its anti-circumvention determination within 300 days from the date of the initiation of the inquiry.[10] Due to the complicated nature of this anti-circumvention inquiry, we previously extended the deadline for the final determination of this anti-circumvention inquiry by 150 days. Therefore, Commerce intends to issue the final determination in this anti-circumvention inquiry by February 27, 2019.[11]

This preliminary affirmative circumvention determination is published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: November 8, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[6] *See* Preliminary Analysis Memorandum at 4 for Diamond Tools' accounting and production system in its normal course of business.

[7] *See, e.g., Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016,* 83 FR 17527, 17528 (April 20, 2018).

[8] *See* Preliminary Analysis Memorandum at 4 for Diamond Tools' accounting and production system in its normal course of business. Some, but not all, of the reasons stated contain business proprietary information.

[9] *See* 19 CFR 351.309(d)(1)–(2).

[10] *See also* 19 CFR 351.225(f)(iii)(5) (explaining that Commerce will issue a final anticircumvention ruling ''normally within 300 days from the date of the initiation of the . . . inquiry'').

[11] *See* the Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Extension of Deadline for Final Determination of Anti-Circumvention Inquiry,'' dated September 27, 2018.

[FR Doc. 2018–24939 Filed 11–14–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–074]

Countervailing Duty Investigation of Common Alloy Aluminum Sheet From the People's Republic of China: Final Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of common alloy aluminum sheet (common alloy sheet) from the People's Republic of China (China) for the period of investigation (POI) January 1, 2016, through December 31, 2016.

DATES: Applicable November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Yasmin Bordas, Lana Nigro, or John Anwesen, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3813, (202) 482–1779, or (202) 482–0131, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 23, 2018, Commerce published in the **Federal Register** the *Preliminary Determination* and invited interested parties to comment.[1] A summary of the events that occurred since Commerce published *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum that is dated concurrently with this determination and hereby adopted by this notice.[2]

The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version are identical in content.

Scope Comments

We invited parties to comment on Commerce's Scope Comments Preliminary Decision Memorandum.[3] Commerce has reviewed the briefs submitted by interested parties, considered the arguments therein, and has made no changes to the scope of the investigation. For further discussion, *see* Commerce's Scope Comments Final Decision Memorandum.[4]

Methodology

Commerce conducted this countervailing duty (CVD) investigation in accordance with section 701 of the Tariff Act of 1930, as amended (Act). For each of the subsidy programs found to be countervailable, we determine that there is a subsidy (*i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient) and that the subsidy is specific. For a full description of the methodology underlying our final determination, *see* the Issues and Decisions Memorandum.

Scope of the Investigation

The merchandise covered by this investigation is common alloy sheet from China. For a complete description of the scope of this investigation, *see* Appendix I.

Verification

As provided in section 782(i) of the Act, in June 2018, we conducted verification of the questionnaire responses submitted by Henan Mingtai Industrial Co., Ltd. and Zhengzhou Mingtai (collectively, Mingtai); and Yong Jie New Material Co., Ltd. (Yong Jie New Material). We issued verification reports on July 3, 2018.[5] We used standard verification procedures, including an examination of relevant accounting and financial records, and original source documents provided by Mingtai and Yong Jie New Material.

Period of Investigation

The POI is January 1, 2016, through December 31, 2016.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs submitted by the parties, are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice at Appendix II.

Final Affirmative Determination of Critical Circumstances

In the *Preliminary Determination,* we found that critical circumstances exist for the Chalco companies and ''all-others.'' For this final determination, pursuant to section 705(a)(2) of the Act, we continue to find that critical circumstances exist for the Chalco companies and ''all-others.'' For a full description of the methodology and results of Commerce's critical circumstances analysis, see Final Determination Critical Circumstances Analysis Memo [6] and Issues and Decision Memorandum at ''Final Determination of Critical

[1] *See Common Alloy Aluminum Sheet from the People's Republic of China: Preliminary Affirmative Countervailing Duty (CVD) Determination, Alignment of Final CVD Determination with Final Antidumping Duty Determination, and Preliminary CVD Determination of Critical Circumstances,* 83 FR 17651 (April 23, 2018) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China,'' dated concurrently with this determination and hereby adopted by this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Common Alloy Aluminum Sheet from the People's Republic of China: Scope Comments Preliminary Decision Memorandum,'' dated June 15, 2018.

[4] *See* Memorandum, ''Common Alloy Aluminum Sheet from the People's Republic of China: Scope Comments Final Decision Memorandum,'' dated concurrently with this memorandum.

[5] *See* Commerce Memoranda, ''Verification of the Questionnaire Responses of Henan Mingtai Al Industrial Co., ltd. and Zhengzhou Mingtai Industry Co., Ltd.: Countervailing Duty Investigation of Common Alloy Sheet from the People's Republic of China,'' (Mingtai Verification Report) and ''Verification of the Questionnaire Responses of Yong Jie New Material: Countervailing Duty Investigation of Common Alloy Sheet from the People's Republic of China,'' (Yong Jie New Material Verification Report), both dated July 3, 2018.

[6] *See* Memorandum, ''Calculations for Final Determination of Critical Circumstances in the Countervailing Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China,'' dated concurrently with final determination; *see also* Memorandum, ''Calculations for Preliminary Determination of Critical Circumstances in the Countervailing Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China,'' dated April 16, 2018.

Circumstances, In Part'' and Comments 2 and 3.

Use of Adverse Facts Available (AFA)

For purposes of this final determination, we relied on facts available, and because certain respondents did not act to the best of their ability in responding to Commerce's requests for information, we drew an adverse inference, where appropriate, in selecting from among the facts otherwise available.[7] The subsidy rates for Chalco Ruimin Co., Ltd. and Chalco-SWA Cold Rolling Co., Ltd. (collectively, the Chalco companies) are based entirely on AFA. A full discussion of our decision to rely on AFA is presented in the ''Use of Facts Otherwise Available and Adverse Inferences'' section of the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, and minor corrections presented at verification, we made certain changes to the respondents' subsidy rate calculations since the *Preliminary Determination.* For a discussion of these changes, *see* the Issues and Decision Memorandum and the Final Calculation Memoranda.[8]

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual rate for each producer/exporter of the subject merchandise individually investigated.

In accordance with section 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an ''all-others'' rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as mandatory respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the ''all-others'' rate excludes zero and *de minimis* rates calculated for the exporters and producers individually investigated as well as rates based entirely on facts otherwise available. Where the rates for the individually investigated companies are all zero or *de minimis,* or determined entirely using facts otherwise available, section 705(c)(5)(A)(ii) of the Act instructs Commerce to establish an ''all-others'' rate using ''any reasonable method.''

Pursuant to section 705(c)(5)(A)(i) of the Act, we calculated the ''all-others'' rate using the subsidy rates of Mingtai and Yong Jie New Material, the only two mandatory respondents not receiving a subsidy rate based totally on section 776 of the Act. However, we have not calculated the ''all-others'' rate by weight-averaging these two rates because doing so risks disclosure of proprietary information.[9] Therefore, and consistent with Commerce's practice, for the ''all-others'' rate, we calculated a simple average of these two mandatory respondents' subsidy rates.

Company	Subsidy rate (percent)
Chalco Ruimin Co., Ltd	116.49
Chalco-SWA Cold Rolling Co., Ltd	116.49
Henan Mingtai Industrial Co., Ltd./Zhengzhou Mingtai Industry Co., Ltd[10]	46.48
Yong Jie New Material Co., Ltd[11]	55.02
All-Others	50.75

Final Determination

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

As a result of our *Preliminary Determination,* and pursuant to sections 703(d)(1)(B) and (2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of merchandise under consideration from China that were entered or withdrawn from warehouse, for consumption, on or after April 23, 2018, the date of publication of the *Preliminary Determination* in the **Federal Register**. Also, as a result of our *Preliminary Determination,* we instructed CBP to suspend liquidation on entries of merchandise under consideration from China for the Chalco companies and ''all-others'' effective January 23, 2018. In accordance with section 703(d) of the Act, on August 20, 2018, we instructed CBP to discontinue the suspension of liquidation of all entries at that time.

If the U.S. International Trade Commission (the ITC) issues a final affirmative injury determination, we will issue a CVD order, will reinstate the suspension of liquidation under section 706(a) of the Act, and will require a cash deposit of estimated CVDs for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

International Trade Commission Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Return or Destruction of Proprietary Information

In the event the ITC issues a final negative injury determination, this

[7] *See* sections 776(a) and (b) of the Act.

[8] *See* Memoranda, ''Countervailing Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China: Final Determination Calculation Memorandum for Henan Mingtai Industrial Co., Ltd. and Zhengzhou Mingtai,'' dated November 5, 2018 (Mingtai Final Calculation Memorandum) and ''Countervailing Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China: Final Determination Calculation Memorandum for Yong Jie New Material Co., Ltd.,'' dated November 5, 2018 (Yong Jie New Material Final Calculation Memorandum).

[9] We could not use the submitted publicly ranged data to calculate the all-others rate because, Yong Jie New Material did not establish its publicly ranged data in the manner required by 19 CFR 351.304(c).

[10] As discussed in the Preliminary Decision Memorandum, Commerce has found Henan Gongdian Thermal Co., Ltd. to be cross-owned with Henan Mingtai Industrial Co., Ltd. and Zhengzhou Mingtai Industry Co., Ltd.

[11] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Yong Jie New Material: Zhejiang Yongjie Aluminum Co., Ltd.; Zhejiang Nanjie Industry Co., Ltd; Zhejiang Yongjie Holding Co., Ltd; and Nanjie Resources Co., Ltd.

notice serves as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

Dated: November 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by the investigation is aluminum common alloy sheet (common alloy sheet), which is a flat-rolled aluminum product having a thickness of 6.3 mm or less, but greater than 0.2 mm, in coils or cut-to-length, regardless of width. Common alloy sheet within the scope of the investigation includes both not clad aluminum sheet, as well as multi-alloy, clad aluminum sheet. With respect to not clad aluminum sheet, common alloy sheet is manufactured from a 1XXX-, 3XXX-, or 5XXX-series alloy as designated by the Aluminum Association. With respect to multi-alloy, clad aluminum sheet, common alloy sheet is produced from a 3XXX-series core, to which cladding layers are applied to either one or both sides of the core.

Common alloy sheet may be made to ASTM specification B209–14, but can also be made to other specifications. Regardless of specification, however, all common alloy sheet meeting the scope description is included in the scope. Subject merchandise includes common alloy sheet that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the common alloy sheet.

Excluded from the scope of the investigation is aluminum can stock, which is suitable for use in the manufacture of aluminum beverage cans, lids of such cans, or tabs used to open such cans. Aluminum can stock is produced to gauges that range from 0.200 mm to 0.292 mm, and has an H–19, H–41, H–48, or H–391 temper. In addition, aluminum can stock has a lubricant applied to the flat surfaces of the can stock to facilitate its movement through machines used in the manufacture of beverage cans. Aluminum can stock is properly classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7606.12.3045 and 7606.12.3055.

Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set for the above.

Common alloy sheet is currently classifiable under HTSUS subheadings 7606.11.3060, 7606.11.6000, 7606.12.3090, 7606.12.6000, 7606.91.3090, 7606.91.6080, 7606.92.3090, and 7606.92.6080. Further, merchandise that falls within the scope of these investigation may also be entered into the United States under HTSUS subheadings 7606.11.3030, 7606.12.3030, 7606.91.3060, 7606.91.6040, 7606.92.3060, 7606.92.6040, 7607.11.9090. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2018–24867 Filed 11–14–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–932]

Certain Steel Threaded Rod From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that Jiaxing Brother Fastener Co., Ltd. (Jiaxing Brother), RMB Fasteners Ltd. (RMB), and IFI & Morgan Ltd. (IFI), collectively RMB/IFI, had no shipments during the period of review (POR), April 1, 2016, through March 31, 2017. We also continue to find that Fastenal Canada Ltd. (Fastenal Canada) did not cooperate to the best of its ability and have based its margin on adverse facts available (AFA) for these final results.

DATES: Applicable November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Paul Walker, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202.482.0413.

SUPPLEMENTARY INFORMATION:

Background

On May 17, 2018, Commerce published the *Preliminary Results* of the antidumping duty order on certain steel threaded rod (STR) from the People's Republic of China (China).[1] In accordance with 19 CFR 351.309, we invited parties to comment on our *Preliminary Results.* On June 18, 2018, RMB/IFI submitted its case brief.[2] On June 19, 2018, RMB/IFI re-submitted its case brief because the original brief inadvertently included certain proprietary information in one of the exhibits.[3] On June 26, 2018, the petitioner, Vulcan Threaded Products Inc., submitted its rebuttal brief.[4] On September 12, 2018, Commerce extended the deadline for the final

[1] *See Certain Steel Threaded Rod from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review, and Rescission of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 22945 (May 17, 2018) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* RMB/IFI's June 18, 2018 submission.

[3] *See* RMB/IFI's June 19, 2018 submission.

[4] The petitioner is Vulcan Threaded Products Inc. *See* the petitioner's June 26, 2018 submission.

results to November 8, 2018.[5] On September 19, 2018, Commerce rejected RMB/IFI's case brief because it contained new factual information.[6] In addition, on September 19, 2018, Commerce rejected the petitioner's rebuttal brief because it contained new argument which did not rebut any arguments made by RMB/IFI in its case brief.[7] On September 21, 2018, RMB/IFI refiled its case brief.[8] The petitioner did not refile its rebuttal brief. To complete the administrative record, Commerce requested that Jiaxing Brother submit a no shipments certification, if it had no shipments during the POR.[9] On October 31, 2018, Jiaxing Brother submitted a no shipments certification.[10]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the order includes steel threaded rod. The subject merchandise is currently classifiable under subheading 7318.15.5051, 7318.15.5056, 7318.15.5090, and 7318.15.2095 of the United States Harmonized Tariff Schedule (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order, which is contained in the accompanying Issues and Decision Memorandum (I&D Memo), is dispositive.[11]

Analysis of Comments Received

We addressed the issue raised in RMB/IFI's case brief in the I&D Memo dated concurrently with, and hereby adopted by, this notice. The issue it raised is attached in the Appendix to this notice. The I&D Memo is a public document and is on file in the Central Records Unit (CRU), Room B8024 of the main Commerce building, as well as electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the CRU. In addition, a complete version of the I&D Memo can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed I&D Memo and the electronic versions of the I&D Memo are identical in content.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that RMB/IFI did not have any reviewable transactions during the POR. For these final results, we continue to find that Jiaxing Brother is a part of RMB/IFI,[12] and that Jiaxing Brother Standard Part Co., Ltd. is a ''doing-business-as'' name for Jiaxing Brother.[13] Moreover, consistent with Commerce's assessment practice in non-market economy (NME) cases, we completed the review with respect to RMB/IFI. Based on our analysis of the record information, including CBP information, we continue to determine that RMB/IFI (a single entity that includes Jiaxing Brother Standard Part Co., Ltd./Jiaxing Brother Fastener Co., Ltd.) did not have any shipments during the POR. As noted in the ''Assessment Rates'' section below, Commerce intends to issue appropriate instructions to CBP for the above-named companies based on the final results of this review.

Final Results

No interested party submitted comments on Commerce's preliminary determination to apply AFA to Fastenal Canada. Therefore, we have continued to apply AFA with respect to Fastenal Canada, and have continued to assign it an AFA rate of 206.00 percent. Moreover, we continue to find that Brother Holding Group Co. Ltd, and Zhejiang Morgan Brother Technology Co. Ltd. are a part of the China-wide entity and subject to its rate of 206.00 percent.[14] Although in the *Preliminary Results* we found Jiaxing Brother Standard Part Co., Ltd. to be a part of the China-wide entity, for these final results, and as noted above, we find this company to be a part of RMB/IFI (which had no shipments during the POR), and that it is not a part of the China-wide entity.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review. Commerce will assess duties only on entries of subject merchandise (*i.e.,* Chinese-origin STR).

Pursuant to Commerce's assessment practice, because we found it had no shipments, for all entries claiming RMB/IFI as the exporter or producer, Commerce will direct CBP to liquidate such entries and to assess antidumping duties pursuant to the *Reseller Policy, i.e.,* at the rate for the China-wide entity.[15]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this

[5] *See* Memorandum to James Maeder, Associate Deputy Assistant Secretary, from James C. Doyle, Director, ''Certain Steel Threaded Rod from the People's Republic of China: Extension of Deadline for Final Results of 2016–2017 Antidumping Duty Administrative Review,'' dated September 12, 2018.

[6] *See* Commerce's letter to RMB/IFI dated September 19, 2018.

[7] *See* Commerce's letter to the petitioner dated September 19, 2018.

[8] *See* RMB/IFI's September 21, 2018 submission (RMB/IFI's Case Brief).

[9] *See* Commerce's memo to the File, October 29, 2018.

[10] *See* RMB/IFI's October 31, 2018 submission.

[11] For a full description of the scope of the order, *see* Memorandum from James Maeder, Associate Deputy Assistant Secretary, to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Certain Steel Threaded Rod from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Eighth Administrative Review'' (I&D Memo), dated concurrently with, and hereby adopted by, this notice.

[12] Commerce determined that Jiaxing Brother, RMB and IFI constituted a single entity in the investigation on steel threaded rod from China. *See Certain Steel Threaded Rod from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 73 FR 58931, 58932 (October 8, 2008), unchanged in *Certain Steel Threaded Rod from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 8907 (February 27, 2009). We have received no information in this review to call into question that finding and therefore continue to treat them as a single entity for purposes of this review.

[13] *See, e.g., Certain Steel Threaded Rod From the People's Republic of China: Preliminary Results and Partial Rescission of the Antidumping Duty Administrative Review; 2014–2015,* 81 FR 29843 (May 13, 2016) and accompanying PDM at 1, 2, unchanged in *Certain Steel Threaded Rod from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 83800 (November 22, 2016) and accompanying IDM at 2; *see also* RMB/IFI's October 31, 2018 submission.

[14] The rate for the China-wide entity was set in the investigation, *see Certain Steel Threaded Rod from the People's Republic of China: Final Determination of Sales at Less than Fair Value,* 74 FR 8907 (February 27, 2009). This rate has been applied in each subsequent administrative review in which there was a party considered as part of the China-wide entity. Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013). Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, the entity is not under review and the entity's rate is not subject to change.

[15] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) (*Reseller Policy*).

administrative review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For Fastenal Canada's Chinese-origin merchandise, the cash deposit rate will be 206.00 percent; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all Chinese exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the China-wide rate of 206.00 percent; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporters that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with the final results within five days of its public announcement, or if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because Commerce has not calculated a weighted-average dumping margin for any respondent, there are no calculations to disclose.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h) and 351.221(b)(5).

Dated: November 7, 2018.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Issues and Decision Memorandum

[FR Doc. 2018–24942 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG233

Northeast Regional Stock Assessment Workshop and Stock Assessment Review Committee Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: NMFS and the Northeast Regional Stock Assessment Workshop (SAW) will convene the 66th SAW Stock Assessment Review Committee for the purpose of reviewing stock assessments of Summer Flounder and Striped Bass. The Northeast Regional SAW is a formal scientific peer-review process for evaluating and presenting stock assessment results to managers for fish stocks in the offshore U.S. waters of the northwest Atlantic. Assessments are prepared by SAW working groups and reviewed by an independent panel of stock assessment experts called the Stock Assessment Review Committee, or SARC. The public is invited to attend the presentations and discussions between the review panel and the scientists who have participated in the stock assessment process.

DATES: The public portion of the Stock Assessment Review Committee Meeting will be held from November 27, 2018–November 30, 2018. The meeting will commence on November 27, 2018 at 10 a.m. Eastern Standard Time. Please see **SUPPLEMENTARY INFORMATION** for the daily meeting agenda.

ADDRESSES: The meeting will be held in the S.H. Clark Conference Room in the Aquarium Building of the National Marine Fisheries Service, Northeast Fisheries Science Center (NEFSC), 166 Water Street, Woods Hole, MA 02543.

FOR FURTHER INFORMATION CONTACT: James Weinberg, 508–495–2352; email: *james.weinberg@noaa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please visit the NEFSC website at *http://www.nefsc.noaa.gov.* For additional information about the SARC meeting and the stock assessment review, please visit the NMFS/NEFSC SAW web page at *http://www.nefsc.noaa.gov/saw/.*

Daily Meeting Agenda—SAW/SARC 66 Benchmark Stock Assessment for Summer Flounder and Striped Bass (Subject to Change; All Times Are Approximate and May Be Changed at the Discretion of the SARC Chair)

Tuesday, November 27, 2018

10 a.m.–10:45 a.m. Welcome Introductions, James Weinberg, SAW Chair; and Robert Latour, SARC Chair
10:45 a.m.–12:45 p.m. Summer Flounder Assessment Presentation, Mark Terceiro
12:45 p.m.–1:45 p.m. Lunch
1:45 p.m.–3:45 p.m. Summer Flounder Presentation (cont.), Mark Terceiro
3:45 p.m.–4 p.m. Break
4 p.m.–5:45 p.m. Summer Flounder SARC Discussion, Robert Latour, SARC Chair
5:45 p.m.–6 p.m. Public Comment Period

Wednesday, November 28, 2018

8:30 a.m.–10:30 a.m. Striped Bass Assessment Presentation, Katie Drew
10:30 a.m.–10:45 a.m. Break
10:45 a.m.–12:30 a.m. Striped Bass presentation (cont.), Katie Drew
12:30–1:30 p.m.—Lunch
1:30 p.m.–3:30 p.m. Striped Bass SARC Discussion, Robert Latour, SARC Chair
3:30 p.m.–3:45 p.m. Public comments
3:45 p.m.–4 p.m. Break
4 p.m.–6 p.m. Revisit with Presenters (Summer Flounder), Robert Latour, SARC Chair

Thursday, November 29, 2018

8:30 a.m.–10:30 a.m. Revisit with Presenters (Striped Bass), Robert Latour, SARC Chair

10:30 a.m.–10:45 a.m. Break
10:45 a.m.–12:15p.m. Review/Edit Assessment Summary Report (Summer Flounder), Robert Latour, SARC Chair
12:15–1:15 p.m. Lunch
1:15 p.m.–2:45 p.m. Review/Edit Assessment Summary Report (Summer Flounder), Robert Latour, SARC Chair
2:45 p.m.–3 p.m. Break
3 p.m.–6 p.m. Review/Edit Assessment Summary Report (Striped Bass), Robert Latour, SARC Chair

Friday, November 30, 2018

9 a.m.–5 p.m. SARC Report Writing

The meeting is open to the public; however, during the 'SARC Report Writing' session on Friday November 30th the public should not engage in discussion with the SARC.

Special Accommodations

This meeting is physically accessible to people with disabilities. Special requests should be directed to James Weinberg at the NEFSC, 508–495–2352, at least 5 days prior to the meeting date.

Dated: November 2, 2018.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–24956 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG559

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Boost-Back and Landing of Falcon 9 Rockets

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from Space Exploration Technology Corporation (SpaceX) for authorization to take marine mammals incidental to boost-back and landing of Falcon 9 rockets at Vandenberg Air Force Base (VAFB) in California, and at contingency landing locations in the Pacific Ocean. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in *Request for Public Comments* at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than December 17, 2018.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Fowler@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process

or making a final decision on the IHA request.

Summary of Request

On August 30, 2018, NMFS received a request from SpaceX for an IHA to take marine mammals incidental to Falcon 9 First Stage recovery activities, including in-air boost-back maneuvers and landings of the First Stage of the Falcon 9 rocket at VAFB in California, and at contingency landing locations offshore. A revised application was received October 23, 2018. NMFS deemed that request to be adequate and complete. SpaceX's request is for take of a small number of six species by Level B harassment only. Neither SpaceX nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS has previously issued regulations and Letters of Authorization (LOA) that authorize the take of marine mammals, by Level B harassment, incidental to launches of up to 50 rockets per year (including the Falcon 9) from VAFB (79 FR 18528; April 2, 2014). The regulations, titled *Taking of Marine Mammals Incidental to U.S. Air Force Launches, Aircraft and Helicopter Operations, and Harbor Activities Related to Vehicles from Vandenberg Air Force Base, California,* published February 24, 2014, are effective from March 2014 to March 2019. The activities proposed by SpaceX are limited to Falcon 9 First Stage recovery events (Falcon 9 boost-back maneuvers and landings); launches of the Falcon 9 rocket are not part of the proposed activities, and incidental take (Level B harassment) resulting from Falcon 9 rocket launches from VAFB is already authorized in the above referenced LOA. As such, NMFS does not propose to authorize take of marine mammals incidental to launches of the Falcon 9 rocket in this IHA; incidental take resulting from Falcon 9 rocket launches is therefore not analyzed further in this document. The LOA application (USAF 2013a), and links to the **Federal Register** notice of the final rule (79 FR 10016; February 24, 2014) and the **Federal Register** notice of issuance of the LOA (79 FR 18528; April 2, 2014), can be found online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* After the expiration of the existing LOA for VAFB, NMFS anticipates that the entire suite of SpaceX's Falcon 9 activities at VAFB (Falcon 9 rocket launches and First Stage boost-backs and landings) will be incorporated into future authorizations for VAFB.

Additionally, NMFS has previously issued two IHAs to SpaceX for similar activities (81 FR 34984, June 1, 2016; 82 FR 60954, December 26, 2017). SpaceX complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHAs and information regarding their monitoring results may be found in the *Estimated Take* section.

Description of Proposed Activity

Overview

The Falcon 9 is a two-stage rocket designed and manufactured by SpaceX for transport of satellites and SpaceX's Dragon spacecraft into orbit. SpaceX currently operates the Falcon Launch Vehicle Program at Space Launch Complex 4 East (SLC–4E) at VAFB. SpaceX proposes regular employment of First Stage recovery by returning the Falcon 9 First Stage to SLC–4 West (SLC–4W) at VAFB for potential reuse, up to twelve times per year. This includes performing boost-back maneuvers (in-air) and landings of the Falcon 9 First Stage on the pad at SLC–4W. The reuse of the Falcon 9 First Stage enables SpaceX to efficiently conduct lower cost launch missions from VAFB in support of commercial and government clients.

During descent, a sonic boom (overpressure of high-energy impulsive sound) would be generated when the First Stage reaches a rate of travel that exceeds the speed of sound. Sonic booms would occur in proximity to the landing areas and may be heard during or after the boost-back and landing, depending on the location of the observer. Sound from the sonic boom would have the potential to result in harassment of marine mammals, either on the mainland at or near VAFB or at the Northern Channel Islands (NCI), as described in more detail later in this document.

Dates and Duration

SpaceX's activities are conducted throughout the year. Up to twelve Falcon 9 First Stage recovery activities would occur per year. Precise dates of Falcon 9 First Stage recovery activities are not known. Falcon 9 First Stage recovery activities may take place at any time of year and at any time of day. The IHA, if issued, would be valid for one year from the date of issuance.

Specific Geographic Region

Falcon 9 First Stage recovery activities will originate at VAFB. Areas potentially affected include VAFB, areas on the coastline surrounding VAFB, and the NCI. VAFB operates as a missile test base and aerospace center, supporting west coast space launch activities for the U.S. Air Force (USAF), Department of Defense, National Aeronautics and Space Administration, and commercial contractors. VAFB is the main west coast launch facility for placing commercial government, and military satellites into polar orbit on expendable (unmanned) launch vehicles, and for testing and evaluating intercontinental ballistic missiles and sub-orbital target and interceptor missiles.

VAFB occupies approximately 99,100 acres of central Santa Barbara County, California. VAFB is divided by the Santa Ynez River and State Highway 246 into two distinct parts: North Base and South Base. SLC–4W, the preferred landing location for the Falcon 9 First Stage, is located on South Base, approximately 0.5 miles (mi) (0.8 kilometers (km)) inland from the Pacific Ocean (see Figure 1–2 in the IHA application). SLC–4E, the launch facility for SpaceX's Falcon 9 program, is located approximately 715 feet (ft) (218 meters (m)) to the east of SLC–4W.

Although SLC–4W is the preferred landing location for the Falcon 9 First Stage, SpaceX has identified two contingency landing locations should it not be feasible to land the First Stage at SLC–4W. The first contingency landing location is on a barge located at least 27 nautical miles (nmi) (50 km) offshore of VAFB. The second contingency landing location is on a barge within the Iridium Landing Area, an approximately 12,800 square mile (mi^2) (33,153 square kilometers (km^2)) area located approximately 122 nmi (225 km) southwest of San Nicolas Island and 133 nmi (245 km) southwest of San Clemente Island (see Figure 1–3 in the IHA application). The NCI are also considered part of the project area for the purposes of this proposed authorization, as landings at VAFB could result in sonic booms that impact the NCI. The NCI are four islands (San Miguel, Santa Rosa, Santa Cruz, and Anacapa) located approximately 31 mi (50 km) south of Point Conception, which is located on the mainland approximately 4 mi (6.5 km) south of the southern border of VAFB. The closest part of the NCI to VAFB (Harris Point on San Miguel Island) is located more than 34 mi (55 km) south-southeast of SLC–4E, the launch facility for the Falcon 9 rocket.

Detailed Description of Specific Activity

The Falcon 9 is a two-stage rocket designed and manufactured by SpaceX for transport of satellites into orbit. The First Stage of the Falcon 9 is designed to be reusable, while the second stage is not reusable. The Falcon 9 First Stage is

12 ft (3.7 m) in diameter and 160 ft (48.8 m) in height, including the interstage that would remain attached during landing. The proposed action includes up to twelve Falcon 9 First Stage recoveries, including in-air boost-back maneuvers and landings of the First Stage, at VAFB or at a contingency landing location as described above.

After launch of the Falcon 9, the boost-back and landing sequence begins when the rocket's First Stage separates from the second stage and the Merlin engines of the First Stage cut off. After First Stage engine cutoff, rather than dropping the First Stage in the Pacific Ocean, exoatmospheric cold gas thrusters would be triggered to flip the First Stage into position for retrograde burn. Three of the nine First Stage Merlin engines would be restarted to conduct the retrograde burn in order to reduce the velocity of the First Stage and to place the First Stage in the correct angle to land. Once the First Stage is in position and approaching its landing target, the three engines would cut off to end the boost-back burn. The First Stage would then perform a controlled descent using atmospheric resistance to slow the stage down and guide it to the landing pad target. The First Stage is outfitted with grid fins that allow cross range corrections as needed. The landing legs on the First Stage would then deploy in preparation for a final single engine burn that would slow the First Stage to a velocity of zero before landing on the landing pad at SLC–4W.

Sonic Boom

During descent, a sonic boom (overpressure of high-energy impulsive sound) would be generated when the First Stage reaches a rate of travel that exceeds the speed of sound. Sonic booms would occur in proximity to the landing area with the highest sound levels generated from sonic booms generally focused in the direction of the landing area, and may be heard during or briefly after the boost-back and landing, depending on the location of the receiver. Sound from the sonic booms would have the potential to result in harassment of marine mammals, as described in greater detail later in this document. Based on model results, a boost-back and landing of the Falcon 9 First Stage at SLC–4W would produce sonic booms with overpressures that would potentially be as high as 8.5 pounds per square foot (psf) at VAFB and potentially as high as 3.1 psf at the NCI (see Figures 2–2 and 2–5 in the IHA application). Sonic boom modeling indicates that landings that occur at either of the proposed contingency landing locations offshore would result in sonic booms with received overpressures below 1.0 psf at VAFB and the NCI. Take of pinnipeds that are hauled out of the water are expected to occur only when those hauled out pinnipeds experience sonic booms greater than 1.0 psf (discussed in greater detail below in the *Estimated Take* section). Therefore, take of marine mammals may occur as a result of landings that occur at VAFB; however, take of marine mammals is not expected to occur as a result of landings that occur at either of the proposed contingency landing locations offshore. Please see Figure 1–4 in the IHA application for a graphical depiction of the boost-back and landing sequence, and see Figure 1–5 in the IHA application for an example of the boost-back trajectory of the First Stage and the second stage trajectory.

As a contingency action to landing the Falcon 9 First Stage on the SLC–4W pad at VAFB, SpaceX proposes to return the Falcon 9 First Stage booster to a barge in the Pacific Ocean (Figure 1–6 in the IHA application). The maneuvering and landing process described above for a pad landing would be the same for a barge landing. Three vessels would be required to support a barge landing, if it were required: A barge/landing platform (300 ft (91 m) long and 150 ft (46 m) wide); a support vessel (165 ft (50 m) long research vessel); and an ocean tug (120 ft (37 m) long open water commercial tug).

Landing Noise

Landing noise would be generated during each boost-back event. SpaceX proposes to use a three-engine burn during landing. This engine burn, lasting approximately 17 seconds, would generate noise between 70 and 110 decibels (dB) re 20 micro Pascals (μPa) (non-pulse, in-air noise) centered on SLC–4W, but affecting an area up to 15 nmi (27.8 km) offshore of VAFB (Figure 2–10 in the IHA application). This landing noise event would be of short duration (approximately 17 seconds). Although, during a landing event at SLC–4W, landing noise between 70 and 90 dB would be expected to overlap pinniped haulout areas at and near Point Arguello and Purisima Point, no pinniped haulouts would experience landing noises of 90 dB or greater (see Figure 2–10 in the IHA application).

NMFS's recommended acoustic thresholds for in-air acoustic impacts assume that Level B harassment of harbor seals may occur at 90 dB root mean square (rms) re 20 μPa and Level B harassment of all other pinnipeds may occur at 100 dB rms re 20 μPa. Therefore, harassment of marine mammals hauled out at VAFB from engine noise generated during landings is not expected to occur. Engine noise would also be produced during a contingency barge landing of the Falcon 9 First Stage. Engine noise during a barge landing is expected to be between 70 and 110 dB re 20 μPa affecting a radial area up to 15 nmi (27.8 km) around the contingency landing location (Figure 2–11 in the IHA application) and the Iridium 38 Landing Area (Figure 2–12 in the IHA application). No pinniped haulouts are located within the areas predicted to experience engine noise of 90 dB and above during Falcon 9 First Stage landings at contingency landing locations and the Iridium Landing Area (Figures 2–11 and 2–12 in the IHA application). Therefore, the likelihood of engine noise associated with the landing of the Falcon 9 First Stage resulting in take of marine mammals is considered so low as to be discountable, and landing noise is therefore not discussed further in this document.

Unsuccessful Barge Landing

In the event of an unsuccessful barge landing, the First Stage would explode upon impact with the barge. The direct sound from an explosion would last less than a second. Furthermore, the proposed activities would be dispersed in time, with maximum of twelve barge landing attempts occurring within a twelve month time period. If an explosion occurred on the barge, as in the case of an unsuccessful barge landing attempt, some amount of the explosive energy would be transferred through the ship's structure and would enter the water and propagate away from the ship.

There is very little published literature on the ratio of explosive energy that is absorbed by a ship's hull versus the amount of energy that is transferred through the ship into the water. However, based on the best available information, we have determined that exceptionally little of the acoustic energy from the explosion would transmit into the water (Yagla and Stiegler, 2003). An explosion on the barge would create an in-air blast that propagates away in all directions, including toward the water's surface; however the barge's deck would act as a barrier that would attenuate the energy directed downward toward the water (Yagla and Stiegler, 2003). Most sound enters the water in a narrow cone beneath the sound source (within 13 degrees of vertical) (National Research Council 2003). Since the explosion

would occur on the barge, most of this sound would be reflected by the barge's surface, and sound waves would approach the water's surface at angles higher than 13 degrees, minimizing transmission into the ocean. An explosion on the barge would also send energy through the barge's structure, into the water, and away from the barge. This effect was investigated in conjunction with the measurements described in Yagla and Steigler (2003). Yagla and Steigler (2003) reported that the energy transmitted through a ship to the water for the firing of a typical 5-inch round was approximately six percent of that from the in-air blast impinging on the water (Yagla and Stiegler, 2003). Therefore, sound transmitted from the blast through the hull into the water was a minimal component of overall firing noise, and would likewise be expected to be a minimal component of an explosion occurring on the surface of the barge.

Depending on the amount of fuel remaining in the booster at the time of the explosion, the intensity of the explosion would likely vary. Based on previous Falcon 9 boost-back and landing activities, the explosive equivalence of the First Stage with maximum fuel and oxidizer would be expected to be approximately 500 lb. of trinitrotoluene (TNT). Explosion shock theory has proposed specific relationships for the peak pressure and time constant in terms of the charge weight and range from the detonation position (Pater 1981; Plotkin *et al.* 2012). For an in-air explosion equivalent to 500 lb. of TNT, at 0.5 ft the explosion would be approximately 250 dB re 20 μPa. Based on the assumption that the structure of the barge would absorb and reflect approximately 94 percent of this energy, with approximately 6 percent of the energy from the explosion transmitted into the water (Yagla and Stiegler 2003), the amount of energy that would be transmitted into the water would be far less than the threshold for Level B harassment for marine mammals based on NMFS's current acoustic criterion for in-water explosive noise (160 dB re 1 μPa). As a result, the likelihood of in-water sound generated by an explosion of the Falcon 9 First Stage during an unsuccessful barge landing attempt resulting in take of marine mammals is considered so low as to be discountable and is therefore not discussed further in this document.

As discussed above, in the event of an unsuccessful contingency landing attempt, the First Stage would be expected to explode upon impact with the barge. SpaceX has experience performing recovery operations after water and unsuccessful barge landings for previous Falcon 9 First Stage landing attempts. This experience, in addition to the debris catalog that identifies all floating debris, has revealed that approximately 25 pieces of debris remain floating after an unsuccessful barge landing. The approximately 25 pieces of debris would primarily be made of Carbon Over Pressure Vessels (COPVs), the liquid oxygen fill line, and carbon fiber constructed legs. The vast majority of debris would be recovered. All other debris is expected to sink to the bottom of the ocean. Denser debris that would not float on the surface would sink relatively quickly and is composed of inert materials which would not affect water quality or bottom substrate potentially used by marine mammals. The rate of deposition would vary with the type of debris; however, none of the debris is so dense or large that benthic habitat would be meaningfully degraded.

The surface area potentially impacted with debris would be expected to be less than 0.46 km^2. Since the area impacted by debris is very small, the likelihood of adverse effects to marine mammals is very low. During previous landing attempts in other locations, SpaceX has performed successful debris recovery. All of the recovered debris would be transported back to Long Beach Harbor for proper disposal. Most of the fuel remaining in the First Stage would be released onto the barge deck at the location of impact. Therefore, the likelihood of take of marine mammals as a result of contact with exploded First Stage materials is considered so low as to be discountable, and explosion of the Falcon 9 First Stage is therefore not discussed further in this document.

In the event that a contingency landing action is required, there is the potential that the Falcon 9 First Stage would miss the barge entirely and land instead in the ocean. However, the likelihood of the First Stage missing the barge entirely and landing in the Pacific Ocean is considered so unlikely as to be discountable. This is supported by several previous attempts by SpaceX at Falcon 9 First Stage barge landings, none of which have missed the barge. Therefore, the likelihood of take of marine mammals associated with a Falcon 9 First Stage landing in the ocean is considered so low as to be discountable, and landing of the Falcon 9 First Stage in the ocean is not considered further in this document.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see *Proposed Mitigation* and *Proposed Monitoring and Reporting*).

Description of Marine Mammals in the Area of Specified Activities

There are six marine mammal species with expected occurrence in the project area (including at VAFB, on the NCI, and in the waters surrounding VAFB, the NCI and the contingency landing location) that are expected to be affected by the specified activities. These include the Steller sea lion (*Eumetopias jubatus*), northern fur seal (*Callorhinus ursinus*), northern elephant seal (*Mirounga angustirostris*), Guadalupe fur seal (*Arctocephalus philippii townsendi*), California sea lion (*Zalophus californianus*), and Pacific harbor seal (*Phoca vitulina richardii*). This section provides summary information regarding local occurrence of these species. We have reviewed SpaceX's detailed species descriptions, including life history information, for accuracy and completeness and refer the reader to Section 3 of SpaceX's IHA application, as well as to NMFS's Stock Assessment Reports (SAR; *https://www.fisheries.noaa.gov/topic/population-assessments#marine-mammals*), rather than reprinting all of the information here. Additional general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

There are an additional 28 species of cetaceans with expected or possible occurrence in the project area. However, we have determined that the only potential stressor associated with the activity that could result in take of marine mammals (sonic booms) only has the potential to result in harassment of marine mammals that are hauled out of the water (*i.e.,* pinnipeds). Therefore, we have concluded that the likelihood of the proposed activities resulting in the harassment of any cetacean to be so low as to be discountable. As we have concluded that the likelihood of any cetacean being taken incidentally as a result of SpaceX's proposed activities to be so low as to be discountable, cetaceans are not considered further in this proposed authorization. Please see Table 3–1 in SpaceX's IHA application for a complete list of species with expected or potential occurrence in the project area.

Table 1 lists all species with expected potential for occurrence in the vicinity of the project during the project timeframe that are likely to be affected by the specified activities, and summarizes information related to the population or stock, including

regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2017). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Pacific and Alaska SARs (*e.g.,* Carretta *et al.,* 2018; Muto *et al.,* 2018). All values presented in Table 1 are the most recent available at the time of publication and are available in the 2017 SARs (Carretta *et al.,* 2018; Muto *et al.,* 2018) and draft 2018 SARs (available online at: *https://www.fisheries.noaa.gov/topic/population-assessments#marine-mammals*).

TABLE 1—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN THE PROJECT AREA

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California sea lion	*Zalophus californianus*	U.S.	-; N	257,606 (n/a, 233,515, 2014).	14,011	≥197
Northern fur seal	*Callorhinus ursinus*	California	-; N	14,050 (n/a, 7,524, 2013)	451	≥0.8
Steller sea lion	*Eumetopias jubatus*	Eastern U.S.	-; N	41,638 (n/a, 41,638, 2015).	2,498	108
Guadalupe fur seal	*Arctocephalus philippii*	Mexico	T/D; Y	20,000 (n/a, 15,830, 2010).	542	≥3.2
Family Phocidae (earless seals):						
Pacific harbor seal	*Phoca vitulina richardii*	California	-; N	30,968 (n/a, 27,348, 2012).	1,641	30
Northern elephant seal	*Mirounga angustirostris*	California breeding	-; N	179,000 (n/a, 81,368, 2010).	4,882	4

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/topic/population-assessments#marine-mammals.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

All species that could potentially occur in the proposed survey areas are included in Table 1. As described below, all six species (with six managed stocks) temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing it.

Pacific Harbor Seal

Harbor seals inhabit coastal and estuarine waters and shoreline areas of the northern hemisphere from temperate to polar regions. The eastern North Pacific subspecies is found from Baja California north to the Aleutian Islands and into the Bering Sea. Multiple lines of evidence support the existence of geographic structure among harbor seal populations from California to Alaska (Carretta *et al.,* 2016). However, because stock boundaries are difficult to meaningfully draw from a biological perspective, three separate harbor seal stocks are recognized for management purposes along the west coast of the continental United States: (1) Washington inland waters (2) Oregon and Washington coast, and (3) California (Carretta *et al.,* 2016). In addition, harbor seals may occur in Mexican waters, but these animals are not considered part of the California stock. Only the California stock is considered in this proposed authorization due to the distribution of the stock and the geographic scope of the proposed activities. Although the need for stock boundaries for management is real and is supported by biological information, it should be noted that the exact placement of a boundary between California and Oregon for stock delineation purposes was largely a political/jurisdictional convenience (Carretta *et al.* 2015).

Pacific harbor seals are nonmigratory, with local movements associated with such factors as tides, weather, season, food availability, and reproduction (Scheffer and Slipp 1944, Fisher 1952, Bigg 1969, 1981, Hastings *et al.* 2004). In California, over 500 harbor seal haulout sites are widely distributed along the mainland and offshore islands, and include rocky shores, beaches and intertidal sandbars (Lowry *et al.* 2005). Harbor seals mate at sea and females give birth during the spring and summer, though the pupping season varies with latitude. Harbor seal pupping takes place at many locations and rookery size varies from a few pups to many hundreds of pups.

Harbor seals are the most common marine mammal inhabiting VAFB, congregating on multiple rocky haulout sites along the VAFB coastline. Biologists from the Center for Environmental Management of Military Lands (CEMML) and 30 SW, 30th Civil Engineer Squadron (30 CES) survey marine mammal haulout sites on VAFB on a monthly basis (CEMML 2018). There are 12 harbor seal haulout sites on south VAFB; of these, 10 sites represent an almost continuous haulout area which is used by the same animals.

Virtually all of the haulout sites at VAFB are used during low tides and are wave-washed or submerged during high tides. Additionally, the harbor seal is the only species that regularly hauls out near the VAFB harbor (CEMML 2018). The main harbor seal haulouts on VAFB are near Purisima Point and at Lion's Head (approximately 0.6 km south of Point Sal) on north VAFB and between the VAFB harbor north to South Rocky Point Beach on south VAFB (ManTech 2009).

Pups are generally present in the region from March through July. Within the affected area on VAFB, a total of up to 332 adults and 34 pups have been recorded, at all haulouts combined, in monthly counts from 2013 to 2015 (ManTech 2015). Harbor seals also haul out, breed, and pup in isolated beaches and coves throughout the coasts of San Miguel, Santa Rosa, and Santa Cruz Islands (Lowry 2002). During aerial surveys conducted by NMFS in May 2002 and May and June of 2004, between 521 and 1,004 harbors seals were recorded at San Miguel Island, between 605 and 972 at Santa Rosa Island, and between 599 and 1,102 at Santa Cruz Island (M. Lowry, NOAA Fisheries, unpubl. data).

The harbor seal population at VAFB has undergone an apparent decline in recent years (USAF 2013b). This decline has been attributed to a series of natural landslides at south VAFB, resulting in the abandonment of many haulout sites. These slides have also resulted in extensive down-current sediment deposition, making these sites accessible to coyotes, which are now regularly seen in the area. Some of the displaced seals have moved to other sites at south VAFB, while others likely have moved to Point Conception, about 6.5 km south of the southern boundary of VAFB. Additionally, at one haulout, harbor seals have been displaced by elephant seals, who have begun using the haulout for giving birth (CEMML 2018).

Pacific harbor seals frequently use haulout sites on the NCI, including San Miguel, Santa Rosa, Santa Cruz, and Anacapa islands. On San Miguel Island, they occur along the north coast at Tyler Bight and from Crook Point to Cardwell Point. Additionally, they regularly breed on San Miguel Island. On Santa Cruz Island, they inhabit small coves and rocky ledges along much of the coast. Harbor seals are scattered throughout Santa Rosa Island and also are observed in small numbers on Anacapa Island.

California Sea Lion

California sea lions range from the Gulf of California north to the Gulf of Alaska, with breeding areas located in the Gulf of California, western Baja California, and southern California. Five genetically distinct geographic populations have been identified: (1) Pacific Temperate, (2) Pacific Subtropical, (3) Southern Gulf of California, (4) Central Gulf of California, and (5) Northern Gulf of California (Schramm *et al.,* 2009). Rookeries for the Pacific Temperate population are found within U.S. waters and just south of the U.S.-Mexico border, and animals belonging to this population may be found from the Gulf of Alaska to Mexican waters off Baja California. Animals belonging to other populations (*e.g.,* Pacific Subtropical) may range into U.S. waters during non-breeding periods. For management purposes, a stock of California sea lions comprising those animals at rookeries within the United States is defined (*i.e.,* the U.S. stock of California sea lions) (Carretta *et al.,* 2017). The carrying capacity of the stock was estimated at 275,298 animals in 2014 (Laake *et al.,* 2018).

Beginning in January 2013, elevated strandings of California sea lion pups were observed in southern California, with live sea lion strandings nearly three times higher than the historical average. Findings to date indicate that a likely contributor to the large number of stranded, malnourished pups was a change in the availability of sea lion prey for nursing mothers, especially sardines. The Working Group on Marine Mammal Unusual Mortality Events determined that the ongoing stranding event meets the criteria for an Unusual Mortality Event (UME) and declared California sea lion strandings from 2013 through 2017 to be one continuous UME. The causes and mechanisms of this event remain under investigation. For more information on the UME, see: *https://www.fisheries.noaa.gov/national/marine-life-distress/2013-2017-california-sea-lion-unusual-mortality-event-california.*

Rookery sites in southern California are limited to San Miguel Island and the southerly Channel Islands of San Nicolas, Santa Barbara, and San Clemente (Carretta *et al.,* 2015). Males establish breeding territories during May through July on both land and in the water. Females come ashore in mid-May and June where they give birth to a single pup approximately four to five days after arrival and will nurse pups for about a week before going on their first feeding trip. Adult and juvenile males will migrate as far north as British Columbia, Canada while females and pups remain in southern California waters in the non-breeding season. In warm water (El Niño) years, some females are found as far north as Washington and Oregon, presumably following prey.

California sea lions are common offshore of VAFB and haul out on rocks and beaches along the coastline of VAFB. At south VAFB, California sea lions haul out on north Rocky Point, with numbers often peaking in spring. They have been reported at Point Arguello and Point Pedernales (both on south VAFB) in the past, although none have been noted there over the past several years. Individual sea lions have been noted hauled out throughout the VAFB coast; these were transient or stranded specimens. They regularly haul out on Lion Rock, north of VAFB and immediately south of Point Sal, and occasionally haul out on Point Conception, south of VAFB. In 2014, counts of California sea lions at haulouts on VAFB ranged from 47 to 416 during monthly counts. Despite their prevalence at haulout sites at VAFB, California sea lions rarely pup on the VAFB coastline (ManTech 2015); no pups were observed in 2013 or 2014 (ManTech 2015) and 1 pup was observed in 2015 (VAFB, unpubl. data).

Pupping occurs in large numbers on San Miguel Island at the rookeries found at Point Bennett on the west end of the island and at Cardwell Point on the east end of the island (Lowry 2002). Sea lions haul out at the west end of Santa Rosa Island at Ford Point and Carrington Point. A few California sea lions have been born on Santa Rosa Island, but no rookery has been established. On Santa Cruz Island, California sea lions haul out from Painted Cave almost to Fraser Point, on the west end. Fair numbers haul out at Gull Island, off the south shore near Punta Arena. Pupping appears to be increasing there. Sea lions also haul out near Potato Harbor, on the northeast end of Santa Cruz. California sea lions haul out by the hundreds on the south side of East Anacapa Island.

During aerial surveys conducted by NMFS in February 2010 of the NCI, 21,192 total California sea lions (14,802 pups) were observed at haulouts on San Miguel Island and 8,237 total (5,712 pups) at Santa Rosa Island (M. Lowry, NOAA Fisheries, unpubl. data). During aerial surveys in July 2012, 65,660 total California sea lions (28,289 pups) were recorded at haulouts on San Miguel Island, 1,584 total (3 pups) at Santa Rosa Island, and 1,571 total (zero pups) at Santa Cruz Island (M. Lowry, NOAA Fisheries, unpubl. data).

Northern Elephant Seal

Northern elephant seals range in the eastern and central North Pacific Ocean,

from as far north as Alaska and as far south as Mexico. They spend much of the year, generally about nine months, in the open ocean. They spend much of their lives underwater, diving to depths of about 1,000 to 2,500 ft (330–800 m) for 20- to 30-minute intervals with only short breaks at the surface, and are rarely seen at sea for this reason. Northern elephant seals breed and give birth in California and Baja California (Mexico), primarily on offshore islands, from December to March (Stewart *et al.* 1994). Adults return to land between March and August to molt, with males returning later than females. Adults return to their feeding areas again between their spring/summer molting and their winter breeding seasons.

Populations of northern elephant seals in the U.S. and Mexico are derived from a few tens or hundreds of individuals surviving in Mexico after being nearly hunted to extinction (Stewart *et al.,* 1994). Given the recent derivation of most rookeries, no genetic differentiation would be expected. Although movement and genetic exchange continues between rookeries, most elephant seals return to their natal rookeries when they start breeding (Huber *et al.,* 1991). The California breeding population is now demographically isolated from the Baja California population and is considered to be a separate stock.

Northern elephant seals haul out sporadically on rocks and beaches along the coastline of VAFB; monthly counts in 2013 and 2014 recorded between 0 and 191 elephant seals within the affected area (ManTech 2015) and northern elephant seal pupping at VAFB was documented for the first time in January 2017 (Pers. comm., R. Evans, USAF, to J. Carduner, NMFS, February 1, 2017). The nearest regularly used haulout site on the mainland coast is at Point Conception. Eleven northern elephant seals were observed during aerial surveys of the Point Conception area by NMFS in February of 2010 (M. Lowry, NOAA Fisheries, unpubl. data).

Point Bennett on the west end of San Miguel Island is the primary northern elephant seal rookery in the NCI, with another rookery at Cardwell Point on the east end of San Miguel Island (Lowry 2002). They also pup and breed on Santa Rosa Island, mostly on the west end. Northern elephant seals are rarely seen on Santa Cruz and Anacapa Islands. During aerial surveys of the NCI conducted by NMFS in February 2010, 21,192 total northern elephant seals (14,802 pups) were recorded at haulouts on San Miguel Island and 8,237 total (5,712 pups) were observed at Santa Rosa Island (M. Lowry, NOAA Fisheries, unpubl. data). None were observed at Santa Cruz Island (M. Lowry, NOAA Fisheries, unpubl. data).

Steller Sea Lion

Steller sea lions are distributed mainly around the coasts to the outer continental shelf along the North Pacific rim from northern Hokkaido, Japan through the Kuril Islands and Okhotsk Sea, Aleutian Islands and central Bering Sea, southern coast of Alaska and south to California (Loughlin *et al.,* 1984). The species as a whole was ESA-listed as threatened in 1990 (55 FR 49204, November 26, 1990). In 1997, the species was divided into western and eastern distinct population segments (DPS), with the western DPS reclassified as endangered under the ESA and the eastern DPS retaining its threatened listing (62 FR 24345, May 5, 2997). On October 23, 2013, NMFS found that the eastern DPS has recovered; as a result of the finding, NMFS removed the eastern DPS from ESA listing. Only the eastern DPS is considered in this proposed authorization due to its distribution and the geographic scope of the action.

Prior to 2012, there were no records of Steller sea lions observed at VAFB. In April and May 2012, Steller sea lions were observed hauled out at North Rocky Point on VAFB, representing the first time the species had been observed on VAFB during launch monitoring and monthly surveys conducted over the past two decades (Marine Mammal Consulting Group and Science Applications International Corporation 2013). Since 2012, Steller sea lions have been observed frequently in routine monthly surveys, with as many as 16 individuals recorded. In 2014, up to five Steller sea lions were observed in the affected area during monthly marine mammal counts (ManTech 2015) and a maximum of 12 individuals were observed during monthly counts in 2015 (VAFB, unpublished data). However, up to 16 individuals were observed in 2012 (SAIC 2012). Steller sea lions once had two small rookeries on San Miguel Island, but these were abandoned after the 1982–1983 El Niño event (DeLong and Melin 2000; Lowry 2002); these rookeries were once the southernmost colonies of the eastern stock of this species. In recent years, between two to four juvenile and adult males have been observed on a somewhat regular basis on San Miguel Island (pers. comm. Sharon Melin, NMFS Alaska Fisheries Science Center, to J. Carduner, NMFS, Feb 11, 2016). Steller sea lions are not observed on the other NCI.

Northern Fur Seal

Northern fur seals occur from southern California north to the Bering Sea and west to the Okhotsk Sea and Honshu Island, Japan. Due to differing requirements during the annual reproductive season, adult males and females typically occur ashore at different, though overlapping, times. Adult males occur ashore and defend reproductive territories during a three month period from June through August, though some may be present until November (well after giving up their territories). Adult females are found ashore for as long as six months (June–November). After their respective times ashore, fur seals of both sexes spend the next seven to eight months at sea (Roppel 1984). Peak pupping is in early July and pups are weaned at three to four months. Some juveniles are present year-round, but most juveniles and adults head for the open ocean and a pelagic existence until the next year. Northern fur seals exhibit high site fidelity to their natal rookeries. Two stocks of northern fur seals are recognized in U.S. waters: An eastern Pacific stock and a California stock (formerly referred to as the San Miguel Island stock). While animals from the eastern Pacific stock are known to travel as far south as Oregon and California (Muto *et al.,* 2018), only the California stock is considered in this proposed authorization due to its geographic distribution.

Northern fur seals have rookeries on San Miguel Island at Point Bennett and on Castle Rock. Comprehensive count data for northern fur seals on San Miguel Island are not available. San Miguel Island is the only island in the NCI on which northern fur seals have been observed. Although the population at San Miguel Island was established by individuals from Alaska and Russian Islands during the late 1960s, most individuals currently found on San Miguel are considered resident to the island. No haulout or rookery sites exist for northern fur seals on the mainland coast. The only individuals that appear on mainland beaches are stranded animals.

Guadalupe Fur Seal

Guadalupe fur seals are found along the west coast of the United States. They were abundant prior to seal exploitation, when they were likely the most abundant pinniped species on the Channel Islands, but are considered uncommon in Southern California. They are typically found on shores with abundant large rocks, often at the base of large cliffs (Belcher and Lee 2002).

Increased strandings of Guadalupe fur seals started occurring along the entire coast of California in early 2015. This event was declared a marine mammal UME. Strandings were eight times higher than the historical average, peaking from April through June 2015, and have since lessened but continue at a rate that is well above average. Most stranded individuals have been weaned pups and juveniles (1–2 years old). For more information on this ongoing UME, see: *https://www.fisheries.noaa.gov/national/marine-life-distress/2015-2018-guadalupe-fur-seal-unusual-mortality-event-california.*

Comprehensive survey data on Guadalupe fur seals in the NCI is not readily available. On San Miguel Island, one to several male Guadalupe fur seals had been observed annually between 1969 and 2000 (DeLong and Melin 2000) and juvenile animals of both sexes have been seen occasionally over the years (Stewart *et al.* 1987). The first adult female at San Miguel Island was seen in 1997. In June 1997, she gave birth to a pup in rocky habitat along the south side of the island and, over the next year, reared the pup to weaning age. This was apparently the first pup born in the Channel Islands in at least 150 years. Since 2008, individual adult females, subadult males, and between one and three pups have been observed annually on San Miguel Island. There are estimated to be approximately 20–25 individuals that have fidelity to San Miguel, mostly inhabiting the southwest and northwest ends of the island. A total of 14 pups have been born on the island since 2009, with no more than 3 born in any single season (pers. comm., S. Melin, NMFS National Marine Mammal Laboratory, to J. Carduner, NMFS, Aug. 28, 2015). Thirteen individuals and two pups were observed in 2015 (NMFS 2016). No haulout or rookery sites exist for Guadalupe fur seals on the mainland coast, including VAFB. The only individuals that do appear on mainland beaches are stranded animals.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Pinnipeds in water; Phocidae (true seals): Generalized hearing is estimated to occur between approximately 50 hertz (Hz) to 86 kilohertz (kHz); and
- Pinnipeds in water; Otariidae (eared seals): Generalized hearing is estimated to occur between 60 Hz and 39 kHz.

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Six species of marine mammal (four otariid and two phocid) species) have the reasonable potential to co-occur with the proposed activities. Please refer to Table 1.

TABLE 2—RELEVANT MARINE MAMMAL FUNCTIONAL HEARING GROUPS AND THEIR GENERALIZED HEARING RANGES

Hearing group	Generalized hearing range *
Phocid pinnipeds (PW) (underwater) (true seals).	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals).	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The *Estimated Take* section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The *Negligible Impact Analysis and Determination* section considers the content of this section, the *Estimated Take* section, and the *Proposed Mitigation* section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Acoustic Effects

This section contains a brief technical background on sound, the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document.

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in Hz or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ''loudness''

of a sound and is typically described using the relative unit of the dB. A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of 1 m from the source while the received level is the SPL at the listener's position. Note that all airborne sound levels in this document are referenced to a pressure of 20 µPa.

Root mean square is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 μPa^2-s) represents the total energy contained within a pulse and considers both intensity and duration of exposure. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0–p) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source and is represented in the same units as the rms sound pressure. Another common metric is peak-to-peak sound pressure (pk-pk), which is the algebraic difference between the peak positive and peak negative sound pressures. Peak-to-peak pressure is typically approximately 6 dB higher than peak pressure (Southall *et al.,* 2007).

A-weighting is applied to instrument-measured sound levels in an effort to account for the relative loudness perceived by the human ear, as the ear is less sensitive to low audio frequencies, and is commonly used in measuring airborne noise. The relative sensitivity of pinnipeds listening in air to different frequencies is more-or-less similar to that of humans (Richardson et al. 1995), so A-weighting may, as a first approximation, be relevant to pinnipeds listening to moderate-level sounds.

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from a given activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals. Details of source types are described in the following text.

Sounds are often considered as either pulsed or non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts.

Pulsed sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems (such as those used by the U.S. Navy). The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

The effects of sounds on marine mammals are dependent on several factors, including the species, size, behavior (feeding, nursing, resting, etc.), and, if underwater, depth of the animal; the intensity and duration of the sound; and the sound propagation properties of the environment. Impacts to marine species can result from physiological and behavioral responses to both the type and strength of the acoustic signature (Viada *et al.,* 2008). The type and severity of behavioral impacts are more difficult to define due to limited studies addressing the behavioral effects of sounds on marine mammals. Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.,* 1973).

The effects of sounds from the proposed activities are expected to result in behavioral disturbance of marine mammals. Due to the expected sound levels of the activities proposed and the distance of the activity from marine mammal habitat, the effects of sounds from the proposed activities are not expected to result in temporary or permanent hearing impairment (TTS and PTS, respectively), non-auditory physical or physiological effects, or masking in marine mammals. Therefore, TTS, PTS, non-auditory physical or physiological effects, and masking are not discussed further in this section.

Disturbance Reactions

Disturbance includes a variety of effects, including subtle changes in behavior, more conspicuous changes in activities, and displacement. Behavioral responses to sound are highly variable and context-specific and reactions, if any, depend on species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day, and many other factors (Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007).

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. Behavioral state may affect

the type of response as well. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC, 2003; Wartzok *et al.,* 2003).

Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud underwater sound sources (Ridgway *et al.,* 1997; Finneran *et al.,* 2003). Observed responses of wild marine mammals to loud pulsed sound sources (typically seismic guns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; Thorson and Reyff, 2006; see also Gordon *et al.,* 2004; Wartzok *et al.,* 2003; Nowacek *et al.,* 2007).

The onset of noise can result in temporary, short term changes in an animal's typical behavior and/or avoidance of the affected area. These behavioral changes may include: Reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior; avoidance of areas where sound sources are located; and/or flight responses (Richardson *et al.,* 1995).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could potentially be biologically significant if the change affects growth, survival, or reproduction. The onset of behavioral disturbance from anthropogenic sound depends on both external factors (characteristics of sound sources and their paths) and the specific characteristics of the receiving animals (hearing, motivation, experience, demography) and is difficult to predict (Southall *et al.,* 2007).

Marine mammals that occur in the project area could be exposed to airborne sounds associated with Falcon 9 boost-back and landing activities that have the potential to result in behavioral harassment, depending on an animal's distance from the sound. Airborne sound could potentially affect pinnipeds that are hauled out. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon their habitat and move further from the source. Hauled out pinnipeds may flush from a haulout into the water. Though pup abandonment could theoretically result from these reactions, site-specific monitoring data indicate that pup abandonment is not likely to occur as a result of the specified activity. Not all pinnipeds exposed to a sonic boom and/or launch noise flushed from the haulout, and those that did flush returned to the haulout shortly after the event.

Description of Effects From the Specified Activity

This section includes a discussion of the active acoustic sound sources associated with SpaceX's proposed activity and the likelihood for these sources to result in harassment of marine mammals. Potential acoustic sources associated with SpaceX's proposed activity include sonic booms, Falcon 9 First Stage landings, and potential explosions as a result of unsuccessful Falcon 9 First Stage landing attempts. Sounds produced by the proposed activities may be impulsive, due to sonic booms, and non-pulse (but short-duration) noise, due to combustion effects of the Falcon 9 First Stage. As described above, sounds associated with Falcon 9 First Stage landings and potential explosions as a result of unsuccessful Falcon 9 First Stage landing attempts are not expected to result in take of marine mammals and are therefore not addressed here.

Sonic Boom

As described above, during descent when the First Stage is supersonic, a sonic boom would be generated. The USAF has monitored pinniped responses to rocket launches from VAFB for nearly 20 years. Though rocket launches are not part of the proposed activities (as described above), the acoustic stimuli (sonic booms) associated with launches is expected to be substantially similar to those expected to occur with Falcon 9 boost-backs and landings; therefore, we rely on observational data on responses of pinnipeds to sonic booms associated with rocket launches from VAFB in making assumptions about expected pinniped responses to sonic booms associated with Falcon 9 boost-backs and landings.

Observed reactions of pinnipeds at the NCI to sonic booms have ranged from no response to heads-up alerts, from startle responses to some movements on land, and from some movements into the water to very occasional stampedes (especially involving California sea lions on the NCI). We therefore assume sonic booms generated during the return flight of the Falcon 9 First Stage may elicit an alerting or other short-term behavioral reaction, including flushing into the water if hauled out.

Data from launch monitoring by the USAF on the NCI has shown that pinniped reactions to sonic booms are correlated with the level of the sonic boom. Low energy sonic booms (<1.0 psf) have typically resulted in little to no behavioral responses, including head raising and briefly alerting but returning to normal behavior shortly after the stimulus (Table 3). More powerful sonic booms have sometimes resulted in some species of pinnipeds flushing from haulouts. No documented pinniped mortalities have been associated with sonic booms. No sustained decreases in numbers of animals observed at haulouts have been observed after the stimulus. Table 3 presents a summary of monitoring efforts at the NCI from 1999 to 2017. These data show that reactions to sonic booms tend to be insignificant below 1.0 psf and that, even above 1.0 psf, only a portion of the animals present have reacted to the sonic boom. Time-lapse video photography during four launch events revealed that harbor seals that reacted to the rocket launch noise but did not leave the haulout were all adults.

Data from previous monitoring also suggests that for those pinnipeds that flush from haulouts in response to sonic booms, the amount of time it takes for those animals to begin returning to the haulout site, and for numbers of animals to return to pre-launch levels, is correlated with sonic boom sound levels. Pinnipeds may begin to return to the haulout site within 2–55 min of the launch disturbance, and the haulout site usually returned to pre-launch levels within 45–120 min. Monitoring data from launches of the Athena IKONOS rocket from VAFB, with 107.3 and 107.8 dB (A-weighted SEL) recorded at the closest haulout site, showed seals that flushed to the water on exposure to the sonic boom began to return to the haulout approximately 16–55 minutes post-launch (Thorson *et al.,* 1999a; 1999b). In contrast, in the cases of Atlas rocket launches and several Titan II rocket launches with SELs (A-weighted) ranging from 86.7 to 95.7 dB recorded at the closest haulout, seals began to return to the haulout site within 2–8 minutes post-launch (Thorson and Francine, 1997; Thorson *et al.,* 2000).

Monitoring data has consistently shown that reactions among pinnipeds

to sonic booms vary between species, with harbor seals tending to be the most sensitive to disturbance, followed by California sea lions, with northern elephant seals and northern fur seals generally being much less responsive (Table 3). Because Steller sea lions and Guadalupe fur seals occur in the project area relatively infrequently, no data has been recorded on their reactions to sonic booms. At VAFB, harbor seals generally alert to nearby launch noises, with some or all of the animals going into the water. Usually the animals haul out again from within minutes to two hours or so of the launch, provided rising tides or breakers have not submerged the haulout sites. Post-launch surveys often indicate as many or more animals hauled out than were present at the time of the launch, unless rising tides, breakers or other disturbances are involved (SAIC 2012). When launches occurred during high tides at VAFB, no impacts have been recorded because virtually all haulout sites were submerged.

At the Channel Islands, harbor seals have been observed to react more strongly to sonic booms than other species present there, with some animals startling and fleeing into the water (Table 3). California sea lions have also sometimes shown reactiveness to sonic booms, with pups sometimes reacting more than adults, either because they are more easily frightened or because their hearing is more acute (Table 3). Northern fur seals generally show little or no reaction. Northern elephant seals generally exhibit no reaction at all, except perhaps a heads-up response or some stirring, especially if sea lions in the same area or mingled with the elephant seals react strongly to the boom. Post-launch monitoring generally reveals a return to normal patterns within minutes up to an hour or two of each launch, regardless of species (SAIC 2012).

Table 3 summarizes monitoring efforts at San Miguel Island during which acoustic measurements were successfully recorded and during which pinnipeds were observed. Monitoring was conducted at the haulout closest to the predicted sonic boom. During more recent launches, night vision equipment was used. The table shows only launches during which sonic booms were heard and recorded. Many launches from VAFB do not result in sonic booms that are detectable at the NCI due to the westward trajectory of the rockets. To date, SpaceX has landed only one Falcon 9 First Stage at VAFB and the monitoring results are not yet available. The table shows that little or no reaction from the four species usually occurs when overpressures are below 1.0 psf, and sometimes higher. In general, as described above, elephant seals do not react unless other animals around them react strongly or if the sonic boom is extremely loud, and northern fur seals seem to react similarly.

TABLE 3—OBSERVED PINNIPED RESPONSES TO SONIC BOOMS AT SAN MIGUEL ISLAND

Launch event	Sonic boom level (psf)	Monitoring location	Species and associated reactions
Athena II (April 27, 1999)	1.0	Adams Cove	California sea lion: 866 alerted; 232 (27%) flushed into water. Northern elephant seal: Alerted but did not flush. Northern fur seal: Alerted but did not flush.
Athena II (September 24, 1999)	0.95	Point Bennett	California sea lion: 12 of 600 (2%) flushed into water. Northern elephant seal: Alerted but did not flush. Northern fur seal: Alerted but did not flush.
Delta II 20 (November 20, 2000)	0.4	Point Bennett	California sea lion: 60 pups flushed into water; no reaction from focal group. Northern elephant seal: No reaction.
Atlas II (September 8, 2001)	0.75	Cardwell Point	California sea lion (Group 1): No reaction (1,200 animals). California sea lion (Group 2): No reaction (247 animals). Northern elephant seal: No reaction. Harbor seal: 2 of 4 flushed into water.
Delta II (February 11, 2002)	0.64	Point Bennett	California sea lion and northern fur seal: No reaction among 485 animals in 3 groups. Northern elephant seal: No reaction among 424 animals in 2 groups.
Atlas II (December 2, 2003)	0.88	Point Bennett	California sea lion: Approximately 40% alerted; several flushed to water (number unknown—night launch). Northern elephant seal: No reaction.
Delta II (July 15, 2004)	1.34	Adams Cove	California sea lion: 10% alerted (number unknown—night launch).
Atlas V (March 13, 2008)	1.24	Cardwell Point	Northern elephant seal: No reaction (109 pups).
Delta II (May 5, 2009)	0.76	West of Judith Rock	California sea lion: No reaction (784 animals).
Atlas V (April 14, 2011)	1.01	Cuyler Harbor	Northern elephant seal: No reaction (445 animals).
Atlas V (September 13, 2012)	2.10	Cardwell Point	California sea lion: No reaction (460 animals). Northern elephant seal: No reaction (68 animals). Harbor seal: 20 of 36 (56%) flushed into water.
Atlas V (April 3, 2014)	0.74	Cardwell Point	Harbor seal: 1 of ~25 flushed into water; no reaction from others.
Atlas V (December 12, 2014)	1.18	Point Bennett	Calif. sea lion: 5 of ~225 alerted; none flushed.
Atlas V (October 8, 2015)	1.96	East Adams Cove of Point Bennett	Calif. sea lion: Pre-launch counts for California sea lions at the San Miguel Island monitoring location ranged from 42 to 166. ~60% of CSL alerted and raised their heads. None flushed. Northern elephant seal: Pre-launch counts ranged from 107 to 159. No visible response to sonic boom, none flushed. Northern fur seal: Pre-launch counts from 129 to 262. ~60% of NFS alerted and raised their heads. None flushed.
Atlas V (March 1, 2017)	[a] ~0.8	Cuyler Harbor on San Miguel Island	Northern elephant seal: pre-launch counts 235–352. 13 alerted; none flushed.

[a] Peak sonic boom at the monitoring site was ~2.2 psf, but was in infrasonic range—not audible to pinnipeds. Within the audible frequency spectrum, boom at monitoring site estimated at ~0.8 psf.

Physiological Responses to Sonic Booms

To determine if harbor seals experience changes in their hearing sensitivity as a result of sounds associated with rocket launches (including sonic booms), Auditory Brainstem Response (ABR) testing was conducted on 14 harbor seals following four launches of the Titan IV rocket, one launch of the Taurus rocket, and two launches of the Delta IV rocket from VAFB. ABR tests have not yet been performed following Falcon 9 rocket landings nor launches, however results of ABR tests that followed launches of other rockets from VAFB are nonetheless informative as the sound source (sonic boom) is expected to be the same as that associated with the activities proposed by SpaceX.

Following standard ABR testing protocol, the ABR was measured from one ear of each seal using sterile, sub-dermal, stainless steel electrodes. A conventional electrode array was used, and low-level white noise was presented to the non-tested ear to reduce any electrical potentials generated by the non-tested ear. A computer was used to produce the click and an eight kHz tone burst stimuli, through standard audiometric headphones. Over 1,000 ABR waveforms were collected and averaged per trial. Initially the stimuli were presented at SPLs loud enough to obtain a clean reliable waveform, and then decreased in 10 dB steps until the response was no longer reliably observed. Once response was no longer reliably observed, the stimuli were then increased in 10 dB steps to the original SPL. By obtaining two ABR waveforms at each SPL, it was possible to quantify the variability in the measurements.

Good replicable responses were measured from most of the seals, with waveforms following the expected pattern of an increase in latency and decrease in amplitude of the peaks, as the stimulus level was lowered. Detailed analysis of the changes in waveform latency and waveform replication of the ABR measurements for the 14 seals showed no detectable changes in the seals' hearing sensitivity as a result of exposure to the launch noise. The delayed start (1.75 to 3.5 hours after the launches) for ABR testing allows for the possibility that the seals may have recovered from a TTS before testing began. However, it can be said with confidence that the post-launch tested animals did not have permanent hearing changes due to exposure to the launch noise from the sonic booms associated with launches of the rockets from VAFB (SAIC 2013).

We also note that stress from long-term cumulative sound exposures can result in physiological effects on reproduction, metabolism, and general health, or on the animals' resistance to disease. However, this is not likely to occur as a result of the proposed activities because of the infrequent nature and short duration of the noise (up to twelve sonic booms annually). Research indicates that population levels at these haulout sites have remained constant in recent years (with decreases only noted in some areas after coastal erosion), giving support to this conclusion.

In conclusion, based on data from numerous years of monitoring of similar activities to the activities proposed by SpaceX, in the same geographic area as the geographic area of the SpaceX's proposed activities, we expect that any behavioral responses by pinnipeds to sonic booms resulting from the proposed activities would range from no response to heads-up alerts, startle responses, some movements on land, and some movements into the water (flushing).

Non-Acoustic Effects of the Proposed Activity

This section includes a discussion of potential effects of SpaceX's proposed activity other than those related to sound.

Visual Stimuli

Visual stimuli resulting from Falcon 9 First Stage landings would have the potential to cause pinnipeds to lift their heads, move towards the water, or enter the water. However, SpaceX has determined that the trajectory of the return flight includes a nearly vertical descent to the SLC–4W landing pad (see Figure 1–7 and 1–8 in the IHA application) and the contingency landing location (see Figure 1–5 in the IHA application). As a result, the descending Falcon 9 First Stage would either be shielded by coastal bluffs (for a SLC–4W landing) or would be too far away from any pinniped haulouts to result in significant stimuli (in the case of a barge landing). Further, the visual stimulus of the Falcon 9 First Stage would not be coupled with the sonic boom, since the First Stage would be at significant altitude when the overpressure is produced, further decreasing the likelihood of a behavioral response. Therefore, the likelihood of takes of marine mammals resulting from visual stimuli associated with the proposed activity is so low as to be considered discountable. As such, visual stimuli associated with the proposed activity is not discussed further in this document.

Effects on Marine Mammal Habitat

We do not anticipate that the proposed activities would result in any temporary or permanent effects on the habitats used by the marine mammals in the proposed area, including the food sources they use (*i.e.,* fish and invertebrates). Behavioral disturbance caused by in-air acoustic stimuli may result in marine mammals temporarily moving away from or avoiding the exposure area but are not expected to have long term impacts, as supported by over two decades of launch monitoring studies on the NCI by the USAF (MMCG and SAIC 2012).

The proposed activities would not result in in-water acoustic stimuli that would cause significant injury or mortality to prey species and would not create barriers to movement for marine mammal prey. As described above, in the event of an unsuccessful barge landing and a resulting explosion of the Falcon 9 First Stage, up to 25 pieces of debris would likely remain floating. SpaceX would recover all floating debris. Denser debris that would not float on the surface is anticipated to sink relatively quickly and would be composed of inert materials. The area of benthic habitat impacted by falling debris would be very small (approximately 0.000706 km^2) (ManTech 2015) and all debris that would sink are composed of inert materials that would not affect water quality or bottom substrate potentially used by marine mammals. None of the debris would be so dense or large that benthic habitat would be meaningfully degraded. As a result, debris from an unsuccessful barge landing that enters the ocean environment approximately 50 km offshore of VAFB would not have a significant effect on marine mammal habitat.

In summary, since the acoustic impacts associated with the proposed activities are of short duration and infrequent (up to twelve events annually), the associated behavioral responses in marine mammals are expected to be temporary. Therefore, the proposed activities are unlikely to result in long term or permanent avoidance of the exposure areas or loss of habitat. The proposed activities are also not expected to result in any reduction in foraging habitat or adverse impacts to marine mammal prey. Thus, any impacts to marine mammal habitat are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of potential disruption of behavioral patterns for individual marine mammals resulting from exposure to sounds associated with the planned activities. Based on the nature of the activity, Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment). Thresholds have also been developed identifying the received level of in-air sound above which exposed pinnipeds would likely be behaviorally harassed.

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. As described above, for in-air sounds, NMFS predicts that harbor seals exposed above received levels of 90 dB re 20 µPa (rms) will be behaviorally harassed, and other pinnipeds will be harassed when exposed above 100 dB re 20 µPa (rms).

Typically, NMFS relies on the acoustic criteria described above to estimate take as a result of exposure to airborne sound from a given activity. However, in this case we have the benefit of more than 20 years of observational data on pinniped responses to the stimuli associated with the proposed activity that we expect to result in harassment (sonic booms) in the particular geographic area of the proposed activity (VAFB and the NCI). Therefore, we consider these data to be the best available information in regard to estimating take based on modeled exposures among pinnipeds to sounds associated with the proposed activities. These data suggest that pinniped reactions to sonic booms are dependent on the species and the intensity of the sonic boom (Table 3).

As described above, data from launch monitoring by the USAF on the NCI and at VAFB have shown that pinniped reactions to sonic booms are correlated to the level of the sonic boom. Low energy sonic booms (<1.0 psf) have typically resulted in little to no behavioral responses, including head raising and briefly alerting but returning to normal behavior shortly after the stimulus. More powerful sonic booms have sometimes resulted in animals flushing from haulouts (but not resulted in any mortality or sustained decreased in numbers after the stimulus). Table 3 presents a summary of monitoring efforts at the NCI from 1999 to 2017. These data show that reactions to sonic booms tend to be insignificant below 1.0 psf and that, even above 1.0 psf, only a portion of the animals present react to the sonic boom. Therefore, for the purposes of estimating the extent of take that is likely to occur as a result of the proposed activities, we conservatively assume that Level B harassment may occur when a pinniped (on land) is exposed to a sonic boom at or above 1.0 psf. Thus, the number of expected takes by Level B harassment is based on estimates of the numbers of animals that would be within the areas exposed to sonic booms at levels at or above 1.0 psf.

The data recorded by USAF at VAFB and the NCI over the past 20 years has also shown that pinniped reactions to sonic booms vary between species. As described above, little or no reaction has been observed in northern fur seals and northern elephant seals when overpressures were below 1.0 psf. At the NCI harbor seals have reacted more strongly to sonic booms than most other species. Sea lions also appear to be somewhat more sensitive to sonic booms than some of the other pinniped species, sometimes startling and flushing. Northern fur seals generally show little or no reaction, and northern elephant seals generally exhibit no reaction at all, except perhaps a heads-up response or some stirring, especially if sea lions in the same area mingled with the elephant seals react strongly to the boom. No data is available on Steller sea lion or Guadalupe fur seal responses to sonic booms.

Ensonified Area

As described above, modeling was performed to estimate overpressure levels that would be created during the return flight of the Falcon 9 First Stage. Previous acoustic modeling underestimated the near-field overpressures from sonic booms so SpaceX used actual observations from past Falcon 9 First Stage boost-back and landing events. SpaceX and the USAF developed new estimates to better predict the potential overpressures from sonic booms resulting from Falcon 9 First Stage boost-back and landing events. The highest modeled overpressure on the mainland (at or near VAFB and Point Conception) was between 1 and 8.5 psf at SLC–4W. However, the overpressure at known pinniped haulout sites on VAFB would likely be closer to 1 to 3 psf (Figure 6–1 in the IHA application). SpaceX used the Wyle model to predict the far-field sonic boom contours from sonic booms

produced by boost-back and landing events of Falcon 9 First Stage rockets with light and heavy payloads (Figures 2–4 and 2–5 in the IHA application). With a heavy payload, Wyle predicted that a boost-back and landing of the Falcon 9 First Stage at SLC–4W would produce a sonic boom with overpressures up to 3.1 psf on the northern coast of San Miguel Island (Figure 2–5 in the IHA application). The Wyle model for a heavy payload (Figure 205 in the IHA application) shows a sonic boom with overpressure above 1.0 psf will only impact San Miguel Island, with no sonic booms over 1.0 psf impacting the other NCI. Therefore, takes are estimated based on only the animals hauled out at San Miguel Island and the mainland (VAFB and Point Conception).

As stated in the ''*Description of Proposed Activity*'' section above, no takes are anticipated for landings of Falcon 9 First Stage rockets at either of the two contingency landing sites. Estimated takes are therefore based on the possibility of boost-back and landing activities occurring at SLC–4W.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. Data collected from marine mammal surveys, including monthly marine mammal surveys conducted by the USAF at VAFB (beginning in 1993) as well as data collected by NMFS, represent the best available information on the occurrence of the six pinniped species expected to occur in the project area. The quality and amount of information available on pinnipeds in the project area varies depending on species. California sea lions, Steller sea lions, harbor seals, and northern elephant seals are regularly observed at known haulouts during monthly surveys at VAFB (CEMML 2018). Data on pinniped numbers at the NCI is limited as surveys are not conducted as frequently. However, the best available data was used to estimate take numbers. Take estimates for all species are shown in Table 7.

Harbor Seal—Pacific harbor seals are the most common marine mammal inhabiting VAFB, congregating on several rocky haulout sites along the VAFB coastline. They also haul out, breed, and pup in isolated beaches and coves throughout the coasts of the NCI. Harbor seals may be exposed to sonic booms above 1.0 psf on the mainland and San Miguel Island. Take of harbor seals at VAFB was estimated based on the maximum count totals from monthly surveys of VAFB haulout sites in 2017 (USAF, 2017). Take of harbor seals at San Miguel Island and at Point Conception was estimated based on the maximum count totals from aerial survey data collected from 2002 to 2012 by the NMFS SWFSC (M. Lowry, NMFS SWFSC, unpubl. data).

California sea lion—California sea lions are common offshore of VAFB and haul out on rocks and beaches along the coastline of VAFB, though pupping rarely occurs on the VAFB coastline. They haul out in large numbers on the NCI and rookeries exist on San Miguel and Santa Cruz islands. California sea lions may be exposed to sonic booms above 1.0 psf on the mainland and San Miguel Island. Take of California sea lions at VAFB was estimated based on the maximum count totals from monthly surveys of VAFB haulout sites in 2017 (USAF, 2017). Take of California sea lions at San Miguel Island was estimated based on the maximum count totals from aerial survey data collected from 2002 to 2012 by the NMFS Southwest Fisheries Science Center (SWFSC) (M. Lowry, NMFS SWFSC, unpubl. data).

Steller Sea Lion—Steller sea lions occur in small numbers at VAFB and on San Miguel Island. They do not currently have rookeries at VAFB or the NCI. Steller sea lions may be exposed to sonic booms above 1.0 psf on the mainland and San Miguel Island. Take of Steller sea lions at VAFB was estimated based on the largest count totals from monthly surveys of VAFB haulout sites in 2017 (USAF, 2017). Steller sea lions haul out in very small numbers on San Miguel Island, and comprehensive survey data for Steller sea lions in the NCI is not available. Take of Steller sea lions on San Miguel Island was estimated based on subject matter expert input suggesting that as many as four Steller sea lions have been observed on San Miguel Island at a time (pers. comm., S. Melin, NMFS Marine Mammal Laboratory (MML), to J. Carduner, NMFS, Feb 11, 2016).

Northern elephant seal—Northern elephant seals haul out sporadically on rocks and beaches along the coastline of VAFB and at Point Conception and have rookeries on San Miguel Island and Santa Rosa Island and at one location at VAFB. Northern elephant seals may be exposed to sonic booms above 1.0 psf on the mainland and San Miguel Island. Take of northern elephant seals at VAFB was estimated based on the largest count totals from monthly surveys of VAFB haulout sites in 2017 (USAF, 2017). Take of northern elephant seals on San Miguel Island and at Point Conception was estimated based on the maximum count totals from aerial survey data collected from 2002 to 2012 by the NMFS Southwest Fisheries Science Center (SWFSC) (M. Lowry, NMFS SWFSC, unpubl. data).

Northern fur seal—Northern fur seals have rookeries on San Miguel Island, the only island in the NCI on which they have been observed. No haulouts or rookeries exist for northern fur seals on the mainland coast, including VAFB, thus they may be exposed to sonic booms above 1.0 psf on San Miguel Island but not on the mainland. Comprehensive survey data for northern fur seals in the project area is not available. Estimated take of northern fur seals was based on subject matter expert input which suggested a maximum of approximately 6,000–8,000 northern fur seals may be present on San Miguel Island at the height of breeding/pupping season (early July). After the height of the breeding/pupping season, numbers fluctuate but decrease as females go on foraging trips and males begin to migrate in late July/August. Numbers continue to decrease until November when most of the population is absent from the island until the following breeding/pupping period (starting the following June) (pers. comm., T. Orr, NMFS NMML, to J. Carduner, NMFS OPR, February 27, 2016). It was therefore conservatively estimated that numbers peak at 8,000 animals hauled out at any given time in July and decrease to a minimum of 2,000 animals hauled out at any given time in the winter, then increase again until the following July. This results in an average estimate of 5,000 northern fur seals hauled out at San Miguel Island at any given time over the course of the entire year.

Guadalupe fur seal—There are estimated to be approximately 20–25 individual Guadalupe fur seals that have fidelity to San Miguel Island (pers. comm. S. Mellin, NMFS NMML, to J. Carduner, NMFS OPR, February 11, 2016). No haulouts or rookeries exist for Guadalupe fur seals on the mainland coast, including VAFB, thus they may be exposed to sonic booms above 1.0 psf at the NCI but not on the mainland. Comprehensive survey data on Guadalupe fur seals in the project area is not available. Estimated take of Guadalupe fur seals was based on the maximum number of Guadalupe fur seals observed at any one time on San Miguel Island (13) (pers. comm., J. LaBonte, ManTech SRS Technologies Inc., to J. Carduner, NMFS, Feb. 29, 2016); it was therefore conservatively assumed that 13 Guadalupe fur seals may be hauled out at San Miguel Island at any given time.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

NMFS currently uses a three-tiered scale to determine whether the response of a pinniped on land to acoustic or visual stimuli is considered an alert, a movement, or a flush. NMFS considers the behaviors that meet the definitions of both movements and flushes to qualify as behavioral harassment. Thus a pinniped on land is considered by NMFS to have been behaviorally harassed if it moves greater than two times its body length, or if the animal is already moving and changes direction and/or speed, or if the animal flushes from land into the water. Animals that become alert without such movements are not considered harassed. See Table 4 for a summary of the pinniped disturbance scale.

TABLE 4—LEVELS OF PINNIPED BEHAVIORAL DISTURBANCE ON LAND

Level	Type of response	Definition	Characterized as behavioral harassment by NMFS
1	Alert	Seal head orientation or brief movement in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, changing from a lying to a sitting position, or brief movement of less than twice the animal's body length.	No.
2	Movement	Movements away from the source of disturbance, ranging from short withdrawals at least twice the animal's body length to longer retreats over the beach, or if already moving a change of direction of greater than 90 degrees.	Yes.
3	Flush	All retreats (flushes) to the water	Yes.

If issued, this would be the second IHA issued to SpaceX for the proposed activity. SpaceX did not perform any Falcon 9 boost-back and landing activities that resulted in return flights to VAFB nor that generated sonic booms that impacted the NCI. SpaceX did perform boost-back and landing activities at a contingency landing location located offshore during the period of validity for the prior IHA, however the contingency landing location was located so far offshore that there were no impacts predicted to marine mammals by sonic boom modeling, thus marine mammal monitoring was not required. Therefore, we have no activity-specific monitoring data to inform take estimates. NMFS relies on the past monitoring data presented in Table 3 to estimate takes.

Take estimates were calculated by overlaying the modeled acoustic footprints of sonic booms from boost-back and landing events at SLC–4W with known pinniped haulouts on the mainland (including those at VAFB) and the NCI to determine the pinniped haulouts that would potentially be affected by sonic booms with overpressures of 1.0 psf and above. Only haulouts along northeastern San Miguel Island would be expected to experience overpressures greater than 1.0 psf during a boost-back and landing at SLC–4W (Figure 2–5 in the IHA application). Take estimates also account for the likely intensity of the sonic boom as well as the relative sensitivity of the marine mammal species present, based on monitoring data as described above.

As described above, the likelihood of pinnipeds exhibiting responses to sonic booms that would be considered behavioral harassment (based on the levels of pinniped disturbance as shown in Table 4) is dependent on both the species and on the intensity of the sonic boom. Data from rocket launch monitoring by the USAF at VAFB and the NCI show that pinniped reactions to sonic booms are correlated to the level of the sonic boom, with low energy sonic booms (<1.0 psf) typically resulting in little to no behavioral responses, and higher energy sonic booms resulting in responses ranging from no response to heads-up alerts, startle responses, some movements on land, and some movements into the water (flushing). Based on model results, a boost-back and landing of the Falcon 9 First Stage at SLC–4W would produce a sonic boom with greater intensity at VAFB (overpressures potentially as high as 8.5 psf) than at San Miguel Island (overpressures potentially as high as 3.1 psf). Responses of pinnipeds to sonic booms are also highly dependent on species, with harbor seals, California sea lions and Steller sea lions generally displaying greater sensitivity to sonic booms than northern elephant seals and northern fur seals (Table 3). We are not aware of any data on Guadalupe fur seal responses to sonic booms, but we assume responses by Guadalupe fur seal responses to be similar to those observed in northern fur seals as the two species are physiologically and behaviorally very similar.

In their application, SpaceX assumed that all of the California sea lions, harbor seals, northern elephant seals, Steller sea lions, northern fur seals, and Guadalupe fur seals at or near VAFB and Point Conception would be behaviorally harassed by a sonic boom over 1.0 psf resulting from a Falcon 9 First Stage boost-back and landing at SLC–4W. SpaceX also estimated that 5 percent of northern elephant seals, northern fur seals, and Guadalupe fur seals and 100 percent of California sea lions, harbor seals, and Steller sea lions hauled out in the NCI would be behaviorally harassed by a sonic boom over 1.0 psf. However, after reviewing the monitoring information presented in Table 3, NMFS has determined that assuming 100 percent of California sea lions, harbor seals, and Steller sea lions would be behaviorally harassed is an overestimate. Therefore, NMFS has determined that assuming only a fraction of marine mammals exposed to sonic booms over 1.0 psf will be behaviorally harassed represents a more realistic estimate.

NMFS assumes that the minimum sonic boom overpressure with the potential to result in behavioral harassment of pinnipeds is 1.0 psf. However, sonic booms with higher overpressures may result in a higher proportion of exposed animals reacting to the sound. Modeling indicates that the maximum overpressure from a sonic boom resulting from a Falcon 9 First Stage boost-back and landing at SLC–4W is likely to be greater at VAFB and Point Conception than at the NCI (Figures 2–2, 2–4, and 2–5 in the IHA application). Thus, based on previous monitoring data (Table 3), the proportion of animals responding to the sonic boom is likely to be greater at VAFB and Point Conception than at the NCI. Therefore, a boost-back and landing of the Falcon 9 First Stage at SLC–4W that results in a sonic boom of

1.0 psf and above at VAFB was conservatively estimated to result in behavioral harassment of 75 percent of harbor seals hauled out at or near VAFB and Point Conception. A sonic boom of 1.0 psf and above at the NCI was conservatively estimated to result in behavioral harassment of 50 percent of harbor seals at San Miguel Island. A sonic boom of 1.0 psf and above at VAFB was conservatively estimated to result in behavioral harassment of 15 percent of northern elephant seals hauled out at or near VAFB and Point Conception while a sonic boom of 1.0 psf and above at the NCI was conservatively estimated to result in behavioral harassment of 5 percent of northern elephant seals hauled out at San Miguel Island. A sonic boom of 1.0 psf and above at VAFB was conservatively estimated to result in behavioral harassment of 50 percent of California sea lions and Steller sea lions hauled out at or near VAFB while a sonic boom of 1.0 psf and above at the NCI was conservatively estimated to result in behavioral harassment of 25 percent of California and Steller sea lions hauled out at San Miguel Island. A sonic boom of 1.0 psf and above at the NCI was conservatively estimated to result in behavioral harassment of 5 percent of northern fur seals and Guadalupe fur seals.

In their application, SpaceX conservatively assumed 12 landings would occur at SLC–4W. SpaceX modeled sonic booms resulting from rockets with both heavy and light payloads. Modeling of sonic boom contours indicates that light payloads do not create sonic booms with overpressures above 1.0 psf that would impact the NCI. Only heavy payloads have the potential to create sonic booms with overpressures above 1.0 psf along the northern coast of San Miguel Island. SpaceX indicated that of the up to 12 Falcon 9 First Stage boost-back and landing events, up to six would be from a light payload and up to six would be from a heavy payload (pers. comm., M. Thompson, SpaceX, to A. Fowler, NMFS, Oct. 11, 2018). Therefore, to determine the estimated number of marine mammals that could be exposed to a sonic boom over 1.0 psf, the number of boost-back and landing events that could impact each location (12 for the mainland and 6 for the NCI) was multiplied by the number of animals likely to respond.

The take calculations presented in Table 5 are based on the best available information on marine mammal populations in the project location and responses among marine mammals to the stimuli associated with the proposed activities and are considered conservative.

TABLE 5—ESTIMATED NUMBERS OF MARINE MAMMALS, AND PERCENTAGE OF MARINE MAMMAL POPULATIONS, POTENTIALLY TAKEN AS A RESULT OF THE PROPOSED ACTIVITIES

Species	Location	Number at location	Correction factor	Takes per event after correction factor	Number of events at location	Total takes per location	Total takes	Percent of stock
Pacific Harbor Seal	VAFB[a]	197	0.75	147.75	12	1,773	7,347	[e]3.30
	Pt. Conception[b]	516	0.75	387	12	4,644		
	San Miguel Island[b]	310	0.5	155	6	930		
California Sea Lion	VAFB[a]	68	0.5	34	12	408	3,609	1.40
	Pt. Conception[b]	0	N/A	0	N/A	0		
	San Miguel Island[b]	2,134	0.25	533.5	6	3,201		
Northern Elephant Seal	VAFB[a]	225	0.15	33.75	12	405	430.2	0.24
	Pt. Conception[b]	11	0.15	1.65	12	19.8		
	San Miguel Island[b]	18	0.05	0.9	6	5.4		
Steller Sea Lion	VAFB[a]	11	0.5	5.5	12	66	72	0.17
	Pt. Conception[b]	0	N/A	0	N/A	0		
	San Miguel Island[b]	4	0.25	1	6	6		
Northern Fur Seal	VAFB[a]	0	N/A	0	N/A	0	1,500	10.7
	Pt. Conception[b]	0	N/A	0	N/A	0		
	San Miguel Island[c]	5,000	0.05	250	6	1,500		
Guadalupe Fur Seal	VAFB[a]	0	N/A	0	N/A	0	3.9	0.02
	Pt. Conception[b]	0	N/A	0	N/A	0		
	San Miguel Island[d]	13	0.05	0.65	6	3.9		

[a] VAFB monthly marine mammal survey data 2017 (USAF, 2017).
[b] Lowry (2017b).
[c] Testa (2013, 2018); USAF (2013); pers. comm., T. Orr, NMFS NMML, to J. Carduner, NMFS, Feb 27, 2016.
[d] DeLong and Melin (2000); J. Harris, NOAA Fisheries, pers. comm.
[e] As the same individual harbor seals at are likely to be taken repeatedly over the course of the specified activities, we use the estimate of 1,023 individual animals taken per Falcon 9 First Stage recovery activity for the purposes of estimating the percentage of stock abundance likely to be taken over the course of the entire activity.

Take estimates are believed to be conservative based on the assumption that all twelve Falcon 9 First Stage recovery actions would result in landings at SLC–4W, with no landings occurring at the contingency barge landing location. However, some or all actual landing events may ultimately occur at the contingency landing location or within the Iridium Landing Area; as described above, landings at the contingency landing location or within the Iridium Landing Area would be expected to result in no takes of marine mammals. However, the number of landings at each location is not known in advance, therefore we assume all landings would occur at SLC–4W. In addition, as described above, it is conservatively assumed that a fraction of marine mammals hauled out at VAFB, Point Conception, and San Miguel Island would be harassed (Level B harassment only) by a Falcon 9 boost-back and landing events at SLC–4W that result in a psf of <1.0. However, it is possible that a smaller number of hauled out pinnipeds will be behaviorally harassed by a Falcon 9 boost-back and landing at SLC–4W. While there may be some limited behavioral harassment of pinnipeds that occurs at psf levels <1.0, we account for that in the overall conservativeness of the total take number, as described above.

Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice to estimate how many animals are likely to be present within a particular distance of a given activity, or exposed to a particular level of sound. In practice, depending on the amount of information available to

characterize daily and seasonal movement and distribution of affected marine mammals, it can be difficult to distinguish between the number of individuals harassed and the instances of harassment and, when duration of the activity is considered, it can result in a take estimate that overestimates the number of individuals harassed. For instance, an individual animal may accrue a number of incidences of harassment over the duration of a project, as opposed to each incident of harassment accruing to a new individual. This is especially likely if individual animals display some degree of residency or site fidelity and the impetus to use the site is stronger than the deterrence presented by the harassing activity.

Take estimates shown in Table 5 are considered reasonable estimates of the number of instances of marine mammal exposures to sound resulting in Level B harassment that are likely to occur as a result of the proposed activities, and not necessarily the number of individual animals exposed.

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

SpaceX's IHA application contains descriptions of the mitigation measures proposed to be implemented during the specified activities in order to effect the least practicable adverse impact on the affected marine mammal species and stocks and their habitats.

It should be noted that it would not be feasible to stop or divert an inbound Falcon 9 First Stage booster. Once the boost-back and landing sequence is underway, there would be no way for SpaceX to change the trajectory of the Falcon 9 First Stage to avoid potential impacts to marine mammals. The proposed mitigation measures include the following:

- Unless constrained by other factors including human safety or national security concerns (as determined by the USAF), launches would be scheduled to avoid boost-backs and landings during the harbor seal pupping season of March through June, when practicable.

Based on our evaluation of SpaceX's proposed mitigation measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Proposed Monitoring

SpaceX submitted a monitoring plan as part of their IHA application. SpaceX's proposed marine mammal monitoring plan was created with input from NMFS and was based on similar plans that have been successfully implemented by other action proponents under previous authorizations for similar projects, specifically the USAF's monitoring of rocket launches from VAFB. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period.

Marine Mammal Monitoring

SpaceX would determine a monitoring location for each boost-back and landing activity, taking into consideration predictions of the areas likely to receive the greatest sonic boom

intensity as well as current haulout locations and the distribution of pinniped species and their behavior. The selection of the monitoring location would also be based on what species (if any) have pups at haulouts and which of those species would be expected to be the most reactive to sonic booms. SpaceX prioritizes the selection of rookery locations if they are expected to be impacted by a sonic boom and prioritizes the most reactive species if there are multiple species that are expected to be hauled out in the modeled sonic boom impact area. For instance, if harbor seals were pupping, SpaceX would select a harbor seal rookery for monitoring because they tend to be the most reactive species to sonic booms. There is also thought given to the geography and wind exposure of the specific beaches that are predicted to be impacted, to avoid inadvertently selecting a portion of a beach that tends to be abandoned by pinnipeds every afternoon as a result high winds. As VAFB is an active military base, the selection of appropriate monitoring locations must also take into account security restrictions and human safety as unexploded ordnance is present in some areas.

Marine mammal monitoring protocols would vary based on modeled sonic boom intensity, the location, and the season. As described above, sonic boom modeling would be performed prior to all boost-back and landing activities. Although the same rockets would be used, other parameters specific to each launch would be incorporated into each model. These include direction and trajectory, weight, length, engine thrust, engine plume drag, position versus time from initiating boost-back to additional engine burns, among other aspects. Various weather scenarios would be analyzed from NOAA weather records for the region, then run through the model. Among other factors, these would include the presence or absence of the jet stream, and if present, its direction, altitude and velocity. The type, altitude, and density of clouds would also be considered. From these data, the models would predict peak amplitudes and impact locations. As described above, impacts to pinnipeds on the NCI, including pups, have been shown through more than two decades of monitoring reports to be minimal and temporary (MMCG and SAIC 2012a). Therefore monitoring requirements at the NCI would be dependent on modeled sonic boom intensity and would be based on the harbor seal pupping season, such that monitoring requirements would be greater when pups would be expected to be present. At the height of the pupping season (between March 1 and June 30) monitoring is required if sonic boom model results indicate a peak overpressure of 2.0 psf or greater is likely to impact the NCI. Between July 1 and September 30 monitoring is required if sonic boom model results indicate a peak overpressure of 3.0 psf or greater is likely to impact the NCI. Between October 1 and February 28, monitoring is required if sonic boom model results indicate a peak overpressure of 4.0 psf or greater is likely to impact the NCI.

Marine mammal monitoring procedures would consist of the following:

- To conduct monitoring of Falcon 9 First Stage boost-back and landing activities, SpaceX would designate qualified, on-site observers that would be approved in advance by NMFS;
- If sonic boom model results indicate a peak overpressure of 1.0 psf or greater is likely to impact VAFB, then acoustic and biological monitoring at VAFB would be implemented. Monitoring would be conducted at the haulout site closest to the predicted sonic boom impact area that can be safely accessed by observers;
- If sonic boom model results indicate a peak overpressure of 2.0 psf or greater is likely to impact one of the NCI between March 1 and June 30; a peak overpressure of greater than 3.0 psf is likely to impact one of the NCI between July 1 and September 30, or a peak overpressure of greater than 4.0 psf is likely to impact one of the NCI between October 1 and February 28, then monitoring of haulout sites on the NCI would be implemented. Monitoring would be conducted at the haulout site closest to the predicted sonic boom impact area;
- Monitoring would commence at least 72 hours prior to the boost-back and continue until at least 48 hours after the event;
- Monitoring would include multiple surveys each day that record the species; number of animals; general behavior; presence of pups; age class; gender; and reaction to noise associated with Falcon 9 First Stage recovery activities, sonic booms or other natural or human caused disturbances, in addition to recording environmental conditions such as tide, wind speed, air temperature, and swell;
- If the boost-back and landing is scheduled during daylight, time lapse photography or video recording would be used to document the behavior of marine mammals during Falcon 9 First Stage recovery activities;
- For Falcon 9 First Stage recovery activities scheduled during harbor seal pupping season (March through June), follow-up surveys would be conducted within two weeks of the boost-back and landing; and
- New northern elephant seal pupping location(s) at VAFB would be prioritized for monitoring when landings occur at SLC–4W during northern elephant seal pupping season (January through February) when practicable.

Acoustic Monitoring

Acoustic measurements of the sonic boom created during boost-back at the monitoring location would be recorded to determine the overpressure level. Typically this would entail use of a digital audio tape (DAT) recorder and a high quality microphone to monitor the sound environment and measure the sonic boom. This system would be specially tailored for recording the low frequency sound associated with rocket launches and sonic booms. The DAT system would record the launch noise and sonic boom digitally to tape, which would allow for detailed post-analysis of the frequency content, and the calculation of other acoustic metrics, and would record the ambient noise and sonic boom. The DAT recorder would be placed near the marine mammal monitoring site when practicable.

Proposed Reporting

SpaceX would report data collected during marine mammal monitoring and acoustic monitoring as described above. The monitoring report would include a description of project related activities, counts of marine mammals by species, sex and age class, a summary of marine mammal species/count data, and a summary of observed marine mammal responses to project-related activities.

A launch monitoring report would be submitted by SpaceX to the NMFS Office of Protected Resources within 60 days after each Falcon 9 First Stage recovery action. This report would contain information on the date(s) and time(s) of the Falcon 9 First Stage recovery action, the design of the monitoring program; and results of the monitoring program, including, but not necessarily limited to the following:

- Numbers of pinnipeds present on the monitored haulout prior to the Falcon 9 First Stage recovery;
- Numbers of pinnipeds that may have been harassed (based on observations of pinniped responses and the pinniped disturbance scale as shown in Table 3);

- The length of time pinnipeds remained off the haulout or rookery for pinnipeds estimated to have entered the water as a result of Falcon 9 First Stage recovery noise;
- Any other observed behavioral modifications by pinnipeds that were likely the result of Falcon 9 First Stage recovery activities, including sonic boom; and
- Results of acoustic monitoring including comparisons of modeled sonic booms with actual acoustic recordings of sonic booms.

In addition, a final monitoring report would be submitted by SpaceX to the NMFS Office of Protected Resources. A draft of the report would be submitted within 90 days of the expiration of the IHA, or, within 45 days of the requested renewal of the IHA (if applicable). A final version of the report would be submitted within 30 days following resolution of comments on the draft report from NMFS. The report would summarize the information from the 60-day post-activity reports (as described above), including but not necessarily limited to the following:

- Date(s) and time(s) of the Falcon 9 First Stage recovery actions;
- Design of the monitoring program; and
- Results of the monitoring program, including the information components contained in the 60-day launch reports, as well as any documented cumulative impacts on marine mammals as a result of the activities, such as long term reductions in the number of pinnipeds at haulouts as a result of the activities.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner not authorized by the proposed IHA (if issued), such as a Level A harassment, or a take of a marine mammal species other than those proposed for authorization, SpaceX would immediately cease the specified activities and immediately report the incident to the NMFS Office of Protected Resources. The report would include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Description of the incident;
- Status of all Falcon 9 First Stage recovery activities in the 48 hours preceding the incident;
- Description of all marine mammal observations in the 48 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with SpaceX to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. SpaceX would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that SpaceX discovers an injured or dead marine mammal, and the lead observer determines the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition), SpaceX would immediately report the incident to the NMFS Office of Protected Resources and the NMFS West Coast Region Stranding Coordinator. The report would include the same information identified in the paragraph above. Authorized activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with SpaceX to determine whether modifications in the activities are appropriate.

In the event that SpaceX discovers an injured or dead marine mammal, and the lead MMO determines the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), SpaceX would report the incident to the NMFS Office of Protected Resources and NMFS West Coast Region Stranding Coordinator, within 24 hours of the discovery. SpaceX would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analyses applies to all the species listed in Table 1, given that the anticipated effects of this activity on these different marine mammal species are expected to be similar. Activities associated with the proposed Falcon 9 First Stage recovery activities, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment (behavioral disturbance) only, from airborne sounds of sonic booms. Potential takes could occur if marine mammals are hauled out in areas where a sonic boom above 1.0 psf occurs, which is considered likely given the modeled sonic booms of the proposed activities and the occurrence of pinnipeds in the project area. Based on the best available information, including monitoring reports from similar activities that have been authorized by NMFS, behavioral responses will likely be limited to reactions such as alerting to the noise, with some animals possibly moving toward or entering the water, depending on the species and the intensity of the sonic boom. Repeated exposures of individuals to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior. Thus, even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any significant realized decrease in fitness to those individuals, and thus would not result in any adverse impact to the stock as a whole. Level B harassment would be reduced to the level of least practicable impact through use of mitigation measures described above.

If a marine mammal responds to a stimulus by changing its behavior (*e.g.,* through relatively minor changes in locomotion direction/speed), the

response may or may not constitute taking at the individual level, and is unlikely to affect the stock or the species as a whole. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on animals or on the stock or species could potentially be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007). Flushing of pinnipeds into the water has the potential to result in mother-pup separation, or could result in a stampede, either of which could potentially result in serious injury or mortality and thereby could potentially impact the stock or species. However, based on the best available information, including reports from over 20 years of launch monitoring at VAFB and the NCI, no serious injury or mortality of marine mammals is anticipated as a result of the proposed activities.

Even in the instances of pinnipeds being behaviorally disturbed by sonic booms from rocket launches at VAFB, no evidence has been presented of abnormal behavior, injuries or mortalities, or pup abandonment as a result of sonic booms (SAIC 2013). These findings came as a result of more than two decades of surveys at VAFB and the NCI (MMCG and SAIC, 2012). Post-launch monitoring generally reveals a return to normal behavioral patterns within minutes up to an hour or two of each launch, regardless of species. For instance, a total of eight Delta II and Taurus space vehicle launches occurred from north VAFB, near the Spur Road and Purisima Point haulout sites, from February, 2009 through February, 2014. Of these eight launches, three occurred during the harbor seal pupping season. The continued use by harbor seals of the Spur Road and Purisima Point haulout sites indicates that it is unlikely that these rocket launches (and associated sonic booms) resulted in long-term disturbances of pinnipeds using the haulout sites. San Miguel Island represents the most important pinniped rookery in the continental United States, and as such extensive research has been conducted there for decades. From this research, as well as stock assessment reports, it is clear that VAFB operations (including associated sonic booms) have not had any significant impacts on San Miguel Island rookeries and haulouts (SAIC 2012).

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No injury, serious injury, or mortality are anticipated or authorized;
- The anticipated incidences of Level B harassment are expected to consist of, at worst, temporary modifications in behavior (*i.e.,* short distance movements and occasional flushing into the water with return to haulouts shortly after disturbance), which are not expected to adversely affect the fitness of any individuals;
- The proposed activities are expected to result in no long-term changes in the use by pinnipeds of rookeries and haulouts in the project area, based on over 20 years of monitoring data; and
- The presumed efficacy of planned mitigation measures in reducing the effects of the specified activity to the level of least practicable impact.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The numbers of proposed authorized takes are considered small relative to the relevant stocks or populations (less than 11 percent for all species and stocks). It is important to note that the number of expected takes does not necessarily represent the number of individual animals expected to be taken. Our small numbers analysis accounts for this fact. Multiple exposures to Level B harassment can accrue to the same individual animals over the course of an activity that occurs multiple times in the same area (such as SpaceX's proposed activity). This is especially likely in the case of species that have limited ranges and that have site fidelity to a location within the project area, as is the case with Pacific harbor seals.

As described above, harbor seals are non-migratory, rarely traveling more than 50 km from their haulout sites. Thus, while the estimated abundance of the California stock of Pacific harbor seals is 30,968 (Carretta *et al.* 2017), a substantially smaller number of individual harbor seals is likely to occur within the project area. We expect that, because of harbor seals' documented site fidelity to haulout locations at VAFB and the NCI, and because of their limited ranges, the same individuals are likely to be taken repeatedly over the course of the proposed activities (maximum of twelve Falcon 9 First Stage recovery actions). Therefore, the proposed number of instances of Level B harassment among harbor seals over the course of the proposed authorization (*i.e.,* the total number of takes shown in Table 5) is expected to accrue to a much smaller number of individuals encompassing a small portion of the overall regional stock. Thus while we propose to authorize the instances of incidental take of harbor seals shown in Table 5, we believe that the number of individual harbor seals that would be incidentally taken by the proposed activities would, in fact, be substantially lower than this number. The maximum number of harbor seals expected to be taken by Level B harassment, per Falcon 9 First Stage recovery action, is 1,023. As we believe the same individuals are likely to be taken repeatedly over the duration of the proposed activities, we use the estimate of 1,023 individual animals taken per Falcon 9 First Stage recovery activity for the purposes of estimating the percentage of the stock abundance likely to be taken.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally when we propose to authorize take for endangered or threatened species.

There is one marine mammal species (Guadalupe fur seal) listed under the ESA with confirmed occurrence in the area expected to be impacted by the proposed activities. The Permits and Conservation Division has requested initiation of section 7 consultation with the West Coast Region Protected Resources Division Office for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to SpaceX for conducting Falcon 9 First Stage recovery activities at Vandenberg Air Force Base, in the Pacific Ocean offshore Vandenberg Air Force Base, and at the Northern Channel Islands, California, for one year from the date of issuance, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This Incidental Harassment Authorization (IHA) is valid for one year from the date of issuance.

(a) This IHA is valid only for Falcon 9 First Stage recovery activities at Vandenberg Air Force Base, California, and at auxiliary landing sites offshore.

2. General Conditions

(a) A copy of this IHA must be in the possession of SpaceX, its designees, and work crew personnel operating under the authority of this IHA.

(b) The species authorized for taking are the Pacific harbor seal (*Phoca vitulina richardii*), California sea lion (*Zalophus californianus*), Steller sea lion (*Eumetopias jubatus*), northern elephant seal (*Mirounga angustirostris*), northern fur seal (*Callorhinus ursinus*), and Guadalupe fur seal (*Arctocephalus philippii townsendi*).

(c) The taking, by Level B harassment only, is limited to the species listed in condition 2(b). See Table 5 for numbers of take authorized.

(d) The taking by injury (Level A harassment), serious injury, or death of any of the species listed in condition 2(b) of the Authorization or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

3. Mitigation Measures

The holder of this Authorization must implement the following mitigation measure: Unless constrained by other factors including human safety or national security concerns, launches must be scheduled to avoid, whenever possible, boost-backs and landings during the harbor seal pupping season of March through June.

4. Monitoring

The holder of this Authorization must conduct marine mammal and acoustic monitoring as described below.

(a) To conduct monitoring of Falcon 9 First Stage recovery activities, SpaceX must designate qualified, on-site individuals approved in advance by NMFS;

(b) If sonic boom model results indicate that a peak overpressure of 1.0 psf or greater is likely to impact VAFB, then acoustic and biological monitoring at VAFB must be implemented. Monitoring must be conducted at the haulout site closest to the predicted sonic boom impact area that can be safely accessed by observers;

(c) If sonic boom model results indicate a peak overpressure of 1.0 psf or greater is likely to impact VAFB during January and February, then acoustic and biological monitoring must be implemented at northern elephant seal rookeries at VAFB, when practicable;

(d) If sonic boom model results indicate that a peak overpressure of 2.0 psf or greater is predicted to impact the Channel Islands between March 1 and June 30, greater than 3.0 psf between July 1 and September 30, and greater than 4.0 psf between October 1 and February 28, monitoring of haulout sites on the Channel Islands must be implemented. Monitoring must be conducted at the haulout site closest to the predicted sonic boom impact area that can be safely accessed by observers;

(e) Monitoring must be conducted for at least 72 hours prior to any planned Falcon 9 First Stage recovery and continue until at least 48 hours after the event;

(f) For Falcon 9 First Stage recovery activities that occur during March through June, follow-up surveys of harbor seal haulouts must be conducted within two weeks of the Falcon 9 First Stage recovery;

(g) If Falcon 9 First Stage recovery activities are scheduled during daylight, time-lapse photography or video recording must be used to document the behavior of marine mammals during Falcon 9 First Stage recovery activities;

(h) Monitoring must include multiple surveys each day that record the species, number of animals, general behavior, presence of pups, age class, gender and reaction to noise associated with Falcon 9 First Stage recovery, sonic booms or other natural or human caused disturbances, in addition to recording environmental conditions such as tide, wind speed, air temperature, and swell; and

(i) Acoustic measurements of the sonic boom created during boost-back at the monitoring location must be recorded to determine the overpressure level.

5. Reporting

The holder of this Authorization is required to:

(a) Submit a report to the Office of Protected Resources, NMFS, within 60 days after each Falcon 9 First Stage recovery action. This report must contain the following information:

(1) Date(s) and time(s) of the Falcon 9 First Stage recovery action;

(2) Design of the monitoring program; and

(3) Results of the monitoring program, including, but not necessarily limited to:

(i) Numbers of pinnipeds present on the haulout prior to the Falcon 9 First Stage recovery;

(ii) Numbers of pinnipeds that may have been harassed as a result of Falcon 9 First Stage recovery activities;

(iii) For pinnipeds estimated to have been harassed as a result of Falcon 9 First Stage recovery noise, the length of time pinnipeds remained off the haulout or rookery;

(iv) Any other observed behavioral modifications by pinnipeds that were likely the result of Falcon 9 First Stage recovery activities, including sonic boom; and

(v) Results of acoustic monitoring including comparisons of modeled sonic booms with actual acoustic recordings of sonic booms.

(b) Submit an annual report on all monitoring conducted under the IHA. A draft of the annual report must be submitted within 90 calendar days of the expiration of this IHA, or, within 45 calendar days of the requested renewal of the IHA (if applicable). A final annual report must be prepared and submitted within 30 days following resolution of comments on the draft report from

NMFS. The annual report will summarize the information from the 60-day post-activity reports, including but not necessarily limited to:

(1) Date(s) and time(s) of the Falcon 9 First Stage recovery action;

(2) Design of the monitoring program; and

(3) Results of the monitoring program, including, but not necessarily limited to:

(i) Numbers of pinnipeds present on the haulout prior to the Falcon 9 First Stage recovery;

(ii) Numbers of pinnipeds estimated to have been harassed as a result of Falcon 9 First Stage recovery activities at the monitoring location;

(iii) For pinnipeds estimated to have been harassed as a result of Falcon 9 First Stage recovery noise, the length of time pinnipeds remained off the haulout or rookery;

(iv) Any other observed behavioral modifications by pinnipeds that were likely the result of Falcon 9 First Stage recovery activities, including sonic boom;

(v) Any cumulative impacts on marine mammals as a result of the activities, such as long term reductions in the number of pinnipeds at haulouts as a result of the activities; and

(vi) Results of acoustic monitoring including comparisons of modeled sonic booms with actual acoustic recordings of sonic booms.

(c) Reporting injured or dead marine mammals:

(1) In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA (as determined by the lead marine mammal observer), such as an injury (Level A harassment), serious injury, or mortality, SpaceX must immediately cease the specified activities and report the incident to the NMFS Office of Protected Resources and the NMFS West Coast Region Stranding Coordinator. The report must include the following information:

A. Time and date of the incident;

B. Description of the incident;

C. Status of all Falcon 9 First Stage recovery activities in the 48 hours preceding the incident;

D. Description of all marine mammal observations in the 48 hours preceding the incident;

E. Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

F. Species identification or description of the animal(s) involved;

G. Fate of the animal(s); and

H. Photographs or video footage of the animal(s).

Activities may not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with SpaceX to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. SpaceX may not resume their activities until notified by NMFS via letter, email, or telephone.

(2) In the event that SpaceX discovers an injured or dead marine mammal, and the lead observer determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), SpaceX must immediately report the incident to the NMFS Office of Protected Resources and the NMFS West Coast Region Stranding Coordinator. The report must include the same information identified in 5(c)(1) of this IHA. Activities may continue while NMFS reviews the circumstances of the incident and makes a final determination on the cause of the reported injury or death. NMFS will work with SpaceX to determine whether additional mitigation measures or modifications to the activities are appropriate.

(3) In the event that SpaceX discovers an injured or dead marine mammal, and the lead observer determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, scavenger damage), SpaceX must report the incident to the NMFS Office of Protected Resources and the NMFS West Coast Region Stranding Coordinator, within 24 hours of the discovery. SpaceX must provide photographs or video footage or other documentation of the stranded animal sighting to NMFS. The cause of injury or death may be subject to review and a final determination by NMFS.

6. Modification and suspension

(a) This IHA may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if NMFS determines that the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed boost-back and landings of Falcon 9 First Stage rockets. We also request comment on the potential for renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

On a case-by-case basis, NMFS may issue a second one-year IHA without additional notice when (1) another year of identical or nearly identical activities as described in the Specified Activities section is planned or (2) the activities would not be completed by the time the IHA expires and a second IHA would allow for completion of the activities beyond that described in the Dates and Duration section, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to expiration of the current IHA.
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted beyond the initial dates either are identical to the previously analyzed activities or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, take estimates, or mitigation and monitoring requirements; and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

- Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures remain the same and appropriate, and the original findings remain valid.

Dated: November 9, 2018.

Catherine Marzin,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–24977 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; International Billfish Angler Survey

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general

public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 14, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Liana Heberer, at telephone number: 858–546–5626 or *liana.heberer@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The International Billfish Angler Survey began in 1969 and is an integral part of the Billfish Research Program at the National Oceanic and Atmospheric Administration's (NOAA) Southwest Fisheries Science Center (SWFSC). The survey tracks recreational angler fishing catch and effort for billfish in the Pacific and Indian Oceans in support of the Pacific and Western Pacific Fishery Management Councils, authorized under the Magnuson-Stevens Fishery Conservation and Management Act (MSA). The data are used by scientists and fishery managers to assist with assessing the status of billfish stocks. The survey is intended for anglers cooperating in the Billfish Program and is entirely voluntary. This survey is specific to recreational anglers fishing for Istiophorid and Xiphiid billfish in the Pacific and Indian Oceans; as such it provides the only estimates of catch per unit of effort for recreational billfish fishing in those areas.

II. Method of Collection

The paper form is sent to anglers with recent participation in the SWFSC Billfish Research Program and is also available for downloading on the SWFSC Billfish Program website. Completed forms are submitted by mail.

III. Data

OMB Number: 0648–0020.

Form Number: NOAA Form 88–10.

Type of Review: Regular (extension of a current information collection).

Affected public: Individuals or households.

Estimated Number of Respondents: 600.

Estimated Time Per Response: 5 minutes.

Estimated Total Annual Burden Hours: 50.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 9, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–24922 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Designation of Fishery Management Council Members and Application for Reinstatement of State Authority

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 14, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Brian Fredieu, (301) 427–8505 or *Brian.Fredieu@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection.

The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), as amended in 1996, provides for the nomination for members of Fishery Management Councils by state governors and Indian treaty tribes, for the designation of a principal state fishery official who will perform duties under the Magnuson-Stevens Act, and for a request by a state for reinstatement of state authority over a managed fishery. Nominees for council membership must provide the governor or tribe with background documentation, which is then submitted to NOAA with the nomination. The information submitted with these actions will be used to ensure that the requirements of the Magnuson-Stevens Act are being met.

II. Method of Collection

State governors and Indian treaty tribes submit written nominations to the Secretary of Commerce, together with recommendations and statements of candidates' qualifications. Designations of state officials and requests for reinstatement of state authority are also made in writing in response to regulations. NMFS provides guidance on what information to include in order to comply with current regulations. *See* 50 CFR 600.215. No forms are used.

III. Data

OMB Control Number: 0648–0314.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: State, Local or Tribal government.

Estimated Number of Respondents: 275.

Estimated Time per Response: 1 hour to designate a principal state fishery official(s) or for a request to reinstate authority; 80 hours for a nomination for a Council appointment; 16 hours for background documentation for nominees.

Estimated Total Annual Burden Hours: 4,607.

Estimated Total Annual Cost to Public: $795 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 9, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–24921 Filed 11–14–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Co-Exclusive License

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Sirchie Acquisition Company, LLC. (Youngsville, NC) a revocable, nonassignable, co-exclusive license to practice worldwide, the Government-owned inventions described and claimed in U.S. Patent No. 8,5574,658 issued November 5, 2013: FUMELESS LATENT FINGERPRINT DETECTION. The Navy intends to grant no more than two co-exclusive licenses to the above invention.

DATES: Anyone wishing to object to the grant of this co-exclusive license must file written objections along with supporting evidence, if any, not later than November 30, 2018.

ADDRESSES: Written objections are to be filed with the Office of Research and Technology Applications, Naval Air Warfare Center Weapons Division, Code 400000D, 1900 N Knox Road, Stop 6306, China Lake, CA 93555–6106.

FOR FURTHER INFORMATION CONTACT: Dylan Riley, Director, Technology Transfer Office, Naval Air Warfare Center Weapons Division, Code 498400D, 1900 N Knox Road, Stop 6312, China Lake, CA 93555–6106, telephone 760–939–2105, Email: *dylan.riley@navy.mil.*

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: November 9, 2018.

Meredith Steingold Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2018–24910 Filed 11–14–18; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Meetings for the Draft Environmental Impact Statement for the Modernization of the Fallon Range Training Complex, Nevada

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, as implemented by the Council on Environmental Quality, the Department of the Navy (DoN) has prepared and filed with the United States Environmental Protection Agency a Draft Environmental Impact Statement (EIS) to evaluate the potential environmental impacts of modernization of the Fallon Range Training Complex (FRTC), Naval Air Station Fallon, Nevada, to include renewing the current public land withdrawal, expanding land ranges, expanding and modifying airspace, and upgrading range infrastructure. The DoN is not proposing to change the level or type of training, rather activities would be redistributed across the expanded ranges. The DoN will hold seven public meetings to inform the public and receive oral and written comments on the Draft EIS. This notice announces the dates and locations of the public meetings and provides information about the environmental planning effort.

DATES: The 60-day public comment period begins November 16, 2018, and ends January 15, 2019. Public meetings will be held on December 10, 11, 12 and 13, 2018. All public comments are due by January 15, 2019.

ADDRESSES: The public meetings will be held in the following locations:

1. December 10, 2018, 10:00 a.m. to 1:00 p.m., Hawthorne Convention Center, 932 E Street, Hawthorne, NV 89415–2281.

2. December 10, 2018, 5:00 p.m. to 8:00 p.m., Gabbs School Gymnasium, 511 E Avenue, Gabbs, NV 89409–0147.

3. December 11, 2018, 10:00 a.m. to 1:00 p.m., Austin Town Hall, 135 Court Street, Austin, NV 89310–9302.

4. December 11, 2018, 5:00 p.m. to 8:00 p.m., Eureka Opera House, Grand Hall, 31 South Main Street, Eureka, NV 89316–1500.

5. December 12, 2018, 5:00 p.m. to 8:00 p.m., Fallon Convention Center, 100 Campus Way, Fallon, NV 89406–2661.

6. December 13, 2018, 10:00 a.m. to 1:00 p.m., C Punch Inn and Casino, Kumiva Room, 1420 Cornell Avenue, Lovelock, NV 89419–0056.

7. December 13, 2018, 5:00 p.m. to 8:00 p.m., West 2nd Events Center, 600 West 2nd Street, Reno, NV 89503–5312.

The DoN will hold seven public meetings to inform the public about the proposed action, alternatives under consideration, the environmental analysis, and to provide an opportunity for the public to submit oral and written comments on the Draft EIS. Public meetings will include an open house session with informational poster stations staffed by DoN representatives, followed by a brief presentation by the DoN, and a public oral comment session. A stenographer will be available throughout the meeting to record oral comments from the public. In the interest of available time, and to ensure all who wish to provide an oral statement to the stenographer have the opportunity to do so, each speaker's comments will be limited to three minutes. Equal weight will be given to oral and written statements. Federal, state, and local agencies and officials, Native American tribes, and interested organizations and individuals are encouraged to provide comments in person at the public meetings or in writing during the public review period.

Comments may be provided at the public meetings, by mail, and through the project website at: *http://www.FRTCModernization.com.* Mailed comments should be submitted to: Naval Facilities Engineering Command Southwest, Code EV21.SG, 1220 Pacific Highway, Building 1, 5th Floor, San Diego, CA 92132–5190, Attn: Ms. Sara Goodwin, EIS Project Manager.

All comments submitted during the public review period, oral or written, will become part of the public record and will be reviewed and considered in the preparation of the Final EIS. For consideration in the Final EIS, comments must be postmarked or received online by January 15, 2019.

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Command Southwest, Code EV21.SG, 1220 Pacific Highway; Building 1, 5th floor, San Diego, CA 92132–5190, Attn: Ms. Sara Goodwin, EIS Project Manager, 619–532–4463, or project website: *http://www.FRTCModernization.com.*

SUPPLEMENTARY INFORMATION: The Bureau of Land Management, Federal Aviation Administration, and United States Fish and Wildlife Service are federal cooperating agencies for this EIS. Additional state and county cooperating agencies include: Nevada Department of Wildlife, Nevada Division of Minerals, Nevada Department of Agriculture, Nevada Department of Transportation, Nevada Governor's Office of Energy, Churchill County, Eureka County, Lander County, Mineral County, Nye County, and Pershing County. The DoN is also working with thirteen federally recognized Native American tribes and one Tribal Council.

The FRTC is a training complex in the high desert of northern Nevada encompassing airspace, land ranges, and electronic systems used primarily for air and ground training activities. The DoN's proposed action is to modernize the FRTC by expanding land ranges and modifying associated airspace configurations. The proposed action has the following elements:

- Congressional renewal of the 1999 public land withdrawal of 202,864 acres which is scheduled to expire in November 2021.
- Withdrawal and reservation by Congress for military use of up to approximately 618,727 acres of additional federal land.
- Acquisition of approximately 65,153 acres of private or state-owned (non-federal) land.
- Expansion of associated special use airspace and reconfiguration of existing airspace.
- Modification of range infrastructure to support modernization, including construction of new targets.

The purpose of the proposed action is to provide sustainable and modernized airspace, range, maneuver areas, training facilities, and range infrastructure and resources that would support acceptably realistic air warfare training activities as well as special operations ground training activities in order to meet emergent and future threats. The proposed action would enable the DoN's execution of its congressionally mandated roles and responsibilities under 10 United States Code (U.S.C), section 5062 and 10 U.S.C. 167. Current range configurations do not support realistic training. Increasing the size of the range would allow the DoN to realistically train with precision-guided munitions, which require greater safety buffer zones because they are launched from aircraft at higher altitudes and longer distances from targets. It would also allow ground forces to realistically conduct tactical ground mobility training.

The Draft EIS is available at the project website at *http://www.FRTCModernization.com.* A paper copy of the Draft EIS may be reviewed at each of the following public libraries:

1. Austin Branch Library, 88 Main Street, Austin, NV 89310–0121.
2. Carson City Library, 900 North Roop Street, Carson City, NV 89701–3101.
3. Churchill County Library, 553 S. Maine Street, Fallon, NV 89406–3306.
4. Crescent Valley Branch Library, Crescent Valley Town Center, 5045 Tenabo Avenue, Suite 103, Crescent Valley, NV 89821–8051.
5. Downtown Reno Library, 301 S. Center Street, Reno, NV 89501–2102.
6. Eureka Branch Library, 80 South Monroe Street, Eureka, NV 89316–0293.
7. Fernley Branch Library, 575 Silver Lace Blvd., Fernley, NV 89408–1591.
8. Gabbs Community Library, 602 3rd Street, Gabbs, NV 89409–0206.
9. Mineral County Library 110 First Street, Hawthorne, NV 89415–1390.
10. Pershing County Library, 1125 Central Avenue, Lovelock, NV 89419–0781.
11. Yerington Branch Library, 20 Nevin Way, Yerington, NV 89447–2399.

A compact disc of the Draft EIS will be made available upon written request by contacting: Naval Facilities Engineering Command Southwest, Code EV21.SG, 1220 Pacific Highway; Building 1, 5th floor, San Diego, CA 92132–5190, Attn: Ms. Sara Goodwin, EIS Project Manager.

Dated: November 9, 2018.

Meredith Steingold Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2018–24909 Filed 11–14–18; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Navy; DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy (DoN) announces the availability of the inventions listed below, assigned to the United States Government, as represented by the Secretary of the Navy, for domestic and foreign licensing by the Department of the Navy.

ADDRESSES: Requests for copies of the patents cited should be directed to Office of Counsel, Naval Surface Warfare Center Carderock Division, 9500 MacArthur Blvd., West Bethesda, MD 20817–5700.

FOR FURTHER INFORMATION CONTACT: Dr. Joseph Teter, Director, Technology Transfer Office, Naval Surface Warfare Center Carderock Division, Code 00T, 9500 MacArthur Blvd., West Bethesda, MD 20817–5700, telephone 301–227–4299.

SUPPLEMENTARY INFORMATION: The following patents are available for licensing: //U.S. Patent No. 9,783,321: RETRACTABLE VERTICAL FLOW-CONTROL DEVICE FOR TOPSIDE MITIGATION OF AIRWAKES OVER SHIP FLIGHT DECKS//U.S. Patent No. 9,822,040: PRESSURELESS SINTERING-BASED METHOD FOR MAKING A TWO-PHASE CERAMIC COMPOSITE BODY//U.S. Patent No. 9,858,527: ALGORITHMIC METHOD FOR MODELING HUMAN DECISION-MAKING//U.S. Patent No. 9,975,135: LIGHTWEIGHT APPARATUS FOR CAPTURING OVERSPRAY AND AIRBORNE PARTICULATES//U.S. Patent No. 10,024,579: SOLAR PANEL DEPLOYMENT SYSTEM//U.S. Patent No. 10,053,195: SHIPBOARD SIDE-MOUNTED EXTENDING ARTICULATED BOOM FOR FUELING AND MAINTENANCE OPERATIONS//

Authority: 35 U.S.C. 207, 37 CFR part 404

Dated: November 9, 2018.

Meredith Steingold Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2018–24903 Filed 11–14–18; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

List of Borrowers Who Have Defaulted on Their Health Education Assistance Loans

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

SUMMARY: Federal Student Aid (FSA), as required by the Public Health Service Act (the Act) is publishing this list of Health Education Assistance Loan (HEAL) borrowers who have defaulted on their loans as of June 30, 2018. This information is also made available for

use by organizations authorized by the Act.

FOR FURTHER INFORMATION CONTACT:

For Defaulted HEAL Borrowers with Account-Related Questions: A borrower who is in default on a HEAL program loan and who has an account-related question should contact: Accounting Services, Debt Collection Center, Mailstop 10230B, 7700 Wisconsin Avenue, Suite 8–8110D, Bethesda, MD 20857. Telephone: (301) 492–4664.

For General HEAL Information: For general HEAL program questions, contact Tawana Lewis: Telephone: (844) 509–8957. Email: *HEAL@ed.gov.*

For Organizations Requesting HEAL Defaulted Borrower Information or Confirmation under Section 709(c)(2) of the Act (42 U.S.C. 292h(c)(2)): To request information related to a HEAL defaulted borrower or confirmation of the borrower's default status, contact the HEAL program team: Telephone: (844) 509–8957. Email: *HEAL@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: From fiscal year 1978 through fiscal year 1998, the HEAL program insured loans made by participating lenders to eligible graduate students in schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, public health, pharmacy, and chiropractic, and in programs in health administration and clinical psychology. Authorization for new HEAL program loans was discontinued on September 30, 1998.

Under division H, title V, section 525 of the Consolidated Appropriations Act, 2014 (Pub. L. 113–76), and title VII, part A, subpart I of the Public Health Service Act, the authority to administer the HEAL program, including servicing, collecting, and enforcing any loans made under the HEAL program that remain outstanding, was transferred from the Secretary of Health and Human Services to the Secretary of Education effective July 1, 2014. The Act and a system of records notice published in the **Federal Register** on August 4, 2018 (83 FR 40264), permits the publishing of the list of HEAL borrowers who have defaulted on their loans.

Information on the HEAL program is available on the Department of Education's Information for Financial Aid Professionals (IFAP) website at: *www.ifap.ed.gov.*

List of Defaulters: The Appendix at the end of this notice provides the names and other information of borrowers who have defaulted on their HEAL program loans as of June 30, 2018. Specifically, the Appendix includes the borrower's name, last known city and State of residence, area of practice, and the total amount due on the HEAL debt. The Department publishes this information in order to correctly identify the person in default and to provide relevant information to the authorized recipients of this information, such as State licensing boards and hospitals.

In accordance with section 709(c)(2) of the Act (42 U.S.C. 292h(c)(2)), FSA will provide the information included in this **Federal Register** notice and updated information on the borrower's default status, to relevant Federal agencies, and to schools, school associations, professional and specialty associations, State licensing boards, hospitals with which listed borrowers may be associated, and other relevant organizations, upon written request to the email address listed under **FOR FURTHER INFORMATION CONTACT**. Any written request must be on the letterhead of the organization making the request.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the HEAL program team: Telephone: (844) 509–8957. Email: *HEAL@ed.gov.*

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1070b *et seq.* and 1087aa *et seq.;* 42 U.S.C. 2751 *et seq.* and 42 U.S.C. 292h(c)(1).

Dated: November 9, 2018.

James F. Manning,

Acting Chief Operating Officer, Federal Student Aid.

Appendix

Federal Student Aid

U.S. Department of Education

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Abe	Gregory	N	Tujunga	CA	PHA	1/21/1998	$70,973
Ackley	Brainard	L	Kitty Hawk	NC	CHM	1/21/1998	22,784
Acosta-Delgado	Feliberto	D	Bronx	NY	DEN	3/1/1999	91,821
Adams	Stephen		League City	TX	CHM	3/1/1999	88,433
Addison Sr	Michael	A	Allendale	SC	CHM	2/14/2013	9,702
Adeli	Mojgan	E	Los Angeles	CA	DEN	3/1/1999	137,885
Adkins	Margo	M	Austin	TX	MED	1/21/1998	814,047
Aiken	Richard	F	Playa Del Rey	CA	CHM	8/21/2015	83,805
Al-Amin	Ihsaan		Ringgold	GA	MED	11/2/2000	92,759
Alana	Manuela	L	Pharr	TX	POD	9/24/2014	240,556
Alden	Thomas	E	Cambridge	MA	CHM	11/2/2000	125,854
Allen	John	S	Kingford	MI	OPT	2/2/2018	42,077
Allen	Lawrence	P	Temecula	CA	CHM	7/31/1998	332,963
Alter	Dale	N	Lafayette	CA	MED	2/5/2009	423,417
Anderson	Angela	J	Torrance	CA	MED	1/21/1998	165,750
Anderson	Gwendolyn		Lansdowne	PA	POD	1/21/1998	267,198
Anyaji	George	I	San Diego	CA	MED	4/25/2014	121,135
Armstrong	Daniel	J	San Francisco	CA	CHM	5/17/1999	151,399
Arnesen	Douglas	W	Atascadero	CA	CHM	5/17/1999	52,715

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Ayoola-Archie	Olatokunbo	M	Lancaster	CA	MED	11/12/2013	49,724
Azcueta	Justina	Q	San Jose	CA	DEN	5/7/2013	154,820
Bacon	Pamela	M	Hollister	MO	DEN	5/17/1999	243,204
Baez	Ana	V	Somerset	NJ	DEN	5/14/2002	147,799
Bahadue	George	P	Hialeah	FL	OST	3/1/1999	253,815
Baird	Curtis	J	Yucaipa	CA	MED	5/14/2002	111,709
Baker	Gale		Olympia Flds	IL	DEN	5/17/2001	73,494
Baker	Walter	A	Mill Valley	CA	DEN	5/11/2005	436,467
Ball JR	Thomas		Detroit	MI	POD	11/12/2013	111,033
Baranco	Patricia	E	Lake Charles	LA	DEN	3/1/1999	830,242
Baratta	George		Danville	CA	CHM	11/2/2000	29,333
Barber	Mildred	L	Washington	DC	MED	11/14/2007	151,119
Barnes	De Elward	F	Los Angeles	CA	CHM	11/10/2004	54,021
Barnett	Brian	D	Pearland	TX	CHM	1/21/1998	80,454
Barney	Thomas	W	Signal Mountain	TN	CHM	8/22/2017	46,616
Barrows	Joni		Newmarket	NH	DEN	5/19/2009	640,705
Bayles	Jay	C	Westlake Village	CA	CHM	8/11/2005	121,268
Bear	Todd	L	Houston	TX	CHM	9/24/2014	76,941
Beckford	Audrey	L	East Orange	NJ	OST	2/15/2002	72,800
Bennett	Kathy		Caldwell	ID	CHM	8/12/2016	82,567
Bentley JR	James	W	Van Nuys	CA	DEN	8/12/2016	25,463
Bergstrom	Eric	R	Anaheim Hills	CA	CHM	5/7/2013	33,459
Bertin	Michael	W	West Bloomfield	MI	DEN	1/21/1998	12,673
Bertsch	Dar	A	Santa Cruz	CA	CHM	4/25/2014	40,301
Bettis	Gail	M	Bellrose	NY	DEN	1/21/1998	95,004
Biosah-Coleman	Ada	N	Houston	TX	PUB	9/24/2014	50,082
Bittenbender	Robert	G	Clarks Summit	PA	CHM	11/7/2001	42,971
Bland JR	Henry	N	Jacksonville	FL	DEN	5/14/2002	241,584
Blase	Richard	M	Worcester	MA	DEN	1/21/1998	446,738
Bolton	Paul	K	Kansas City	MO	CHM	11/2/2000	128,654
Booher	Janette	L	South San Francisco	CA	CHM	2/1/2001	63,962
Boshes	Perri	D	Deerfield Beach	FL	CHM	1/21/1998	65,201
Bowman	Jeffrey	S	Salt Lake City	UT	CHM	1/21/1998	22,309
Brandt	Susan	J	Winston Salem	NC	MED	7/6/2012	98,819
Brantley	Carl	E	Houston	TX	DEN	9/24/2014	43,100
Breazeale	Michael	E	Marietta	GA	CHM	1/21/1998	319,438
Brodie	Douglas	K	San Antonio	TX	DEN	1/21/1998	370,733
Brodsky	Barbara	L	San Francisco	CA	CHM	1/21/1998	21,274
Bronk	Brian	R	Santa Monica	CA	CHM	1/21/1998	73,217
Broussard	Charlotte	R	Carrollton	TX	CHM	11/2/2000	23,760
Broussard	Linda	C	Los Angeles	CA	CHM	2/10/2011	13,258
Brown	Darla	J	Highlands	TX	CHM	1/21/1998	417,880
Brown	Jeffrey	T	Laguna Niguel	CA	CHM	11/7/2001	31,645
Brown-Collins	Jannas	E	Columbia	SC	DEN	5/31/2018	558,493
Bruyning	Edwin	F	Miami	FL	DEN	1/21/1998	331,250
Buchta	Joseph	F	Bradenton	FL	DEN	7/26/2018	35,208
Buchwald-Heilig	Bonnie	I	Tucson	AZ	CHM	1/21/1998	44,173
Buford	John	I	Philadelphia	PA	OST	5/17/2001	67,880
Bui	Khai	T	Springfield	MA	DEN	8/16/2006	116,675
Bulen	Jerry	L	Brandon	FL	OST	2/28/2005	183,071
Bunce	Christine	T	Sonoma	CA	CPY	2/1/2001	182,337
Burke-Lundy	Elaine	I	Davie	FL	MED	5/16/2011	40,447
Caballero	Jorge	R	Los Angeles	CA	CHM	1/21/1998	262,521
Cabrera	Cecilia	I	Pembroke Pines	FL	OPT	2/5/2009	21,020
Cabrera	Dakila		Fairfield	CA	CHM	8/17/2012	4,876
Caldwell	William	G	Concord	MA	DEN	5/14/2002	111,009
Calix	Raul	O	Lennox	CA	CHM	5/16/2011	11,471
Campanale	Paul	R	Jacksonville	FL	CHM	1/21/1998	90,362
Canillas	Gregorio	L	Long Beach	CA	CPY	5/16/2011	74,564
Caporaso	Nicholas	G	West Liberty	OH	CHM	2/1/2001	35,352
Caputo	Francesco	J	Plainview	NY	CHM	7/6/2012	253,184
Cardenas-Cuyuche	Ines	B	Los Angeles	CA	CHM	11/18/2011	22,422
Carlos	Lester	B	San Leandro	CA	CHM	8/5/2004	71,956
Carney	Timothy	M	East Patchogue	NY	CHM	11/26/2012	34,116
Carpenter	Richard	P	Saginaw	MI	CHM	1/21/1998	47,308
Carrie	Thomas	T	Mount Vernon	NY	MED	3/1/1999	344,043
Carthen	Michael		Brooklyn	NY	POD	1/21/1998	361,705
Castaline	Perren	V	Canyon Country	CA	CHM	8/11/2005	139,473
Castellanos	Loretta	M	Key Biscayne	FL	DEN	2/3/2014	264,343
Castro	Henry	G	Corpus Christi	TX	CHM	5/20/2004	54,055
Caulkins	Robert	M	Shrewsbury	MA	MED	8/5/2004	491,128
Cha	Chris	S	Garden Grove	CA	DEN	11/12/1999	328,352

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Chalgujian	Hilda	A	Palm Desert	CA	CPY	5/16/2011	140,162
Chen	Syng-Fu	F	Pls Vrds Pnsl	CA	MED	5/20/2004	52,655
Cheney	Julian	L	Reseda	CA	CHM	1/21/1998	8,863
Choe	Kevin	K	Lakewood	CA	CHM	1/21/1998	14,082
Choi	Seong	Y	Diamond Bar	CA	DEN	3/1/1999	153,124
Christian	Roy	P	Saratoga	CA	DEN	7/6/2012	68,274
Christiansen	John	C	Taylorsville	UT	CHM	5/19/2009	80,706
Clark	Garth	A	Humble	TX	MED	8/10/2001	141,391
Cleere	Carrol	E	Tulsa	OK	CHM	1/21/1998	222,263
Clifton	Rhea	S	Dallas	TX	CHM	8/5/2004	8,379
Cline	Sherri	L	Sylmar	CA	OST	1/21/1998	13,253
Clouse	William	J	San Antonio	TX	POD	3/1/1999	215,811
Coate	Linda		Reno	NV	CHM	11/9/2010	175,728
Cobrin	Bettina	B	Marina Del Rey	CA	CPY	1/21/1998	255,345
Coleman JR	Harold	J	Tacoma	WA	DEN	5/16/2011	269,018
Collier	George	R	Ponderay	ID	DEN	1/21/1998	275,006
Collier	William	F	Sandpoint	ID	CHM	1/21/1998	229,587
Collins JR	Gail	W	Fullerton	CA	OPT	3/1/1999	33,320
Connaughton	Edward	M	Hermosa Beach	CA	CHM	8/12/2016	39,098
Connor	Kenneth	J	Newport Beach	CA	CHM	11/7/2001	80,438
Conway	Walter	A	Sanford	FL	DEN	5/16/2011	207,156
Cook	Ian	K	Christiansted	VI	POD	2/8/2017	175,572
Cook	Karen		Sedona	AZ	CHM	7/6/2012	467,828
Cooke	Courtney	W	Studio City	CA	CHM	5/18/2010	47,520
Coombs	Timothy	R	Anaheim	CA	CHM	5/15/2000	116,126
Cooney	Carey	E	Eugene	OR	DEN	1/21/1998	41,996
Coonts	Terry	A	Eldorado Springs	MO	CHM	2/17/2000	31,340
Cooper	April	D	Hazel Crest	IL	MED	1/21/1998	444,062
Corcoran	Jamie	M	New York	NY	DEN	4/24/1998	518,968
Cothran	Lonnie	A	Shady Point	OK	CHM	11/12/1999	231,237
Cox	Michael	A	Oakland	CA	CHM	11/15/2005	25,521
Cummins	David	F	St Michael Barbados	FC	DEN	1/21/1998	149,932
Curtin	Michael	M	Fairfax	CA	CHM	1/21/1998	36,462
Cutts	David	P	Temecula	CA	DEN	1/21/1998	202,054
Danchisin	Drew	M	Oakland	CA	CHM	5/16/2011	120,592
Daniels	Peter	J	San Jose	CA	CHM	2/20/2007	97,949
Danielsdixon	Darlene	T	Bloomfield Hills	MI	DEN	9/24/2014	194,818
Darrow	Victoria	L	Boca Raton	FL	CHM	11/26/2012	132,598
Davalos	Steven	M	Carmel Valley	CA	CHM	8/1/2000	50,364
Davidson	Blake	L	Richardson	TX	CHM	8/5/2004	49,395
Davis	Mary	L	Ypsilanti	MI	OPT	3/1/1999	71,678
Davisson	Mark	J	Napa	CA	CHM	3/1/1999	63,532
Davitiashvili	Nodari		Rego Park	NY	DEN	11/12/2013	153,007
De Jesus-Miranda	Luis	A	Fajardo	PR	OPT	5/14/2002	104,273
Deck	Robert	E	Crowley	TX	CHM	2/14/2013	58,470
Deleonardis	Michael	S	Houston	TX	MED	8/10/2001	112,440
Demaria	Lynn	A	Albany	NY	MED	2/2/2018	79,431
Dennis	Gwenda	B	Aliso Viejo	CA	MED	5/14/2016	130,868
Densmore	Robert	D	Tampa	FL	CHM	8/17/2007	49,331
Derbonne	John	R	Lake Jackson	TX	CHM	9/24/2014	47,152
Dewitt	Eldon	L	Palm City	FL	CHM	2/5/2009	136,872
Dhaliwal	Emaline	K	Riverside	CA	CHM	1/21/1998	16,202
Diaz	James	A	Redwood Valley	CA	CHM	8/22/2017	15,049
Diesen	James	D	Jacksonville	FL	CHM	1/21/1998	424,985
Difiore JR	William	E	Fountain Valley	CA	CHM	1/21/1998	69,939
Dinh	Michael	K	Mcallen	TX	CHM	9/24/2014	11,745
Ditroia	Frederick		Warrington	PA	DEN	1/21/1998	60,913
Dominic	Anthony	J	Manasquan	NJ	MED	2/15/2002	53,174
Dominicis	Beth	A	Lake Arrowhead	CA	CHM	2/1/2001	26,090
Doom	Randolph	H	Murrells Inlet	SC	CHM	8/17/2012	153,389
Dorian	Saro	S	Glendale	CA	CHM	11/7/2001	35,408
Ructor	James	D	Pittsburgh	PA	MED	8/10/2001	68,756
Dudley	Raynold	R	Houston	TX	PHA	1/21/1998	113,654
Dungan	Kim	V	Fort Lauderdale	FL	CHM	11/14/2007	116,348
Dupuis	Kenneth	J	Orono	ME	CHM	5/14/2002	185,691
Durham	Ricky	L	Houston	TX	CHM	1/21/1998	235,063
Dwight	Benton	J	Albuquerque	NM	PHA	7/26/2018	19,191
Dykeman	Peter	J	Hawthorne	CA	CHM	1/21/1998	130,989
Elbayar	Nader	K	Port Washington	NY	POD	1/21/1998	146,871
Elder	Terry	M	Glendale Heights	IL	CHM	8/1/2000	285,346
Eli	Desiree	D	Soquel	CA	CHM	1/21/1998	76,131
Ellis	Mark	S	Miami	FL	POD	2/17/2000	131,222

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Emerson	Edwin	A	Selden	NY	CHM	1/21/1998	230,297
Engel	Rob	L	Garden Grove	CA	CHM	2/17/2000	28,928
Ensminger	Aletha	M	Carmichael	CA	DEN	11/9/2010	98,256
Epstein	Judy	J	Carlsbad	CA	CPY	2/17/2000	157,799
Eslao	Caesar	G	Carson	CA	DEN	1/21/1998	155,211
Esmailbeigui	Babak		Pacific Palisades	CA	DEN	9/24/2014	9,895
Etienne	Fernande		West Palm Beach	FL	POD	5/11/2006	169,876
Etumnu	Patrick	C	Houston	TX	CHM	9/24/2014	28,338
Evans	William	L	Spring	TX	CHM	9/24/2014	96,900
Fabricant	Michael	J	Fort Lauderdale	FL	CHM	1/21/1998	244,115
Fair	David	F	Knoxville	TN	CHM	3/1/1999	144,068
Falkinburg	Rory	D	Point Pleasant Boro	NJ	CHM	7/26/2018	88,644
Fallman	James	M	Victorville	CA	CHM	5/15/2000	50,055
Falth-Vanvollenhoven	Annika	M	San Francisco	CA	MED	3/1/1999	135,313
Fanizzi	Thomas		Brightwaters	NY	POD	4/24/1998	496,827
Farris	Farral	W	Wichita Falls	TX	CHM	5/15/2000	64,596
Fayazfar	Mitra		Oak Park	CA	CHM	11/7/2001	28,943
Feinman	Brian	M	Tampa	FL	POD	2/20/2007	723,646
Fenton	Mark	A	Van Nuys	CA	CHM	5/11/2006	97,464
Fiore	James	P	Santa Ana	CA	CHM	8/10/2001	70,010
Fletcher	Leonard	G	Corona	CA	MED	8/21/2015	74,818
Flores	Otto	O	Antario	CA	CHM	1/21/1998	171,824
Fluck	Dennis	W	New Tripoli	PA	OST	10/30/2003	296,668
Flunker	Edward	J	Houston	TX	CHM	8/12/2016	13,287
Ford	Thomas	M	Yorba Linda	CA	CHM	2/1/2001	19,208
Formaker	James	W	West Hollywood	CA	DEN	1/21/1998	107,683
Fox	Carl	A	Dana Point	CA	CHM	5/11/2005	112,315
Franco	Michael	G	Glendale	CA	MED	3/3/2015	211,960
Francus	Irwin	N	East Northport	NY	CHM	4/24/1998	424,063
Franks	Michael	A	Wharton	TX	CHM	9/24/2014	28,047
Fridrick	Tim	P	Las Vegas	NV	CHM	1/21/1998	67,142
Friedman	Marc	H	Huntington Beach	CA	POD	8/12/2016	56,045
Frigard	Scott	N	Marietta	GA	CHM	1/21/1998	7,232
Fulton	William	C	Oakland	CA	CPY	11/7/2001	78,029
Funcia	Ana	T	Miami	FL	DEN	2/1/2001	200,576
Gaber	Alan	M	Levittown	PA	DEN	5/14/2002	59,493
Gain	John	J	Wilmington	DE	MED	5/2/2003	347,905
Galliher	Jack	T	Brea	CA	OPT	11/7/2001	3,520
Gallucci	Don	A	Malden	MA	DEN	3/1/1999	148,868
Gasso	Joaquin	A	Hialeah	FL	CHM	1/21/1998	262,093
Gaydos	Richard	F	Fontana	CA	CHM	11/7/2001	67,231
Gdula	William	J	Brookline	MA	MED	5/16/2011	18,724
Genna	Stephen	A	Bayville	NY	DEN	7/26/2018	39,775
Ghalbi	Abdollnasser		Santa Ana	CA	CHM	5/14/2002	39,769
Gifford	Craig	P	Keller	TX	DEN	2/17/2000	103,506
Gilyot	Glenn	D	New Orleans	LA	DEN	2/15/2002	301,766
Giorgio	Stephen	R	Middle Island	NY	CHM	7/26/2018	25,427
Gipson	Bruce	C	Easton	PA	CHM	5/14/2016	25,533
Giventer	Alex		Los Angeles	CA	CHM	5/16/2011	69,946
Glick	Stanley	B	Pasadena	CA	OPT	1/21/1998	7,072
Gloshinski	Laura	E	Lakeland	FL	CHM	1/21/1998	146,266
Goldbeck	Donald	E	Woodland Hills	CA	CHM	8/12/2016	99,442
Gomes	Steven	P	Santa Rosa	CA	CHM	4/24/1998	51,562
Gomez	Meneleo	P	Glendale	CA	DEN	5/15/2000	279,168
Gonzalez	Maria	E	East Rockaway	NY	DEN	5/15/2000	73,671
Goodman	William	D	Thorp	WI	DEN	1/21/1998	32,914
Goodwin	Randall	J	Satanta	KS	CHM	7/6/2012	103,679
Gosa-Kersee	Angela	J	Chicago	IL	DEN	3/1/1999	278,716
Gottschling	Carl	F	Cleveland	OH	MED	11/7/2001	153,772
Grant	Terry	E	Hempstead	NY	DEN	2/1/2001	77,076
Gray	David	M	San Francisco	CA	POD	3/2/2004	68,566
Greeno	Vincent	A	Bolton	MA	CHM	2/28/2005	61,130
Greeson-Cargioli	Leisa	A	Noblesville	IN	CHM	7/26/2018	36,314
Gregory	Thomas	M	Brentwood	NY	CHM	8/22/2017	333,793
Gregory	Todd	A	Pismo Beach	CA	CHM	1/21/1998	52,281
Gregson	Randall		Kailua	HI	CHM	8/22/2017	95,606
Grenier	Paul	S	Viroqua	WI	CHM	8/9/2010	51,904
Grobes	Preston	R	Newport News	VA	PHA	7/26/2018	2,798
Grob-Mick	Renee	J	Dover	DE	MED	5/31/2018	39,307
Grossman	Brian	W	Tulra	CA	CPY	8/12/2016	92,891
Gulas	Carl	M	Los Gatos	CA	CHM	11/18/2011	42,324
Gulla	Peter	B	Colorado Springs	CO	CHM	11/17/2009	17,102

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Gutierrez	Celso		Arlington	TX	CHM	8/12/2016	28,724
Guyer	Larry	G	Santa Rosa	CA	CHM	11/7/2001	42,653
Gyaami	Opanin		Vacaville	CA	DEN	8/5/2004	400,658
Hahn	Peter	S	Placentia	CA	CHM	1/21/1998	40,778
Haines	Steven	M	Jackson	NJ	CHM	3/1/1999	58,506
Hall	Pamela	A	Fort Lauderdale	FL	CPY	8/17/2007	196,708
Hamilton	Cynthia	R	Chino Hills	CA	MED	5/16/2011	40,585
Hampton	Jubal		Long Beach	CA	POD	11/12/1999	105,386
Hankins	Dean	G	Anaheim	CA	CHM	8/12/2016	93,346
Hankins	Douglas	A	Anaheim	CA	CHM	8/22/2017	56,937
Hansen	Kristen	T	Washington	UT	CHM	2/6/2003	115,447
Harness-Lewis	Donita	M	Bainbridge	GA	CPY	2/17/2000	57,757
Harp	Richard	B	Hacienda Heights	CA	CHM	8/10/2011	24,380
Harris	Conrad	W	Washington	DC	DEN	1/21/1998	130,076
Harrison	Rodney	B	Claremont	CA	DEN	5/19/2009	433,772
Hashemi	Keyvan		San Jose	CA	DEN	1/19/2017	59,076
Hasley	Steven	J	Melbourne	FL	CHM	2/28/2005	76,910
Hassid	Sharona	H	Great Neck	NY	DEN	7/26/2018	30,989
Hatfield	Brian	L	Brentwood	CA	CHM	1/21/1998	58,153
Haygood	Regina	J	Brooklyn	NY	POD	4/24/1998	193,113
Hazelwood III	Harry	H	Daytona Beach	NJ	PUB	3/1/1999	302,153
Heckler	Rodney	R	Wheaton	IL	CHM	11/15/2005	23,493
Hempsey	William	C	North Hollywood	CA	CHM	1/21/1998	112,753
Henderson	Charles	A	Baltimore	MD	POD	8/22/2017	45,579
Hennell-Larue	Renata	A	Mapleton	OR	CHM	9/24/2014	40,332
Hernandez	Agapito		Mcallen	TX	CHM	11/7/2001	190,829
Hernandez	Orestes	M	Los Angeles	CA	CHM	1/21/1998	86,997
Herrera	Diego	F	Long Island City	NY	DEN	8/5/1999	296,505
Hibbert	Harold	H	Mountain View	CA	MED	11/2/2000	28,679
Ho	Wook		Los Angeles	CA	DEN	3/1/1999	55,937
Hoang	Dat	T	Anaheim	CA	MED	8/12/2016	74,582
Hobowsky	Martin	R	South Charleston	OH	OST	11/9/2010	239,874
Hoehn	James	D	Thousand Oaks	CA	DEN	1/21/1998	76,578
Hoffman	Stuart		Venice	CA	CHM	8/12/2016	21,599
Holt	Kenneth	G	Sun City	CA	CHM	1/21/1998	144,022
Holzer	Richard	M	Glendale	AZ	CHM	8/17/2007	158,389
Hopkins	Keith	T	Kissimmee	FL	CHM	1/21/1998	13,066
Horsley	Ronald	G	Yulee	FL	CHM	1/21/1998	93,491
Hough JR	Reginio	T	Lancaster	CA	CHM	8/1/2000	47,579
Howell	Ralph	G	Medford	OR	CHM	11/7/2001	233,195
Hungerford	Richard	D	Portola	CA	CHM	1/21/1998	85,956
Hunt	Richard	D	Pasadena	CA	CHM	2/15/2002	147,452
Hunter	Donald	E	Fairborn	OH	CHM	5/19/2009	75,825
Hush	George	G	Rose City	MI	CHM	1/21/1998	104,317
Ichiuji	Arnold	T	Salinas	CA	DEN	8/10/2001	110,841
Iglesias	Gerald	J	Pleasant Hill	CA	DEN	11/26/2012	120,234
Iliou	Claude	B	Punta Gorda	FL	MED	8/16/2006	24,411
Ionova-Zalivchy	Irina	I	Brooklyn	NY	DEN	7/26/2018	68,222
Iqal	Robert	S	Claremont	CA	PHA	1/21/1998	19,898
Israelsen	John	A	Logan	UT	DEN	8/1/2000	287,801
Ito	Stephen	M	Menifee	CA	CHM	4/24/1998	143,647
Jackson	Francesca	A	San Francisco	CA	CHM	4/24/1998	87,854
Jackson	Harold	O	Atlanta	GA	DEN	5/16/2011	54,823
Jacob-France	Elizabeth		St Petersburg	FL	CHM	2/10/2011	66,767
Jaimes	Laura		Pico Rivera	CA	MED	7/26/2018	34,649
Jansson	Susanne	E	Westhampton Beach	NY	GHA	1/21/1998	116,167
Jeffcoat	Lori	M	Vallejo	CA	CHM	10/30/2003	37,111
Jennifer	Jai		Oakland	CA	MED	7/6/2012	58,880
Jewett	Charles	D	Portsmouth	OH	CHM	1/21/1998	104,322
Joergens JR	Donald	W	Staten Island	NY	CHM	1/21/1998	55,390
Johnson	Anthony		Detroit	MI	MED	1/21/1998	24,743
Johnson	Eric	D	Folsom	CA	CHM	1/21/1998	362,386
Johnson	Gary	M	Burbank	CA	CHM	4/24/1998	94,978
Johnson	John	B	Pasadena	TX	CHM	8/12/2016	16,731
Johnson	Steven	R	Hillsboro	TN	CHM	8/1/2000	148,776
Kahan	Robert	M	Mission Viejo	CA	CHM	1/21/1998	73,626
Kamel	Luca		Canyon Country	CA	MED	8/12/2016	221,857
Kantro	Scott	R	New York	NY	POD	8/16/2006	387,914
Katz	Steven	M	Sherman Oaks	CA	CHM	8/10/2001	192,638
Kaufmann	Todd	S	Corte Madera	CA	CHM	8/5/1999	136,458
Kea	Rattana	D	Highland	CA	DEN	11/7/2001	193,190
Keeler-Jones	Dawn	M	Port Saint Lucie	FL	CHM	5/14/2002	80,649

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Keenan	John	M	Watertown	NY	CHM	2/5/2009	50,675
Kellenberger	Steven	L	Elgin	IL	CHM	5/31/2018	8,598
Kelly	Mark	S	Pomona	CA	CHM	1/21/1998	64,610
Kelly	Paul	D	Cadillac	MI	CHM	2/2/2018	24,303
Kelly-Soluri	Laura		Farmingdale	NY	POD	5/17/1999	242,966
Kempis	Richard	A	San Francisco	CA	DEN	2/17/2000	108,424
Kessinger	Charles	W	Key West	FL	CHM	8/21/2015	44,024
Kessler	Bill	R	Fountain Valley	CA	CHM	8/10/2011	43,202
Khalsa	Gururakha	S	Springfield	VA	CHM	7/31/1998	137,355
Khalsa	Har Hari	S	Beverly Hills	CA	CHM	8/10/2011	65,794
Khan	Tariq	A	San Leandro	CA	DEN	7/6/2012	63,644
Kim	Hui Yum		Pasadena	CA	DEN	8/12/2016	31,203
Kim	Won Kak		Torrance	CA	CHM	8/12/2016	105,017
King	James	H	Washington	DC	DEN	1/21/1998	45,731
King	Susan	M	Apache Junction	AZ	CHM	9/24/2014	189,591
Kirkpatrick	Ira	P	Midland	TX	CHM	7/26/2018	199,344
Kiss	Kathleen	M	Blue Point	NY	CHM	1/21/1998	128,174
Klapper	Gerald	P	Hollywood	FL	POD	2/11/2008	52,655
Klejnot	Timothy	A	Marietta	GA	CHM	1/21/1998	222,670
Knight	Patricia	A	Bayport	NY	CPY	1/21/1998	92,266
Ko	Joo	H	Marina	CA	CHM	4/25/2014	19,555
Kosmides	George	K	Hilo	HI	CHM	7/30/2013	60,137
Koukeh-Sackett	F	M	San Bernardino	CA	CHM	1/21/1998	145,111
Kowalski	Brian	A	Irvine	CA	CHM	8/21/2015	27,599
Kralj	Mladen	M	Chicago	IL	DEN	4/24/1998	544,833
Krichevsky	Rita	A	Newtown	PA	MED	2/2/2018	136,535
Krystosik	James	D	Streetsboro	OH	CHM	11/9/2006	239,602
Kunen	Frederick	J	Miami	FL	MED	3/1/1999	187,512
Kushner	William Iii		Danville	CA	DEN	5/9/2007	47,220
Kyprie	Warren		Boca Raton	FL	CPY	2/14/2012	80,756
Lafleur	Allen	R	Hull	MA	CHM	3/1/1999	434,565
Lamb	Robert	D	Sebastopol	CA	CHM	1/21/1998	185,014
Lampman	Chuck	D	Sylmar	CA	CHM	1/21/1998	259,216
Lancaster	Barry	D	Marietta	GA	CHM	1/21/1998	136,496
Landou	Lissa	S	Belleville	NJ	CHM	5/14/2002	203,365
Langham	Mary	L	Talkeetna	AK	OST	5/19/2009	528,405
Lauffer	Mark	A	Mineral Point	PA	CHM	5/16/2011	87,387
Lawton	Michael	D	Tustin	CA	MED	11/12/1999	230,993
Le	Kenneth	N	Camarillo	CA	PHA	8/22/2017	26,667
Lee	Steve	Y	Livingston	NJ	DEN	8/10/2001	91,126
Lent	Rosella	M	Nahant	MA	CHM	8/11/2005	229,618
Leonor	Lillian		Riverside	CA	DEN	8/10/2011	46,809
Lester	Robert	C	Waxahachie	TX	CHM	2/17/2000	65,171
Leung	Leo	S	Woodside	NY	CHM	1/21/1998	208,386
Levin	Nancy	E	Palm Beach Gardens	FL	CHM	1/21/1998	208,443
Lewis	Richard	C	Colorado Springs	CO	CHM	8/17/2012	31,347
Light	David	N	Winter Garden	FL	DEN	2/28/2005	132,908
Lim	Jong	S	Elmhurst	NY	DEN	11/12/2013	156,598
Lippay	Ronald	W	Fresno	CA	CHM	10/30/2003	71,688
Lipschutz	Robert	B	Philadelphia	PA	POD	2/1/2006	137,733
Little	Carlton	E	Chicago	IL	MED	11/12/2013	299,161
Littleton	Charles	R	Edmond	OK	DEN	7/31/1998	1,044
Lodwig	Michael	J	Walnut Creek	CA	CHM	1/21/1998	51,809
Lopez	Luis		Cathedral City	CA	CHM	5/7/2013	210,714
Lottie	Mark	E	Covina	CA	CHM	8/21/2015	110,167
Lovelace	George	E	Flatwoods	KY	DEN	2/17/2000	27,440
Lowry-Brooks	Paulette	M	Summerville	SC	CHM	1/21/1998	210,996
Lucero	Lucky	E	San Bernardino	CA	DEN	4/25/2014	80,634
Lunceford	Glenn	W	Norco	CA	CHM	1/21/1998	55,707
Luta	Patricia	L	Santa Rosa	CA	CHM	2/17/2000	90,749
Ly	Hoang	X	Garden Grove	CA	OPT	8/12/2016	42,595
Maghloubi	Seyed	M	Pacific Palisades	CA	CHM	8/12/2016	40,608
Major	David	C	Whittier	CA	CHM	8/12/2016	10,957
Mannino	Guy	C	North Pole	AK	CHM	3/1/1999	335,612
Manriquez JR	Antonio	M	Coachella	CA	CHM	5/11/2005	106,468
Manvel	Barry	J	Napa	CA	CHM	7/31/1998	37,906
Marcel	Perry	L	Alvarado	TX	DEN	11/12/2013	175,395
Marcus	Alex		Orlando	FL	CHM	2/10/2011	114,635
Marquez	Evelyn	W	Reseda	CA	CPY	2/28/2005	139,123
Martin JR	John	W	Zephyrhills	FL	CHM	1/21/1998	231,173
Marts	Richard	A	Los Angeles	CA	CHM	11/12/1999	93,653
Mattison Coleman	Sharri	L	Oklahoma City	OK	POD	5/19/2009	613

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Mattson	James	A	Berkeley	CA	OST	11/7/2001	173,088
Maxfield-Brown	Bobbi	L	Evansville	IN	CHM	1/21/1998	633,422
Mays-Good	Kathryn	M	Tarzana	CA	CHM	1/21/1998	325,946
Mazhar	Mark		Los Angeles	CA	CHM	8/11/2005	124,055
McAdams	Glen	R	Spring	TX	CHM	3/1/1999	230,270
McAlees	Raymond	M	North Palm Beach	FL	CHM	11/12/1999	234,058
Mcatamney	John	P	Garden City	NY	CHM	11/9/2010	26,861
McCallum III	Ronald	D	Sunnyvale	CA	CHM	5/20/2004	21,788
McClure	Brian	C	Daytona Beach	FL	DEN	1/21/1998	14,437
McCombs	Martin		Long Beach	CA	CPY	11/12/1999	261,214
McConner	Sadie	B	Daytona Beach	FL	POD	1/21/1998	75,196
McElhinney	Thomas	E	Saint Augustine	FL	CHM	1/21/1998	1,066,703
McGee	Billie	J	Simi Valley	CA	CHM	1/21/1998	126,684
Mcghee	Stephanie	Y	La Marque	TX	CHM	5/19/2009	41,064
Mckay	Kevin	J	Dallas	TX	CHM	11/10/2004	69,894
Mcmahan	Gregory	E	Anaheim	CA	DEN	11/18/2011	30,444
McMorris	Bruce		Long Beach	CA	CHM	11/12/1999	163,115
McRoberts	Lynne	S	Ontario Canada	FC	CHM	1/21/1998	97,601
Meade	Madeline	M	Cleveland	OH	DEN	1/21/1998	69,119
Meadors	David	M	Mcallen	TX	CHM	8/12/2016	25,658
Meggs	Carl	M	Belize	FC	DEN	8/15/2003	104,026
Melendez	Angelina		Bronx	NY	POD	5/19/2009	285,767
Melker	Neil	L	Princeton	NJ	DEN	5/19/2009	225,871
Menezes	Michael	H	Tampa	FL	DEN	2/10/2011	201,270
Mihalakis	Georgia		Bronx	NY	OST	1/21/1998	449,158
Milanes-Scott	Barbara	J	Northridge	CA	MED	1/21/1998	208,784
Milgram	Roman		Brooklyn	NY	DEN	1/19/2017	44,481
Miller	Brad	T	Costa Mesa	CA	CHM	1/21/1998	21,694
Miller	Bradley	G	Beverly Hills	CA	MED	1/21/1998	93,438
Miller	Gaylon	D	Bixby	OK	CHM	2/14/2012	96,115
Millon	Jeffrey	M	Lithonia	GA	MED	1/21/1998	180,320
Mitchell	Warren	A	Yucaipa	CA	DEN	8/1/2000	426,551
Mizell	William	L	Los Lunas	NM	OST	8/12/2016	256,075
Moarefi	Mahmdud	R	Los Angeles	CA	CHM	2/17/2000	71,437
Mohammadkhani	Alireza	D	Chatsworth	CA	CHM	8/11/2005	59,164
Moler	Amy	M	Westerville	OH	MED	8/22/2017	18,925
Moore	Scott	P	Citrus Heights	CA	CHM	2/20/2007	30,988
Moore	Thomas	A	Gray	ME	CHM	3/1/1999	188,500
Morita	Phuong	T	Irvine	CA	CHM	3/1/1999	111,428
Moroney	Raymond	A	Venice	CA	CHM	8/12/2016	98,073
Moroney	William	P	San Mateo	CA	CHM	4/24/1998	72,586
Morrone	Mark	J	Los Angeles	CA	DEN	7/31/1998	216,989
Moulds JR	Dan	R	Chattanooga	TN	DEN	2/1/2001	202,841
Mouton	Marsha	E	Los Angeles	CA	MED	1/21/1998	101,134
Muecke	Lee	N	Houston	TX	MED	8/12/2016	5,181
Muenker	Mark	E	San Francisco	CA	CHM	7/31/1998	266,158
Mullinax	Jeffrey	S	Windsor	CA	CHM	5/11/2005	27,238
Munoz	Luis	R	Chicago	IL	MED	11/12/2013	560,178
Murphy	John	P	Black Earth	WI	CHM	7/6/2012	47,152
Murphy	Marc	A	Rancho Santa Margar	CA	CHM	1/21/1998	146,477
Murphy	Richard	N	North Bergen	NJ	CHM	1/21/1998	1,245,670
Myers	Karen	A	Redondo Beach	CA	MED	10/30/2003	216,569
Myers	Michael	D	San Rafael	CA	CPY	7/6/2012	49,305
Nagel	Douglas		Herndon	VA	CHM	8/12/2016	43,753
Nappi	Neil	A	West Palm Beach	FL	CHM	3/1/1999	205,028
Nason	Christian	W	Holly Springs	NC	CHM	5/18/2010	93,971
Nasseri	Amir Abbas		Santa Ana	CA	MED	5/31/2018	21,960
Navai	Mehdi	N	Alhambra	CA	CHM	1/21/1998	388,527
New	Richard	A	Conway	SC	CHM	2/14/2013	91,692
Newsome	Dorita		Livingston	NJ	DEN	5/19/2009	63,667
Newsome	Raymond	E	Desoto	TX	CHM	11/2/2002	220,828
Nguyen	Anh		Sacramento	CA	DEN	11/18/2011	31,857
Nguyen	Charlene	D	La Habra	CA	CHM	5/7/2013	33,703
Nguyen	Ho	H	La Puente	CA	CHM	11/18/2011	133,702
Nguyen	Michael	M	Milpitas	CA	MED	11/9/2006	52,821
Nguyen	Tuan	H	Fountain Valley	CA	OST	11/12/2013	157,998
Nichols	Victoria	G	Encinitas	CA	CPY	8/12/2016	11,586
Nieman	Edward		Riverside	CA	CHM	2/1/2001	109,036
Ninomiya	Jesse	K	Honolulu	HI	DEN	5/17/2001	159,504
Nipper-Collins	Kristie	L	Lutz	FL	OST	2/10/2011	42,269
Nkuku	Christopher	N	Berkeley	IL	MED	5/17/2001	69,741
Nnokam	Kennedy	I	Jasper	TX	PUB	9/24/2014	58,351

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Nolasco	Elizabeth	R	Brooklyn	NY	MED	11/12/2013	18,148
Norville	Michael	T	Costa Mesa	CA	CHM	1/21/1998	182,616
Ocon	Luis	E	Salinas	CA	CHM	10/30/2003	12,120
Ofor	Chukwu	E	Houston	TX	OPT	8/12/2016	45,784
Olajide	Gbolahan	A	Los Angeles	CA	CHM	5/19/2009	319,617
Olberg	Gregory	S	Hayward	CA	CHM	3/1/1999	110,778
Oliver	John	A	Plainfield	NJ	POD	1/21/1998	8,875
Olynik	Christopher		Brooklyn	NY	DEN	5/3/2016	166,887
Owens	Gregory	A	Claremore	OK	CHM	1/21/1998	60,584
Owens	James	R	Evans	GA	CHM	1/21/1998	20,237
Pacheco	Carlos	A	Mcallen	TX	MED	9/24/2014	31,778
Padilla-Torres	Carlos		Ponce	PR	OPT	5/31/2018	24,895
Palmer	Becky	A	Fallbrook	CA	CHM	1/21/1998	193,613
Palmer	Richard	M	Thousand Oaks	CA	CHM	3/1/1999	242,663
Palmer-Mitchell	Donna	C	Huntington Beach	CA	POD	1/21/1998	132,817
Pankey	John		Alameda	CA	CHM	8/5/2004	144,978
Paranich	Stephen	R	Old Forge	PA	CHM	2/2/2018	3,667
Parkin	Dianne	E	Houston	TX	MED	9/24/2014	20,057
Parsa-Forspte	Sepideh		San Clemente	CA	CHM	11/18/2011	46,651
Patterson JR	Arthur	E	Holmdel	NJ	CHM	9/24/2014	56,929
Paunovic	Susan	J	Hopewell Jct	NY	DEN	11/2/2000	13,072
Peerenboom-Grenier	Paula	J	Viroqua	WI	CHM	11/7/2001	48,183
Pennington	Bradley	R	Denver	CO	CHM	5/31/2018	31,475
Perez	Daysi	E	New York	NY	CHM	4/24/1998	147,088
Perlmutter	Mark	A	Ann Arbor	MI	CHM	2/23/2010	78,970
Perrault	Mark	D	Culver City	CA	MED	5/19/2009	128,778
Perry	John	E	Houston	TX	MED	9/24/2014	56,731
Petrosky	Michael	J	Mandeville	LA	CHM	4/24/1998	271,051
Pham	Nghi	D	Fountain Valley	CA	CHM	1/21/1998	110,633
Pham	Vinh	H	Fountain Valley	CA	DEN	5/17/2001	251,765
Philipson	David		Huntington Beach	CA	CHM	11/12/1999	173,013
Phillips	Brian		Prospect	KY	CHM	5/11/2006	263,077
Pierson	Steven	R	Minneapolis	MN	CHM	8/17/2007	104,184
Pigott	Abu	G	Alameda	CA	CHM	11/12/2013	81,472
Pinson	Jeffrey	R	El Paso	TX	CHM	11/12/1999	110,357
Podry	Robert	J	La Canada Flintridg	CA	CHM	1/21/1998	134,540
Ponder III	Alvin	F	Brooklyn	NY	MED	1/21/1998	200,435
Porter	Jacqueline	R	Washington	DC	POD	1/21/1998	160,478
Potok	Leonard	A	Brooklyn	NY	DEN	3/1/1999	96,627
Potts	David	A	Pasadena	TX	CHM	9/24/2014	30,787
Powell	Carlton	F	Elkins Park	PA	DEN	1/21/1998	131,005
Powers	Thomas	P	Oklahoma City	OK	CHM	2/15/2002	16,662
Pratt	Kerrie	G	Los Angeles	CA	CHM	7/6/2012	57,307
Price	Steven	V	Los Angeles	CA	DEN	1/21/1998	3,831
Prindle-Bush	Sharon	M	Brighton	CO	DEN	11/9/2010	4,098
Pritchard	Doyle	P	El Centro	CA	CHM	11/7/2001	31,380
Prom	Van	S	Modesto	CA	CHM	8/22/2017	67,053
Pulli	Louise	A	Perkiomenville	PA	CHM	8/22/2017	6,249
Puryear	Cheryll	D	Houston	TX	CHM	2/17/2000	190,998
Pust	Keith	W	Lake Elsinore	CA	CPY	1/21/1998	116,964
Quirke	Clement		Venice	FL	POD	2/8/2017	212,772
Radetic	Peter	M	Bay Point	CA	CHM	11/17/2009	131,550
Radtke	Joseph	D	Pueblo	CO	OST	9/24/2014	76,865
Ramirez	Richard	R	Houston	TX	CHM	2/28/2005	39,005
Ramu	Nalaya		Beaumont	CA	DEN	5/14/2002	96,702
Rappa	Richard	J	North Haven	CT	CHM	5/11/2005	68,304
Rashti	Kouros		Tarzana	CA	DEN	5/14/2002	289,080
Ratliff	Cynthia		Santa Cruz	CA	CHM	2/1/2006	274,262
Ravinski	Deborah	G	Plymouth	MA	CHM	8/12/2016	6,566
Rayas-Felix	Magdalena		Los Angeles	CA	CHM	1/21/1998	67,038
Reddick	David	J	Fort Lauderdale	FL	MED	11/14/2007	147,479
Reese-Thurmond	Elaine	M	Dixmoor	IL	MED	1/21/1998	150,439
Renz	Howard	W	Astoria	NY	CHM	1/21/1998	86,875
Rey	Jorge	E	Chino	CA	CHM	2/1/2001	36,279
Reyes	Danniell	J	Bethlehem	PA	CHM	7/6/2012	143,461
Rhine	Cecil	T	Lawrenceville	GA	CHM	1/21/1998	99,100
Ribera	Alfred	R	Miami	FL	CHM	3/1/1999	239,123
Rice	William	M	Malden	MA	CHM	8/5/1999	172,766
Richardson	Joseph	M	Silver Spring	MD	DEN	1/21/1998	717,037
Richardson	Justin	W	Porter Ranch	CA	CHM	1/21/1998	5,689
Richardson	Katherine	J	San Francisco	CA	CPY	7/6/2012	406,384
Richichi	Mark	S	Center Moriches	NY	CHM	2/15/2002	169,492

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Ritto	Sharlene	M	Corona	CA	POD	11/12/2013	238,550
Robinson	Bruce	K	Jupiter	FL	CHM	1/21/1998	383,397
Robinson	Glenn	R	Dallas	TX	CHM	3/3/2015	116,178
Rodrigues	Paul		Cerritos	CA	CHM	5/19/2009	150,288
Rogers	Thomas	C	Santa Ana	CA	CHM	3/1/1999	214,786
Romero	Gloriana	M	Guaynabo	PR	MED	2/8/2017	129,496
Rosenfeld	Jeffre	B	Los Angeles	CA	CHM	1/21/1998	115,602
Roshy	Gary	L	Lake City	FL	CHM	1/21/1998	461,668
Ross	Roger	A	Coraopolis	PA	CHM	1/21/1998	50,642
Rostami	Helena		Calabasas	CA	CHM	5/16/2011	33,300
Rothman	Laura	L	Arroyo Grande	CA	CHM	11/7/2001	10,278
Rubinstein	David	M	Fort Lauderdale	FL	CHM	2/15/2002	66,235
Rushing	Gary	W	Matawan	NJ	CHM	2/15/2002	158,803
Russell	Robert	J	Hollywood	FL	CHM	1/21/1998	10,305
Russell	Rosalind	L	Houston	TX	DEN	3/11/2015	2,220
Ryan	Kathleen		West Springfield	MA	POD	5/19/2009	122,630
Saadia	Sammy		Brooklyn	NY	DEN	7/30/2013	176,274
Sabin	Gregory	M	Colorado Springs	CO	CHM	8/22/2017	74,659
Sainez	Juana	A	Maryland	NY	MED	2/2/2018	98,026
Sainten	Adrienne	C	San Leandro	CA	CHM	8/26/2009	18,069
Saldana-Quinonez	Salvador	S	La Puente	CA	CHM	7/6/2012	37,492
Sambor	David	H	Lockport	NY	DEN	11/12/1999	14,017
Sanborn	Brian	A	Midland	MI	CHM	11/17/2009	116,867
Santa Cruz	Matthew	E	Tampa	FL	CHM	5/19/2009	43,443
Sargent	John	F	Lawndale	CA	CHM	1/21/1998	200,987
Sastre	Armando	A	Cortez	CO	DEN	11/9/2010	121,636
Savage	Robert	L	Harrisburg	PA	DEN	5/31/2018	116,819
Schalk	Ronald	R	Corpus Christi	TX	CHM	5/14/2016	67,089
Schiff	Barbara	S	Woodland Hills	CA	CHM	2/17/2000	121,031
Schow	Kenneth	M	Glendale	CA	CHM	1/21/1998	149,879
Schroder	Anthony	M	Middletown	NY	DEN	1/21/1998	84,414
Schulten	Eric	A	Sarasota	FL	MED	11/2/2000	196,384
Schwartz	Eric	G	Atlantic Beach	NY	DEN	1/21/1998	243,371
Scruggs	Virginia	M	Seneca	SC	OST	11/26/2012	75,002
Scully	Stephen	M	Redondo Beach	CA	CHM	3/1/1999	48,329
Sek	Amaramony	B	Houston	TX	CHM	8/12/2016	22,585
Selko	Robert	L	Novato	CA	CHM	3/1/1999	174,348
Sellitto	Rocco	V	Brooklyn	NY	POD	8/1/2000	249,395
Senatore	Salvatore		Kenilworth	NJ	CHM	11/9/2010	141,940
Serratos	Ernesto		Crestline	CA	CHM	1/21/1998	125,028
Shahrestani	Shahriar		Anaheim	CA	CHM	3/1/1999	52,594
Shanefelter III	Charles	D	San Francisco	CA	CHM	1/21/1998	48,477
Shapiro	Michael	S	Newhall	CA	CHM	1/21/1998	117,401
Shapley	Kevin	N	Concord	CA	CHM	3/2/2004	45,217
Shaw	Linda	J	Gladwyne	PA	DEN	1/21/1998	28,843
Shaw	Michael	G	Inglewood	CA	MED	1/21/1998	106,438
Shear	David	S	Staten Island	NY	CHM	1/21/1998	199,372
Sheehan	Alex	J	West Palm Beach	FL	CHM	9/24/2014	46,153
Sheehy	Daniel	J	Middletown	CA	CHM	2/28/2005	65,592
Shin	Hui-Yong		Los Angeles	CA	DEN	1/21/1998	100,004
Shoeleh	Hossien	M	Costa Mesa	CA	DEN	1/21/1998	221,952
Siguenza	Francisco	A	Maspeth	NY	OST	8/12/2016	158,858
Simon	Greg	L	Murrieta	CA	CHM	1/21/1998	206,792
Simpson	Ashley	L	Allston	MA	MED	2/10/2011	278,975
Slusher-Maroudas	Patricia	L	Gilroy	CA	CHM	11/12/2013	10,930
Small	Tammie	J	Smyrna	GA	CHM	1/21/1998	165,845
Smith	Gary	D	Groton	CT	CHM	1/21/1998	52,698
Smith	George		Philadelphia	PA	MED	1/19/2017	546,869
Smith	Jessica		Downey	CA	CHM	1/21/1998	159,421
Smith	Lee	A	Sterling	VA	CHM	5/31/2018	50,773
Smith	Michael	D	Bethel Park	PA	DEN	8/5/2004	364,436
Smith	Rusty	A	Santa Barbara	CA	CHM	3/1/1999	9,609
Smith	Stacey	D	Malibu	CA	CHM	8/1/2000	159,124
Smukler	Evie	L	Los Angeles	CA	CPY	1/21/1998	36,002
Snavely	Danny	H	San Juan Capistrano	CA	CHM	8/21/2015	292,835
Sokol	Louis	J	Stuart	FL	CHM	11/12/1999	73,809
Sosa	Richard		Colton	CA	CHM	3/1/1999	89,589
Soto	Vera	A	Fort Lauderdale	FL	OPT	5/7/2008	21,479
Sparks	Stacey	L	Houston	TX	CHM	11/26/2012	74,313
Spencer	Keivon	J	Cedar Hill	TX	OPT	8/5/2004	6,677
Spicer	Mary	C	Essex Junction	VT	CHM	7/26/2018	14,550
St Juste	Dominique		Brooklyn	NY	DEN	8/1/2000	106,856

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Staley	Judith	M	Annapolis	MD	CPY	4/25/2014	103,378
Stalker	James	W	Castro Valley	CA	CHM	2/10/2011	15,959
Stanbridge	Gary	R	Whittier	CA	CHM	2/28/2005	66,427
Steder	Sandra		San Rafael	CA	CPY	8/5/2004	77,510
Steiner	Jean Marie		Sunnyvale	CA	CHM	5/15/2000	20,048
Steinfeld	Audrey	G	Tarzana	CA	CHM	2/17/2000	238,406
Stephens	Charles	N	Milledgeville	GA	CHM	5/19/2009	55,911
Stevenson	Teresa	M	Los Angeles	CA	CPY	1/21/1998	142,275
Stoltz	William	D	Grants Pass	OR	CHM	5/19/2009	284,886
Stone	Steven	D	San Leandro	CA	CHM	1/21/1998	57,796
Street	James	F	Davie	FL	CHM	11/12/2013	84,298
Stricklan	David	K	Haverton	PA	MED	7/26/2018	202,781
Strus	Deborah	A	San Antonio	TX	MED	11/12/2013	118,432
Sullivan	Daniel	B	Fruita	CO	DEN	5/31/2018	4,777
Sullivan	John	M	Corpus Christi	TX	CHM	8/22/2017	115,129
Sullivan	Joseph	C	Burbank	CA	CHM	1/21/1998	126,435
Taylor	Scott	M	Thousand Oaks	CA	DEN	7/6/2012	178,545
Tchakalian	Leon	J	Van Nuys	CA	CHM	11/7/2001	19,263
Teague	Jenette		Los Angeles	CA	DEN	11/7/2001	144,932
Tennant	Michael	D	Wheat Ridge	CO	CHM	11/12/1999	92,497
Thomas	Gordon	A	Atlanta	GA	CHM	1/21/1998	210,981
Thomas	Randy	L	Fairbanks	AK	DEN	4/24/1998	221,640
Thomas Sr	Robert	B	Stone Mountain	GA	DEN	1/21/1998	438,554
Thompson	Emma	R	Grenada West Indies	FC	MED	2/15/2002	82,303
Tierney	Richard	W	Atlanta	GA	POD	8/5/1999	395,121
Tindall	Michael	A	Magna	UT	POD	1/21/1998	20,799
Tolbert JR	William		Los Angeles	CA	MED	11/12/2013	71,079
Tomlin-Knight	Teresa	L	Manahawkin	NJ	POD	2/11/2008	75,900
Toporovsky	Nathan	A	White Plains	NY	DEN	2/8/2017	21,298
Townsend	Thomas	E	Fortmill	SC	CHM	4/24/1998	10,614
Tramontana	Raul	E	Cincinnati	OH	OPT	5/14/2002	220,103
Tran	Huong	N	Carpinteria	CA	CHM	8/12/2016	58,998
Tran	Ngoc	H	Simi Valley	CA	CHM	3/1/1999	105,356
Tran	Thuan	K	Henderson	NV	DEN	8/12/2016	100,789
Trumbo	Traig	T	Sunland	CA	CHM	3/1/1999	84,963
Tschabrun	Kevin	L	Holdrege	NE	DEN	3/1/1999	125,260
Tumas	Mary	D	Brielle	NJ	CHM	3/11/2015	95,918
Turner	Nancy	A	San Francisco	CA	CHM	1/21/1998	23,856
Ussery	Marvin		Los Angeles	CA	DEN	8/12/2016	52,824
Vacula	Nicole	A	Tonawanda	NY	CPY	8/12/2016	61,958
Vafaee	Mohammadali		Santa Monica	CA	CHM	2/28/2005	24,360
Vaishvila	Gail	A	Santa Monica	CA	CHM	8/1/2000	223,290
Valde	Jane	D	San Mateo	CA	DEN	11/9/2010	176,977
Valicenti	Patrick	J	Wallkill	NY	DEN	8/5/2004	125,315
Vanrensselaer	Jeffrey	A	Lake Forest	CA	CHM	4/24/1998	98,000
Vardanian	Michael	A	Fullerton	CA	CHM	1/21/1998	110,450
Vega	Javier	J	Rancho Cucamonga	CA	CHM	8/12/2016	48,581
Vernon	Earl	M	Davenport	IA	CHM	1/21/1998	6,469
Vessels	Steven	L	Redlands	CA	CHM	1/21/1998	194,431
Vessey	Ned		Arcadia	CA	CHM	8/1/2000	64,848
Villaverde	John	J	Vestavia	AL	MED	8/22/2017	64,563
Villeta	Javier	G	Kissimmee	FL	MED	3/1/1999	311,035
Viloria-Else	Jenifer	A	Los Angeles	CA	CHM	1/21/1998	179,851
Voboril JR	William	R	Carlisle	IA	POD	8/5/1999	36,053
Vosburgh	Stephen	E	Lutz	FL	CHM	1/21/1998	158,861
Wada	Isao	N	Oakland	CA	CHM	7/6/2012	25,239
Wade	Michael	J	La Quinta	CA	OST	5/19/2009	285,845
Wahdan	Buthayna	W	La Verne	CA	DEN	3/1/1999	106,606
Wainwright	Mark		Oakland	CA	DEN	7/6/2012	30,832
Walcher	Kevin	R	Booker	TX	CHM	5/14/2002	103,890
Walker	Joel	W	Annapolis	MD	MED	8/12/2016	56,108
Wall	Michael	J	Sandy	UT	MED	3/3/2015	135,382
Wallace	Owen		Tonkawa	OK	CHM	1/21/1998	51,491
Walsh	Richard	J	Ventura	CA	CHM	1/21/1998	39,580
Walton	Teri	R	Pasadena	CA	CPY	8/5/1999	181,110
Ward	Fairfield	A	Hampton	VA	DEN	8/12/2016	36,730
Warner	Arthur		San Ramon	CA	DEN	5/20/2004	121,246
Warner	Rick	A	Aurora	CO	CHM	11/7/2001	111,900
Washington	Arthur	C	Houston	TX	MED	9/24/2014	23,189
Washington	George	L	Baldwyn	MS	DEN	5/7/2013	542,312
Washington	Patricia	A	Coto De Caza	CA	MED	2/2/2018	123,265
Washington-Houzell	Patricia	L	Lakewood	CA	POD	8/10/2001	523,142

HEALTH EDUCATION ASSISTANCE LOAN DEFAULTERS BY LAST NAME AS OF JUNE 30, 2018—Continued

Last name	First name	Mi	City	State	Discipline	Date reported	Amount due
Weatherly	Darrel	F	Jacksonville	FL	OST	5/16/2011	542,031
Weil	Mitchell	A	San Clemente	CA	MED	1/21/1998	61,717
Weisheit-Dasylva	Lyn	D	Marietta	GA	CHM	3/1/1999	65,431
Welch	Ronald	B	Sandpoint	ID	CHM	3/1/1999	97,961
Westing	Denise	D	Alameda	CA	CHM	1/21/1998	121,321
Whedbee	Joseph	I	Redlands	CA	DEN	5/14/2002	146,172
Whigham	Gwendolyn	E	Houston	TX	CHM	3/1/1999	63,582
Whipkey	Douglas	G	Jensen Beach	FL	CHM	1/21/1998	126,756
Whitaker	Aaron	T	Washington	DC	DEN	5/19/2009	189,402
White	Judith	U	Huntington Beach	CA	CHM	1/21/1998	36,904
Whittlesey	James	B	Novato	CA	CHM	1/21/1998	57,170
Williams	Brett	S	Los Angeles	CA	MED	5/14/2016	171,668
Williams	David	L	Pasadena	CA	POD	1/21/1998	88,475
Williams	Duane	A	Livermore	CA	CHM	1/21/1998	121,647
Williams	Pamela	A	Buena Park	CA	PUB	1/21/1998	35,269
Williams	Simeon	J	Washington	DC	MED	3/1/1999	107,607
Willis	Adam	C	Safety Harbor	FL	CHM	1/21/1998	25,129
Winston	Gregg	O	Pompano Beach	FL	CHM	3/1/1999	190,104
Wong	Matt	S	Mountain View	CA	CHM	11/9/2010	48,826
Wong	Wan Sing	V	South San Francisco	CA	POD	10/30/2003	197,034
Wright-Benford	Sheila	A	Southfield	MI	POD	2/8/2017	60,834
Yeates	Terrance	C	Brooklyn	NY	DEN	1/21/1998	201,611
Yniguez	Alma	B	Newark	CA	CHM	2/20/2007	271,484
Yoste	Joseph		Brownsville	TX	DEN	8/12/2016	96,530
Yurick	Richard		Bay St Louis	MS	CHM	11/12/2013	61,170
Yurkovich	Mark	R	Bentleyville	PA	CPY	8/12/2016	59,259
Zaun	Timothy	M	Lakewood	OH	DEN	1/21/1998	181,527
Zeitsoff-Mahar	Deborah	L	Aptos	CA	CHM	1/21/1998	122,574
Zucker	Ronald	G	Long Beach	NY	CHM	4/24/1998	195,607
Totals	696						92,200,289

[FR Doc. 2018–25000 Filed 11–14–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–11–000, PF18–3–000]

Sabine Pass LNG, L.P.; Notice of Application

Take notice that on October 29, 2018, Sabine Pass LNG, L.P. (SPLNG), 700 Milam Street, Suite 1900, Houston, Texas 77002, filed an application under section 3(a) of the Natural Gas Act (NGA) and Part 153 and 380 of the Commission's regulations, seeking authorization to site, construct and operate an expansion of the existing Sabine Pass liquefied natural gas (LNG) facility (SPLNG Terminal), located in Cameron Parish, Louisiana on the Sabine Pass Channel. The proposed expansion of the SPLNG Terminal consists of the addition of a third marine berth (Third Berth) and supporting facilities (SPLNG Third Berth Expansion Project), all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding the application should be directed to Karri Mahmoud, Cheniere Energy, Inc., 700 Milam Street, Suite 1900, Houston, TX 77002, or by telephone at (713) 375–5000, or email at *Karri.Mahmoud@cheniere.com.*

On March 8, 2018 the Commission granted SPLNG's request to utilize the Pre-Filing Process and assigned Docket No. PF18–3–000 to staff activities involved in the Project. Now, as of the filing of the October 29, 2018 application, the Pre-Filing Process for this Project has ended. From this time forward, this proceeding will be conducted in Docket No. CP19–11–000 as noted in the caption of this Notice.

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list

maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 3 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new Natural Gas Act section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to ''show good cause why the time limitation should be waived,'' and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 3 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: November 28, 2018.

Dated: November 7, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–24872 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC ¶61,167 at ¶50 (2018).

[2] 18 CFR 385.214(d)(1).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–238–001.
Applicants: Southwest Gas Transmission Company, A Limited Partnership.
Description: Tariff Amendment: Stipulation in Lieu of Filing Form 501–G to be effective 1/1/2019.
Filed Date: 11/7/18.
Accession Number: 20181107–5125.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–245–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement-CapacityRelease Macquarie 11072018 to be effective 11/7/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5069.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–246–000.
Applicants: Saltville Gas Storage Company L.L.C.
Description: § 4(d) Rate Filing: SGSC RCC In-service Filing to be effective 12/1/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5070.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–247–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—Yankee release to Direct Energy 798171 to be effective 11/8/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5076.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–248–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Newfield 18) to be effective 11/7/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5078.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–249–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2018–11–07 Encana to be effective 11/7/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5110.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–250–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: § 4(d) Rate Filing: Aethon/1849 Energy Negotiated Rate to be effective 11/2/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5116.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–251–000.
Applicants: Gulf Shore Energy Partners, LP.
Description: eTariff filing per 1430: Form 501G Filing.
Filed Date: 11/7/18.
Accession Number: 20181107–5117.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–252–000.
Applicants: Gulf Shore Energy Partners, LP.
Description: § 4(d) Rate Filing: Limited Section 4 Rate Filing to be effective 11/7/2018.
Filed Date: 11/7/18.
Accession Number: 20181107–5118.
Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–253–000.
Applicants: Dominion Energy Questar Pipeline, LLC.
Description: eTariff filing per 1430: Form 501–G of Dominion Energy Questar Pipeline, LLC.
Filed Date: 11/8/18.
Accession Number: 20181108–5000.
Comments Due: 5 p.m. ET 11/20/18.

Docket Numbers: RP19–254–000.
Applicants: Guardian Pipeline, L.L.C.
Description: eTariff filing per 1430: Filing in Compliance with Order No. 849—Form No. 501–G.
Filed Date: 11/8/18.
Accession Number: 20181108–5001.
Comments Due: 5 p.m. ET 11/20/18.

Docket Numbers: RP19–255–000.
Applicants: Lucid Energy Delaware, LLC, EOG Resources, Inc.
Description: Joint Petition for Temporary Waiver of Capacity Release Regulations and Policies, et al. of Lucid Energy Delaware, LLC, et al. under RP19–255.

Filed Date: 11/7/18.
Accession Number: 20181107–5139.
Comments Due: 5 p.m. ET 11/14/18.
Docket Numbers: RP19–256–000.
Applicants: Fayetteville Express Pipeline LLC.
Description: eTariff filing per 1430: FERC Form No. 501–G Report.
Filed Date: 11/8/18.
Accession Number: 20181108–5002.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–257–000.
Applicants: Southwest Gas Storage Company.
Description: eTariff filing per 1430: FERC Form No. 501–G Report.
Filed Date: 11/8/18.
Accession Number: 20181108–5003.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–258–000.
Applicants: Lake Charles LNG Company, LLC.
Description: eTariff filing per 1430: FERC Form No. 501–G Report.
Filed Date: 11/8/18.
Accession Number: 20181108–5004.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–259–000.
Applicants: Gulf States Transmission LLC.
Description: eTariff filing per 1430: FERC Form No. 501–G Report.
Filed Date: 11/8/18.
Accession Number: 20181108–5005.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–260–000.
Applicants: Bison Pipeline LLC.
Description: eTariff filing per 1430: Bison Form No. 501–G Filing.
Filed Date: 11/8/18.
Accession Number: 20181108–5027.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–261–000.
Applicants: Blue Lake Gas Storage Company.
Description: Compliance filing Blue Lake 501–G Settlement.
Filed Date: 11/8/18.
Accession Number: 20181108–5028.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–262–000.
Applicants: Hardy Storage Company, LLC.
Description: Compliance filing Hardy Storage 501–G Settlement.
Filed Date: 11/8/18.
Accession Number: 20181108–5029.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–263–000.
Applicants: Black Hills Shoshone Pipeline, LLC.
Description: eTariff filing per 1430: BHS FERC 501–G Filing.
Filed Date: 11/8/18.
Accession Number: 20181108–5030.
Comments Due: 5 p.m. ET 11/20/18.
Docket Numbers: RP19–264–000.
Applicants: PGPipeline LLC.
Description: eTariff filing per 1430: PGPipeline LLC FERC Form 501–G Filing.
Filed Date: 11/8/18.
Accession Number: 20181108–5031.
Comments Due: 5 p.m. ET 11/20/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 8, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24881 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2100–185—California]

Notice of Availability of Draft Environmental Assessment: California Department of Water Resources

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC's) regulations, 18 Code of Federal Regulations (CFR) Part 380, the Office of Energy Projects has reviewed an application filed by the California Department of Water Resources (California DWR), licensee for the Feather River Hydroelectric Project, to repair the Oroville Dam main spillway, modify the existing emergency spillway, and relocate a buried transmission line. The specifications for the proposal were filed with the Commission on January 29, 2018, and supplemented with additional supporting information on February 13, July 16, and August 1, 2018. The project is located on the Feather River in Butte County, California.

California DWR proposes to repair and reconstruct the Lake Oroville main spillway as a result of the failure of the main spillway beginning on February 7, 2017. California DWR also proposes to fortify the existing emergency spillway located adjacent to the main spillway and to relocate a buried transmission line near the Hyatt Power Plant. The proposed work would take place over two years, with major portions of the work at the main spillway completed on an expedited basis prior to the commencement of the normal wet season on November 1, 2017. The remainder of the work would be completed by January 2019. Staff prepared a draft environmental assessment (EA), which analyzes the potential environmental effects associated with the reconstruction and modification of project structures. The draft EA also discusses the environmental effects of California DWR's response to the spillway failure and concludes that California DWR's proposed activities, with specified environmental protection measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the draft EA is available for review at the Commission's Public Reference Room or it may be viewed on the Commission's website at *www.ferc.gov* using the eLibrary link. Enter the docket number P–2100 in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, 202–502–8659. *All comments must be filed by December 10, 2018.*

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can also submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2100–185.

For further information, contact Mr. John Aedo at (415) 369–3335 or by email at *john.aedo@ferc.gov.*

Dated: November 8, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–24885 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–12–000]

Notice of Request Under Blanket Authorization Florida Gas Transmission Company, LLC

Take notice that on November 1, 2018, Florida Gas Transmission Company, LLC (FGT), 1300 Main St., Houston, Texas 77002, filed in Docket No. CP19–12–000 a prior notice request pursuant to sections 157.205, 157.208, and 157.210 of the Commission's regulations under the Natural Gas Act and FGT's blanket certificate issued in Docket No. CP82–553–000 for authorization of the East Louisiana Project. FGT proposes to construct/modify, own, and operate, certain natural gas mainline facilities and appurtenances at an existing compressor station site in Perry County, Mississippi. In addition, FGT proposes to install a new regulator, valves, Electronic Flow Meter and Supervisory Control and Data Acquisition, and appurtenances, in FGT's permanent right of-way easement at an existing mainline valve site in Washington Parish, Louisiana. This project will allow FGT to provide additional capacity of up to 75 million cubic feet per day of available firm transportation service to Entergy Louisiana, LLC in Washington Parish, Louisiana, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Blair Lichtenwalter, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main St., Houston, Texas 77002, or via eMail to *Blair.Lichtenwalter@energytransfer.com,* or call (713) 989–2605.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 3 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE, Washington, DC 20426.

Dated: November 8, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–24887 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–122–000.

Applicants: GridLiance High Plains LLC.

Description: Response to October 11, 2018 Deficiency Letter of GridLiance High Plains LLC.

Filed Date: 11/7/18.

Accession Number: 20181107–5128.

Comments Due: 5 p.m. ET 11/28/18.

Docket Numbers: EC19–24–000.

Applicants: Northern Iowa Windpower LLC, Black Hills Electric Generation, LLC, Black Hills Corporation, Top Deer Wind Ventures, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act, et al. of Northern Iowa Windpower LLC, et al.

Filed Date: 11/7/18.

Accession Number: 20181107–5130.

Comments Due: 5 p.m. ET 11/28/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–115–000.

Applicants: FL Solar 5, LLC.

Description: Supplement to October 16, 2018 FL Solar 5, LLC tariff filing.

Filed Date: 11/7/18.

Accession Number: 20181107–5140.

Comments Due: 5 p.m. ET 11/21/18.

Docket Numbers: ER19–302–000.

Applicants: NTE Southeast Electric Company, LLC.

Description: Baseline eTariff Filing: Baseline new to be effective 1/1/2019.

Filed Date: 11/7/18.

Accession Number: 20181107–5114.

Comments Due: 5 p.m. ET 11/28/18.

Docket Numbers: ER19–303–000.

Applicants: Duquesne Light Company.

Description: Application for Incentive Rate Treatment, et al. of Duquesne Light Company.

Filed Date: 11/7/18.

Accession Number: 20181107–5132.
Comments Due: 5 p.m. ET 11/28/18.

Docket Numbers: ER19–304–000.
Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: MAIT submits an ECSA, Service Agreement No. 5195 with MetEd to be effective 1/8/2019.
Filed Date: 11/8/18.
Accession Number: 20181108–5026.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–305–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Rev to Day-ahead Energy Mrkt Timeline Expedited Action Shortened Comment Period to be effective 12/31/9998.
Filed Date: 11/8/18.
Accession Number: 20181108–5032.
Comments Due: 5 p.m. ET 11/15/18.

Docket Numbers: ER19–306–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC–NCEMC NITSA (SA No. 210) Amendment to be effective 1/1/2019.
Filed Date: 11/8/18.
Accession Number: 20181108–5099.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–307–000.
Applicants: Hudson Shore Energy Partners LLC.
Description: § 205(d) Rate Filing: Notice of Succssion to be effective 11/9/2018.
Filed Date: 11/8/18.
Accession Number: 20181108–5111.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–308–000.
Applicants: California Independent System Operator Corporation.
Description: Petition for Approval of Disposition of Proceeds of Penalty Assessments of California Independent System Operator Corporation.
Filed Date: 11/8/18.
Accession Number: 20181108–5116.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–309–000.
Applicants: ISO New England Inc., NSTAR Electric Company.
Description: § 205(d) Rate Filing: ISO–NE and NSTAR; Original Service Agreement under Schedule 21–ES of the OATT to be effective 1/7/2019.
Filed Date: 11/8/18.
Accession Number: 20181108–5122.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–310–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–11–08_SA 3200 Sholes Wind-MidAmerican FCA (C027) to be effective 10/25/2018.
Filed Date: 11/8/18.
Accession Number: 20181108–5124.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–311–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–11–08_SA 3201 Shiawassee Wind-METC GIA (J602) to be effective 10/25/2018.
Filed Date: 11/8/18.
Accession Number: 20181108–5155.
Comments Due: 5 p.m. ET 11/29/18.

Docket Numbers: ER19–312–000.
Applicants: Cedar Creek Wind Energy, LLC.
Description: § 205(d) Rate Filing: Category 2 Notice for NW Region and Revised Market-Based Rate Tariff to be effective 11/9/2018.
Filed Date: 11/8/18.
Accession Number: 20181108–5161.
Comments Due: 5 p.m. ET 11/29/18.

Take notice that the Commission received the following foreign utility company status filings:

Docket Numbers: FC19–1–000.
Applicants: I Squared Capital.
Description: Notification of Self-Certification of Foreign Utility Company Status of the Ibereolica Solar Companies.
Filed Date: 11/8/18.
Accession Number: 20181108–5081.
Comments Due: 5 p.m. ET 11/29/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 8, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24882 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL19–13–000; QF16–1090–002; QF16–1091–002; QF17–475–001; QF17–579–001; QF17–476–001]

Notice of Petition for Declaratory Order; Blue Marmot V LLC, Blue Marmot VI LLC, Blue Marmot VII LLC, Blue Marmot VIII LLC, and Blue Marmot IX LLC

Take notice that on November 7, 2018, pursuant to Rule 207 of the Commission's Rules of Practice and Procedure,[1] Blue Marmot V LLC, Blue Marmot VI LLC, Blue Marmot VII LLC, Blue Marmot VIII LLC, and Blue Marmot IX LLC (collectively, Petitioners) filed a petition for declaratory order (petition) requesting that the Commission find that transmission congestion does not mitigate the purchase obligation under section 210 of the Public Utility Regulatory Policies Act of 1978, as amended,[2] and that transmission costs associated with the delivery of power on the Portland General Electric Company system are within the Commission's authority, all as more fully explained in the petition.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioners.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

[1] 18 CFR 385.207 (2017).

[2] 16 U.S.C. 824a–3.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on December 7, 2018.

Dated: November 8, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–24884 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19–302–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; NTE Southeast Electric Company, LLC

This is a supplemental notice in the above-referenced NTE Southeast Electric Company, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 28, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 8, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24883 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2804–035]

Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions; Goose River Hydro, Inc.

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection.

a. *Type of Application:* New Minor License.

b. *Project No:* 2804–035.

c. *Date filed:* February 2, 2018.

d. *Applicant:* Goose River Hydro, Inc.

e. *Name of Project:* Goose River Hydroelectric Project.

f. *Location:* On the Goose River, in Waldo County, Maine. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Nicholas Cabral, Goose River Hydro, Inc., 41 Sedgewood Drive, Kennebunk, ME 04043; (207) 604–4394; or email at *gooseriverhydro@gmail.com.*

i. *FERC Contact:* Julia Kolberg at (202) 502–8261; or email at *julia.kolberg@ferc.gov.*

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include the relevant docket number P–2804–035.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is now ready for environmental analysis.

l. The project consists of the following existing facilities:

Swan Lake Dam

(1) A 14-foot-high, 250-foot-long rock masonry gravity dam impounding Swan Lake with a surface area of approximately 1,364 acres at an elevation of 201 feet above sea level; (2) a concrete inlet structure; (3) three 3.5-foot-high, 4-foot-wide manually operated butterfly gates that regulate flow through the inlet structure; (4) two culverts that convey flow under Route 141; and (5) appurtenant facilities.

Mason's Dam

(1) A 15-foot-high, 86-foot-long rock masonry dam impounding a reservoir with a storage capacity of approximately 1,621 acre-feet at an elevation of 188 feet above sea level; (2) a concrete inlet structure; (3) a manually operated butterfly gate regulating flow from the inlet structure to the penstock; (4) a 3-foot-diameter, 350-foot-long steel penstock; (5) a 266-square-foot concrete powerhouse containing two Kaplan turbines and generating units with a licensed capacity of 100 kW; (6) a 300-foot-long, 12-kilovolt (kV) transmission line; and (7) appurtenant facilities. Mason's Development generates when flows in excess of 5 cfs are available and when an operator is present.

Kelly Dam

(1) A 15-foot-high, 135-foot-long masonry gravity dam impounding a reservoir with a storage capacity of approximately 200 acre-feet at an elevation of approximately 159 feet above sea level; and (2) three 3-foot-high, 2.5-foot-wide manually operated butterfly gates.

Mill Dam

(1) A 6-foot-tall, 70-foot-wide masonry dam impounding a reservoir with a storage capacity of approximately 7 acre-feet at an elevation of approximately 128 feet above sea level; (2) a concrete inlet structure; (3) a trash sluice with wooden stop logs; (4) a powerhouse containing a Francis-type turbine and generator unit with a licensed capacity of 75 kW; (5) a 60-foot-wide concrete spillway; and (6) an approximately 100-foot-long, 12-kV transmission line. The penstock used to deliver water to the powerhouse has been removed due to deterioration and subsequent leakage; thus, the powerhouse is not operating.

CMP Dam

(1) A 21-foot-high, 231-foot-long buttress dam impounding a reservoir with a storage capacity of approximately 72 acre-feet at an elevation of approximately 109 feet above sea level; (2) a manually operated low-level water release lift gate; (3) a manually operated lift gate regulating flow to the penstock; (4) a 5-foot-diameter, 1,200-foot-long steel penstock; (5) a 300-square-foot concrete and timber powerhouse with a Kaplan-type turbine and generator unit with a licensed capacity of 200 kW; (6) a 42-foot-long spillway; and (7) an approximately 500-foot-long, 12-kV transmission line. The penstock used to deliver water to the powerhouse is currently out of service due to damage, deterioration, and subsequent leakage; thus, the powerhouse is not operating.

m. Copies of the applications are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. Copies are also available for inspection and reproduction at the address in item h above.

All filings must (1) bear in all capital letters the title COMMENTS, REPLY COMMENTS, RECOMMENDATIONS, TERMS AND CONDITIONS, or PRESCRIPTIONS; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the applications directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *A license applicant must file no later than 60 days following the date of issuance of this notice:* (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

o. *Procedural schedule:* The applications will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Commission issues EA—June 2019
Comments on EA due—July 2019

Dated: November 8, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–24886 Filed 11–14–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0604; FRL–9986–45]

Draft TSCA Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of and seeking public comment on the draft Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29) and associated documents developed under EPA's existing chemical substance process under the Toxic Substances Control Act (TSCA). The purpose of the risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. EPA is also submitting these same documents to the TSCA Science Advisory Committee on Chemicals (SACC) which will peer review the draft risk evaluation, and EPA will provide the peer review meeting details in a separate **Federal Register** notice. All comments submitted on the draft risk evaluation in response to this Notice of Availability will be provided to the TSCA SACC peer review panel, which will have the opportunity to consider the comments during its discussions. In addition, the subsequent **Federal Register** notice providing details on the peer review meeting will explain the process for submitting information and views to the peer review panel. EPA will consider the public comments on the draft risk evaluation submitted in response to this Notice of Availability, along with peer reviewer comments and recommendations, to finalize the risk evaluation.

DATES: Comments must be received on or before January 14, 2019.

ADDRESSES: Submit your written comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0604, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPPT Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Dawson, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–0331; email address: *dawson.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are interested in risk evaluations of existing chemical substances under the Toxic Substances Control Act (TSCA). Since other entities may also be interested in this draft risk evaluation, the Agency has not attempted to describe all the entities that may be interested in this action.

B. What action is the agency taking?

EPA is announcing the availability of and seeking public comment on the draft Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29) and associated documents, which is available at the docket identified by ID No. EPA–HQ–OPPT–2018–0604 at *http://www.regulations.gov.* EPA is providing 60 days for public comment on all aspects of this draft risk evaluation, including any conclusions, findings, determinations, and the submission of any additional information that might be relevant to the science underlying the risk evaluation and the outcome of the systematic review associated with C.I. Pigment Violet 29. This 60-day comment period on the draft risk evaluation satisfies TSCA section 6(b)(4)(H), which requires EPA to ''provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.''

In addition to any new comments on the draft risk evaluation, the public should resubmit or clearly identify at this time any previously filed comments, modified as appropriate, that are relevant to this risk evaluation and that the submitter feels have not been addressed. EPA does not intend to further respond to comments submitted prior to the release of this draft risk evaluation.

All comments on the draft risk evaluation in response to this Notice of Availability, and all information and views submitted to the peer review panel as directed in the subsequent **Federal Register** notice announcing the TSCA SACC panel meeting, are being directed to the same docket, identified by docket ID No. EPA–HQ–OPPT–2018–0604 at *http://www.regulations.gov.* As such, comments submitted or resubmitted during this 60-day period will be provided to the TSCA SACC for consideration during their peer review.

C. What is the Agency's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.'' 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and completion of the risk evaluation. The law also requires that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) Integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. 15 U.S.C. 2605(b)(4)(F)(i), and (iii)–(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

The statute requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G). The statute also requires that the Agency allow for no less than a 30-day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or via email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on our website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca.* As explained the in the preamble to EPA's procedural final rule (82 FR 33726, July 20, 2017) (FRL–9964–38), the specific regulatory process set out in 40 CFR part 702 will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

B. What is Pigment Violet 29?

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d′e′f′] diisoquinoline-1,3,8,10(2H,9H)-tetrone) (pigment violet 29) is a perylene derivative used to color materials and as an intermediate for other perylene pigments. The pigment is utilized as an intermediate to create or adjust the color of other pigments, as well as in commercial paints, coatings, plastics, and rubber products. C.I. Pigment Violet 29 is an organic pigment that has a low solubility, low volatility, is expected to be highly persistent and has low bioaccumulation potential in fish and other animals.

Information about the problem formulation and scope phases of the risk evaluation for this chemical is available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-pigment-violet-29-anthra219-def6510.*

C. Purpose of the TSCA SACC

The TSCA SACC was established by EPA to support activities under TSCA, 15 U.S.C. 2601 *et seq.,* the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.,* and other applicable statutes. The TSCA SACC provides expert independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. Given the SACC's expertise, EPA is submitting the draft risk evaluation and related documents to the TSCA SACC for peer review and scheduling a public meeting for the panel's discussion of those materials. Consistent with EPA's peer review policy and requirements associated with the Federal Advisory Committee Act (FACA), 5 U.S.C Appendix 2 *et seq.,* EPA will announce the TSCA SACC public meeting and provide related details about that meeting in a future **Federal Register** notice.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 9, 2018.

Nancy B. Beck,

Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–24972 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2018–0576; FRL–9985–70]

Pesticide Product Registration; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before December 17, 2018.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol or EPA Registration Number of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

III. New Uses

1. *EPA Registration Numbers:* 100–815, 100–816, 100–1406, and 100–1407. *Docket ID number:* EPA–HQ–OPP–2017–0465. *Applicant:* Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro NC 27419. *Active ingredient:* s-metolachlor. *Product type:* Herbicide. *Proposed use:* Stevia; chicory; Swiss chard; vegetable, brassica, head and stem, group 5–16; the brassica, leafy greens, subgroup 4–16B, except Chinese broccoli; the leaf petiole vegetable subgroup 22B; stalk and stem vegetable subgroup 22A, except celtuce, Florence fennel and kohlrabi; the cottonseed subgroup 20C; celtuce; Florence fennel; Kohlrabi; and Chinese broccoli. *Contact:* RD.

2. *EPA Registration Number:* 264–678. *Docket ID number:* EPA–HQ–OPP–2018–0623. *Applicant:* Bayer CropScience LP. *Active ingredient:* Propamocarb hydrochloride. *Product type:* Fungicide. *Proposed use:* Guava; leafy greens subgroup 4–16A; starfruit; vegetable, fruiting, group 8–10; vegetable, tuberous and corm, subgroup 1C. *Contact:* RD.

3. *EPA Registration Numbers:* 4787–55, 4787–61, 279–GAGG. *Docket ID number:* EPA–HQ–OPP–2018–0297. *Applicant:* Cheminova A/S, P.O. Box 9, DK–7620, Lemvig, Denmark and on behalf of FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. *Active ingredient:* Flutriafol. *Product type:* Fungicide. *Proposed uses:* Turf (golf course, athletic fields, commercial sod farms, and public, industrial and commercial property lawns) and ornamentals (field and greenhouse). *Contact:* RD.

4. *EPA Registration Numbers:* 10163–361 and 10163–363. *Docket ID number:* EPA–HQ–OPP–2017–0420. *Applicant:* Gowan Company P.O. Box 5569 Yuma, AZ 85366–5569. *Active ingredient:* Trifluralin. *Product type:* Herbicide. *Proposed use:* Rosemary. *Contact:* RD.

5. *File Symbols:* 62719–TGE and 62719–TGR and *EPA Registration Number:* 62719–697. *Docket ID number:* EPA–HQ–OPP–2018–0645. *Applicant:* Dow AgroSciences LLC, 9330 Zionsville Road Indianapolis, IN 46268. *Active ingredient:* Florpyrauxifen-benzyl. *Product type:* Herbicide. *Proposed uses:* Pome fruit, stone fruit, citrus fruit, tree nuts, olives, coffee, pineapple, papaya, corn, sorghum, cereals, sugarcane, cotton, fallow, burndown, cole crops, bulb vegetables, and non-cropland. *Contact:* RD.

6. *EPA Registration Numbers:* 66330–35 and 66330–36. *Docket ID number:* EPA–HQ–OPP–2018–0560. *Applicant:* Arysta LifeScience, North America, LLC. *Active ingredient:* Fenhexamid. *Product type:* Fungicide. *Proposed use:* Arugula; berry, low growing, subgroup 13–07G; bushberry subgroup 13–07B; caneberry subgroup 13–07A; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; fruit, stone, group 12–12, except plum, prune, fresh, postharvest; garden cress; kiwifruit, fuzzy; leafy greens, subgroup 4–16A, except spinach; onion, bulb, crop subgroup 3–07A; onion, green, subgroup 3–07B; upland cress; vegetable, fruiting, group 8–10, except nonbell pepper. *Contact:* RD.

7. *EPA Registration Number:* 71512–24 and 71512–25. *Docket ID number:* EPA–HQ–OPP–2018–0677. *Applicant:* ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio, 44077. *Active ingredient:* Pyriofenone. *Product type:* Fungicide. *Proposed use:* Fruiting Vegetables, Crop Group 8–10. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 23, 2018.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018–24971 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9986–52–OAR]

Notice of Public Meeting of the Interagency Steering Committee on Radiation Standards (ISCORS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA) will host a meeting of the Interagency Steering Committee on Radiation Standards (ISCORS) on Thursday, December 6, 2018 in Washington, DC. The purpose of ISCORS is to foster early resolution and coordination of regulatory issues associated with radiation standards. Member agencies include: EPA; the Nuclear Regulatory Commission; and Departments of Energy; Defense; Transportation; Homeland Security; Health and Human Services; and Labor's Occupational Safety and Health Administration. Observer agencies include: The Office of Science and Technology Policy, Office of Management and Budget, Defense Nuclear Facilities Safety Board, as well as state representatives from Pennsylvania and Washington. ISCORS maintains several objectives: Facilitate a consensus on allowable levels of radiation risk to the public and workers; promote consistent and scientifically sound risk assessment and risk management approaches in setting and implementing standards for occupational and public protection from ionizing radiation; promote completeness and coherence of Federal standards for radiation protection; and identify interagency radiation protection issues and coordinate their resolution. ISCORS meetings include presentations by Subcommittee Chairs and discussions of current radiation protection issues. Committee meetings normally involve pre-decisional intra-governmental discussions and, as such, are normally not open for observation by members of the public or media. This particular ISCORS meeting is open to all interested members of the public. Time will be reserved on the agenda for members of the public to ask questions and provide comments.

Please Note: The final meeting agenda will be posted on the website shortly before the meeting.

DATES: The meeting will be held on Thursday, December 6, 2018, from 1:00 p.m. to 4:30 p.m.

ADDRESSES: The ISCORS meeting will be held in Room 1153 at the USEPA William Jefferson Clinton East Building (WJC East), 1201 Constitution Avenue NW, Washington, DC. Attendees are required to present a photo ID such as a government agency photo identification badge or valid driver's license. The Department of Homeland Security has begun implementing REAL ID Act requirements for visitors who present state-issued driver's licenses as IDs at restricted federal facilities. Driver's licenses from states and territories that do not comply with the REAL ID Act will not be accepted as identification. More details on these ID requirements can be found at *http://www2.epa.gov/aboutepa/visiting-epa-headquarters* and clicking on the Building Access tab. Visitors and their belongings will be screened by EPA security guards. Visitors must sign the visitors log at the security desk and will be issued a visitors badge by the security guards to gain access to the meeting.

FOR FURTHER INFORMATION CONTACT: Marisa D. Thornton, Radiation Protection Division, Office of Radiation and Indoor Air, Mailcode 6608T, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; email *thornton.marisa@epa.gov.*

SUPPLEMENTARY INFORMATION: Pay parking is available for visitors at multiple garages around the Ronald Reagan building and Federal Triangle complex. Visitors can also ride metro to the Federal Triangle station (Blue Orange and Silver Line). After exiting the turnstiles, go up both escalators to street level. Turn around and walk towards 12th Street NW. Turn right on 12th street and continue walking until you get to Constitution Avenue. Then turn right onto Constitution Avenue and 1201 William Jefferson Clinton EAST is the first building on your right.

Visit the ISCORS website, *www.iscors.org/index.htm* for more detailed information.

Dated: November 6, 2018.

Jonathan D. Edwards,

Director, Office of Radiation and Indoor Air.

[FR Doc. 2018–24976 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2018–0014; FRL–9984–05]

Product Cancellation Order for Certain Pesticide Registrations and Amendments To Terminate Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations and amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1, Table 1A, Table 1B and Table 2 of Unit II, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows an August 10, 2018 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 3 of Unit II to voluntarily cancel and amend to terminate uses of these product registrations. In the August 10, 2018 notice, EPA indicated that it would issue an order implementing the cancellations and amendments to terminate uses, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and amendments to terminate uses. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations and amendments are effective November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Christopher Green, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–0367; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0014, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces the cancellations and amendments to delete uses, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1, Table 1A, Table 1B, and Table 2 of this unit. The cancellations of the two triforine products, EPA Reg. Nos. 239–2435 and 82534–1, are the last registered products containing this active ingredient. The cancellation of the ten siduron products listed in Table 1A, are the last registered products containing this active ingredient.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
100–797	100	Apron XL WS	Metalaxyl-M.
100–1065	100	Scimitar WP Insecticide in Water-Soluble Packs	Lambda-Cyhalothrin.
100–1174	100	Impasse Termite Bait	Lufenuron.
100–1181	100	Zyrox Plus Termite Baiting Technology	Lufenuron.
100–1257	100	Lufenuron Termite Bait	Lufenuron.
239–2435	239	Ortho Rose Disease Control	Triforine.
279–3312	279	Capture 8% ME Insecticide/Miticide	Bifenthrin.
279–9533	279	Fluthiacet-Methyl WSP Herbicide	Fluthiacet-methyl.
352–392	352	DuPont Velpar L Herbicide	Hexazinone.
352–570	352	DuPont DPX–E9636 75 DF Herbicide	Rimsulfuron.
352–572	352	DuPont DPX–79406 75 DF Herbicide	Nicosulfuron & Rimsulfuron.
352–573	352	DuPont Synchrony STS DF Herbicide	Chlorimuron & Thifensulfuron.
352–574	352	DuPont Synchrony STS SP Herbicide	Chlorimuron & Thifensulfuron.
352–576	352	DuPont Staple Herbicide	Pyrithiobac-sodium.
352–581	352	DuPont Velpar DF Herbicide	Hexazinone.
352–585	352	Basis Gold Herbicide	Atrazine, Nicosulfuron & Rimsulfuron.

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Company No.	Product name	Active ingredients
352–599	352	DuPont Synchrony STS Herbicide	Chlorimuron & Thifensulfuron.
352–619	352	DuPont Steadfast ATZ Herbicide	Atrazine, Nicosulfuron & Rimsulfuron.
352–650	352	DuPont Synchrony XP (MP) Herbicide	Chlorimuron & Thifensulfuron.
352–667	352	DuPont Stout (MP)	Thifensulfuron & Nicosulfuron.
352–721	352	DuPont Stout Herbicide	Thifensulfuron & Nicosulfuron.
352–749	352	DuPont STS07 Broadleaf Herbicide	Thifensulfuron & Chlorimuron.
352–759	352	DuPont DPX–QFU30 (MP) Herbicide	Thifensulfuron & Rimsulfuron.
1448–52	1448	Busan 40	Metam-Potassium.
1448–74	1448	PNMDC	Metam-Potassium.
1839–30	1839	BTC 824 P100	Alkyl* dimethyl benzyl ammonium chloride *(100% C14).
2693–11	2693	Supertrop Antifouling Bottom Paint 46 Red	Cuprous oxide.
2693–12	2693	Bottomkote Antifouling 49 Red	Cuprous oxide.
2693–19	2693	Viny-Lux Vinyl Antifouling Paint 350 Red	Cuprous oxide.
2693–33	2693	Offshore Antifouling Red 1605	Cuprous oxide.
2693–54	2693	International NB Supertrop Antifouling Paint NB1609	Cuprous oxide.
2693–58	2693	Bottomkote Antifouling Paint 59 Green	Cuprous oxide.
2693–59	2693	Bottomkote Antifouling Paint 69 Blue	Cuprous oxide.
2693–90	2693	Red Hand Antifouling 72 Blue	Cuprous oxide.
2693–97	2693	Supertrop Antifouling Paint 45 Blue	Cuprous oxide.
2693–121	2693	Super Viny-Lux Vinyl Antifouling Red 459	Cuprous oxide.
2693–135	2693	XUU 284	Cuprous oxide.
2693–143	2693	Ultra-Kote 2669H Blue	Cuprous oxide.
2693–146	2693	Seaproof Paint X–255 Evertox Blue Copper Anti-Fouling	Cuprous oxide.
2693–147	2693	Regatta 3900 Anti-Fouling Red Latex	Cuprous oxide.
2693–165	2693	Seaproof X–254 Evertox Green Copper Anti-Fouling	Cuprous oxide.
2693–166	2693	Seaproof 42 90 Tritox Red Anti-Fouling	Cuprous oxide.
2693–167	2693	Seaproof X–253 Evertox Red Copper Anti-Fouling	Cuprous oxide.
2693–168	2693	Regatta Vinyltex 55 Fast Red Antifouling	Cuprous oxide.
2693–169	2693	Seaproof 1600 Plastic Red Copper Antifouling	Cuprous oxide.
2693–171	2693	Baltimore Red Copper Paint	Cuprous oxide.
2693–192	2693	Ultra with Bio-Lux Blue	Cuprous oxide & 1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N′-(1,1-dimethylethyl)-6-(methylthio)-.
2693–201	2693	Ultra Plus Blue	Cuprous oxide & 1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N′-(1,1-dimethylethyl)-6-(methylthio)-.
2693–205	2693	Ultra Plus Blue	Cuprous oxide & 1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N′-(1,1-dimethylethyl)-6-(methylthio)-.
2693–219	2693	Super KL Plus with Irgarol II Black	1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N′-(1,1-dimethylethyl)-6-(methylthio)- & Cuprous oxide.
2935–389	2935	Nusan 30 E.C.	2-(Thiocyanomethylthio) benzothiazole.
4787–65	4787	Azoxystrobin Technical	Azoxystrobin.
9688–107	9688	Chemsico Insect Spray	Piperonyl butoxide & Pyrethrins.
9688–110	9688	Chemsico Patio Spray	Piperonyl butoxide; Tetramethrin & Permethrin.
9688–150	9688	Chemsico Aerosol Insecticide PP	Pyrethrins & Piperonyl butoxide.
9688–225	9688	Chemsico Insect Spray PP	Pyrethrins & Piperonyl butoxide.
9688–228	9688	Chemsico Wasp & Hornet Killer FEQ 24	Piperonyl butoxide; Permethrin & Tetramethrin.
9688–236	9688	Chemsico Aerosol Insecticide TPP	Piperonyl butoxide; Permethrin & Tetramethrin.
9688–247	9688	Chemsico Wasp & Hornet Killer FEQ C24	Piperonyl butoxide; Permethrin & Tetramethrin.
9688–273	9688	Chemsico Insecticide RTU OP	Pyrethrins.

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Company No.	Product name	Active ingredients
10324–195	10324	Maquat 615 SRTU–BOV	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride & Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
15136–9	15136	Wavicide-06 Plus	Ethanol & Glutaraldehyde.
23566–10	23566	Racing Vinyl 640 Red	Cuprous oxide.
23566–18	23566	America's Cup 681 Blue	Cuprous oxide.
34160–1	34160	Pine-Oil Disinfectant Detergent Concentrate	Pine oil.
61282–53	61282	Biophene Liquid Disinfectant	2-Benzyl-4-chlorophenol; 4-tert-Amylphenol & o-Phenylphenol (NO INERT USE).
61842–43	61842	DuPont Velpar Alfamax MP Herbicide	Diuron & Hexazinone.
61842–44	61842	DuPont Velpar K–4 Max Herbicide	Diuron & Hexazinone.
63838–6	63838	Dibrom NPA	2,2-Dibromo-3-nitrilopropionamide.
73770–1	73770	Fresh Aire	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
81964–3	81964	Acephate 90% SP	Acephate.
82523–1	82523	Aerisguard Bioactive Coil Treatment	Triclosan.
82534–1	82534	Triforine Technical	Triforine.
83122–1	83122	Pro-Tek 50 Fabric/Apparel (Garment) Treatment	Permethrin.
83122–2	83122	Bond-It Insect Repellent Fabric Treatment	Permethrin.
88751–1	88751	A-Liquid	Silver & Copper as elemental.
OR–030029	19713	Drexel Captan 4L Fungicide	Captan.
OR–040004	100	Fulfill	Pymetrozine.
OR–040005	100	Fulfill	Pymetrozine.
OR–900019	10163	Treflan TR–10 Granules	Trifluralin.
OR–940037	62719	Sonalan HFP	Ethalfluralin.
OR–950013	100	Fusilade DX	Fluazifop-P-butyl.
OR–990039	100	Bravo 825	Chlorothalonil.
OR–990040	100	Bravo 720	Chlorothalonil.
VA–110002	100	Ridomil Gold SL	Metalaxyl-M.
WA–040024	100	Fusilade DX Herbicide	Fluazifop-P-butyl.
WA–050002	5481	Orthene 75 S Soluble Powder (Water Soluble Packets)	Acephate.

TABLE 1A—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
538–60	538	Starter Fertilizer with Crabgrass Preventer	Siduron.
961–297	961	Greenfield Modern Trebl	Siduron.
961–309	961	Greenskeeper Crabgrass Killer Contains 4.6% Tupersan	Siduron.
961–319	961	Lebanon Spring Seeding Crabgrass Preventer with Grass Food	Siduron.
8378–63	8378	Shaw's Turf Food with Tupersan 350	Siduron.
8378–64	8378	Shaw's Tupersan 470 Granules	Siduron.
9198–50	9198	The Andersons Fertilizer with 3.5% Tupersan	Siduron.
10163–213	10163	Tupersan Herbicide	Siduron.
10163–214	10163	Tupersan 70 Herbicide	Siduron.
10163–216	10163	Siduron Technical	Siduron.

The registrants for the pesticide product registrations listed in Table 1A have requested to the Agency via letter, that the cancellations become effective December 31, 2020.

TABLE 1B—PRODUCT CANCELLATION

Registration No.	Company No.	Product name	Active ingredients
432–1412	432	Armada 50 WP	Triadimefon & Trifloxystrobin.

The registrant for the pesticide product registration listed in Table 1B has requested to the Agency via letter, that the cancellation becomes effective at the federal level on December 31, 2018.

TABLE 2—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE USES

Registration No.	Company No.	Product name	Active ingredients	Uses to be terminated
1839–208	1839	BTC 1455	Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2%C16).	Golf courses and golf commercial turf/lawns.
19713–691	19713	Drexel Chlorothalonil Technical	Chlorothalonil	Antimicrobial uses.
47000–103	47000	CT 10 Concentrate	Permethrin	Golf courses.
53883–379	53883	Quali-Pro Prodiamine 4L	Prodiamine	Use in drainage ditches for California & Arizona.
61842–13	61842	Sinbar Herbicide	Terbacil	Grass grown for seed (Grass seed crops).
61842–14	61842	Terbacil Technical Herbicide	Terbacil	Grass grown for seed (Grass seed crops).
61842–27	61842	Sinbar WDG (Status—Inactive), (Sinbar WDG Agricultural Herbicide—(Status—Active).	Terbacil	Grass grown for seed (Grass seed crops).
70553–2	70553	Permethrin Technical	Permethrin	Terrestrial food and feed uses.

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Table 1, Table 1A, Table1B and Table 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1, Table 1A, Table1B and Table 2 of this unit.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS

EPA Company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419–8300.
239	The Scotts Company, d/b/a The Ortho Group, 14111 Scottslawn Rd., Marysville, OH 43041.
279	FMC Corporation, 2929 Walnut St., Philadelphia, PA 19104.
352	E. I. Du Pont De Nemours and Company, Attn: Manager, US Registration, DuPont Crop Protection, Chestnut Run Plaza (CRP 720/2E5), 974 Centre Rd., Wilmington, DE 19805.
432	Bayer Environmental Science, A Division of Bayer CropScience, LP, 2 T. W. Alexander Dr., Research Triangle Park, NC 27709.
538	Scotts Company, The, 14111 Scottslawn Rd., Marysville, OH 43041.
961	Lebanon Seaboard Corporation, 1600 East Cumberland St., Lebanon, PA 17042.
1448	Buckman Laboratories, Inc., 1256 North McLean Blvd., Memphis, TN 38108.
1839	Stepan Company, 22 W. Frontage Rd., Northfield, IL 60093.
2693	International Paint, LLC, 6001 Antoine Dr., Houston, TX 77091.
2935	Wilbur-Ellis Company, LLC, 2903 S. Cedar Ave., Fresno, CA 93725.
4787	Cheminova A/S, Agent Name: FMC Corporation, 1735 Market St., Room 1971, Philadelphia, PA 19103.
5481	Amvac Chemical Corporation, 4695 MacArthur Ct., Suite 1200, Newport Beach, CA 92660–1706.
8378	Knox Fertilizer Company, Inc., Agent Name: Fred Betz Regulatory Strategies, 922 Melvin Rd., Annapolis, MD 21403.
9198	The Andersons, Inc., 1947 Briarfield Blvd, P.O. Box 119, Maumee, OH 43537.
9688	Chemsico, A Division of United Industries Corp., P.O. Box 142642, St. Louis, MO 63114–0642.
10163	Gowan Company, P.O. Box 5569, Yuma, AZ 85366.
10324	Mason Chemical Company, 2744 E. Kemper Rd., Cincinnati, OH 45241.
15136	Medical Chemical Corp., 19430 Van Ness Ave., Torrance, CA 90501.
19713	Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–0327.
23566	International Paint, LLC, 6001 Antoine Dr., Houston, TX 77091.
34160	Lighthouse for The Blind of Houston, Agent Name: Laird's Regulatory Consultants, Inc., 17804 Braemar Pl., Leesburg, VA 20175–7046.
47000	Chem-Tech, Ltd., 620 Lesher Pl., Lansing, MI 48912.
53883	Control Solutions, Inc., 5903 Genoa Red Bluff Rd., Pasadena, TX 77507.
61282	Hacco, Inc., 620 Lesher Pl., Lansing, MI 48912.
61842	Tessenderlo Kerley, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
62719	Dow Agrosciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268–1054.
63838	Enviro Tech Chemical Services, Inc., 500 Winmoore Way, Modesto, CA 95358.
70553	Meghmani Organics Limited, Meghmani House, Shree Nivas Society, Agent Name: Butz Consulting, LLC, 13411 Marble Rock Dr., Chantilly, VA 20151.
73770	Dial Manufacturing, Inc., 25 South 51st Ave., Phoenix, AZ 85043.
81964	Chemstarr, LLC, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct NW, Gig Harbor, WA 98332.
82523	Aeris Environmental, Ltd., Agent Name: Scientific & Regulatory Consultants, Inc., 201 W. Van Buren Street, Columbia City, IN 46725.
82534	Summit Agro North America Holding Corporation, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
83122	Garnik Industries, LLC, 261 5th Ave., Suite 2001, New York, NY 10016.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS—Continued

EPA Company No.	Company name and address
88751	Toto USA, Inc., Agent Name: Technology Sciences Group, Inc., 1150 18th St. NW, Suite 1000, Washington, DC 20036.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the August 10, 2018 **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations and amendments to terminate uses of products listed in Table 1, Table 1A, Table1B, and Table 2 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)(1)), EPA hereby approves the requested cancellations and amendments to terminate uses of the registrations identified in Table 1, Table 1A, Table1B, and Table 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 and Table 2 of Unit II are canceled and amended to terminate the affected uses effective November 15, 2018. The product registrations identified in Table 1A of Unit II will be canceled effective December 31, 2020. The product registration identified in Table 1B of Unit II will be canceled effective December 31, 2018. Any distribution, sale, or use of existing stocks of the products identified in Table 1, Table 1A, Table1B, and Table 2 of Unit II in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI will be a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of August 10, 2018 (83 FR 39746) (FRL–9980–44). The comment period closed on September 10, 2018.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

A. For Product 10324–195

The registrant has requested to the Agency via letter, an 18-month sell thru period so the registrant may continue to sell and distribute existing stocks of this product for 18 months after the effective date of the cancellation, which is the date of publication of this cancellation order in the **Federal Register**.

B. For Products in Table 1

Registrants may continue to sell and distribute existing stocks of these products for 1 year after the effective date of the cancellation, which is the date of publication of this cancellation order in the **Federal Register**.

C. For Products in Table 1A

Registrants may continue to sell and distribute existing stocks of these products until December 31, 2021, which is 1 year after the effective date of the cancellation.

D. For Products in Table 1B

The registrant may continue to sell and distribute existing stocks of this product until December 31, 2019, which is 1 year after the effective date of the cancellation.

Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1, Table 1A, and Table 1B of Unit II, except for export in accordance with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Now that EPA has approved product labels reflecting the requested amendments to terminate uses, registrants are permitted to sell or distribute products listed in Table 2 of Unit II under the previously approved labeling for 18 months after the effective date of the cancellation, which is the date of publication of this order in the **Federal Register**, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal. Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 16, 2018.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018–24970 Filed 11–14–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Radio Broadcasting Services; AM or FM Proposals To Change the Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

DATES: The agency must receive comments on or before January 14, 2019.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, 202–418–2054.

SUPPLEMENTARY INFORMATION: The following applicants filed AM or FM proposals to change the community of license: ETERNITY MEDIA GROUP WERM, LLC, WERM(AM), Fac. ID No. 32848, Channel 1220 kHz, To AFRICA TOWN, AL, From FAIRHOPE, AL, BP–20180723AAR; HI–LINE RADIO FELLOWSHIP INC., KNPC(FM), Fac. ID No. 177237, Channel 203C3, To HARDIN, MT, From COLSTRIP, MT, BPED–20180723AAK; FLORIDA KEYS MEDIA, LLC, WAVK(FM), Fac. ID No. 23294, Channel 249C1, To CUDJOE KEY, FL, From MARATHON, FL, BPH–20181012AAN; UNIVISION RADIO STATIONS GROUP, INC., KRGT(FM),

Fac. ID No. 11614, Channel 257C2, To SUNRISE MANOR, NV, From INDIAN SPRINGS, NV, BPH–20180905ABJ; TOWNSQUARE MEDIA BOZEMAN LICENSE, LLC, KXLB(FM), Fac. ID No. 30566, Channel 264C1, To CHURCHILL, MT, From LIVINGSTON, MT, BPH–20180828ABV; and FULLER BROADCASTING INTERNATIONAL, LLC, WWRX(FM), Fac. ID No. 58731, Channel 299A, To NORTH STONINGTON, CT, From BRADFORD, RI, BPH–20180814AAD.

The full text of these applications is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street SW, Washington, DC 20554 or electronically via the Media Bureau's Consolidated Data Base System, *http://licensing.fcc.gov/prod/cdbs/pubacc/prod/cdbs_pa.htm.*

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2018–24880 Filed 11–14–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 10, 2018.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Redwood Financial, Inc., Redwood Falls, Minnesota;* to become a bank holding company by acquiring 100 percent of the voting shares of HomeTown Bank, Redwood Falls, Minnesota, upon its conversion from a savings association to a bank.

Board of Governors of the Federal Reserve System, November 9, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–24926 Filed 11–14–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0007; Docket No. 2018–0003; Sequence No. 6]

Submission for OMB Review; Subcontracting Plans

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding small business subcontracting plans.

DATES: Submit comments on or before December 17, 2018.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to *http://www.regulations.gov* and follow the instructions on the site.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 9000–0007, Subcontracting Plans.

Instructions: Please submit comments only and cite Information Collection 9000–0007, Subcontracting Plans, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or email *zenaida.delgado@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection requirement, OMB Control No. 9000–0007, currently titled ''Summary Subcontract Report,'' is proposed to be retitled ''Subcontracting Plans,'' due to consolidation with currently approved information collection requirement OMB Control No. 9000–0006, Subcontracting Plans/Individual Subcontract Report (SF 294) and ISRS, and 9000–0192, Utilization of Small Business Subcontractors.

This clearance covers the information that offerors and contractors must submit to comply with the requirements in Federal Acquisition Regulation (FAR) 52.219–9, Small Business Subcontracting Plans, regarding subcontracting plans as follows:

1. Subcontracting plan. In accordance with Section 8(d) of the Small Business Act (15 U.S.C. 637(d)), any contractor receiving a contract for more than the simplified acquisition threshold must agree in the contract that small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns will have the maximum practicable opportunity to participate in contract performance. Further, 15 U.S.C. 637(d) imposes the requirement that contractors receiving a contract that is expected to exceed, or a contract modification that causes a contract to exceed, $700,000 ($1.5 million for

construction) and has subcontracting possibilities, shall submit an acceptable subcontracting plan that provides maximum practicable opportunities for small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Specific elements required to be included in the plan are specified in section 8(d) of the Small Business Act and implemented in FAR subpart 19.7 and the clause at 52.219–9.

2. Summary Subcontract Report (SSR). In conjunction with the subcontracting plan requirements, contractors with subcontracting plans must submit an annual summary of subcontracts awarded as prime and subcontractors for each specific Federal Government agency. Contractors submit the information in a SSR through the Electronic Subcontracting Reporting System (eSRS). This is required for all contractors with subcontracting plans regardless of the type of plan (*i.e.,* commercial or individual).

3. Individual Subcontract Report (ISR). In conjunction with the subcontracting plan requirements, contractors with individual subcontracting plans must submit semi-annual reports of their small business subcontracting progress. Contractors submit the information through eSRS in an ISR, the electronic equivalent of the Standard Form (SF) 294, Subcontracting Report for Individual Contracts. Contracts that are not reported in the Federal Procurement Data System (FPDS) in accordance with FAR 4.606(c)(5) do not submit ISRs in eSRS; they will continue to use the SF 294 to submit the information to the agency.

4. Written explanation for not using a small business subcontractor as specified in the proposal or subcontracting plan. Section 1322 of the Small Business Jobs Act of 2010 (Jobs Act), Public Law 111–240, amends the Small Business Act (15 U.S.C. 637(d)(6)) to require as part of a subcontracting plan that a prime contractor make good faith effort to utilize a small business subcontractor during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. If a prime contractor does not utilize a small business subcontractor as described above, the prime contractor is required to explain, in writing, to the contracting officer the reasons why it is unable to do so.

B. Public Comment

A 60 day notice was published in the **Federal Register** at 83 FR 38311, on August 6, 2018. No comments were received.

C. Annual Reporting Burden

1. Subcontracting plan. Subcontracting plans are provided on a contract-by-contract basis for individual subcontracting plans. Individual subcontracting plans cover the entire contract period, including options. Commercial plans are provided on an entity basis and cover the fiscal year of the contractor. The time required for development of the plan (including commercial and individual plans) is estimated as follows:

Respondents: 4,350.
Responses per Respondent: 1.
Total Annual Responses: 4,350.
Hours per Response: 5.
Total Burden Hours: 21,750.

2. Summary Subcontract Report (SSR). SSRs are submitted annually for all types of subcontracting plans. One SSR is submitted for each commercial subcontracting plan. For individual subcontracting plans, an SSR is required for every agency that funds work under the contract that the plan covers. Time required for reading, preparing information, and data entry into eSRS is estimated as follows:

Commercial Plan

Respondents: 1,653.
Responses per Respondent: 1.
Total Annual Responses: 1,653.
Hours per Response: 2.
Total Burden Hours: 3,306.

Individual Plan Without Order Level Reporting

Respondents: 10,885.
Responses per Respondent: 1.
Total Annual Responses: 10,885.
Hours per Response: 1.5.
Total Burden Hours: 16,327.5.

Individual Plan With Order Level Reporting

Respondents: 197.
Responses per Respondent: 3.
Total Annual Responses: 591.
Hours per Response: 1.5.
Total Burden Hours: 886.5.

3. Individual Subcontract Report (ISR). ISRs are submitted semi-annually for each contract with an individual subcontracting plan. The ISR consists of data for subcontracting under a given contract. ISRs are not required for commercial plans. Time required for reading, preparing information, and data entry into eSRS is estimated as follows:

Individual Plan Without Order-Level Reporting Requirement

Respondents: 10,855.
Responses per Respondent: 2.
Total Annual Responses: 21,710.
Hours per Response: 2.
Total Burden Hours: 43,420.

Individual Plan—With Order-Level Reporting Requirement

Respondents: 197.
Responses per Respondent: 2.
Total Annual Responses: 394.
Hours per Response: 5.
Total Burden Hours: 1,970.

4. Written explanation for not using a small business subcontractor as specified in the proposal or subcontracting plan. This explanation is submitted on a contract-by-contract basis. FPDS for FY 2017 identified 3,808 contracts with individual subcontracting plans and 542 entities awarded contracts with commercial plans, for a total of 4,350 plans for FY 2017. We estimate that at most 50%, or 2,175, of these contracts with subcontracting plans may have instances of the prime contractor not using a small business subcontractor to the same extent used in preparing the bid or proposal. We estimate two hours as the average time required to read and prepare information for this collection.

Respondents: 2,175.
Responses per Respondent: 1.
Total Annual Responses: 2,175.
Hours per Response: 2.
Total Burden Hours: 4,350.

5. Summary.

Respondents: 30,312.
Total Annual Responses: 41,758.
Total Burden Hours: 92,010.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0007, Subcontracting Plans, in all correspondence.

Dated: November 9, 2018.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2018–24931 Filed 11–14–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30 Day–19–0047]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 1, 2018 to obtain comments from the public and affected agencies. ATSDR received four non-substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *OMB@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control Number 0923–0047, Expiration Date 12/31/2018)—Extension—National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (NCEH/ATSDR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received four non-substantive comments in response to the 60-day notice published in the **Federal Register** on March 1, 2018 (83 FR 8870).

Respondents will be screened and selected from Individuals and Households, Businesses, Organizations, and/or State, Local or Tribal Government. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 7,075.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals and Households, Businesses, Organizations, and/or State, Local or Tribal Government.	Small discussion groups	300	1	90/60
	Request for customer comment cards/complaint forms/post-conference or training surveys.	1,500	1	15/60
	Focus groups of customers, potential customers, delivery partners, or other stakeholders.	2,000	1	2
	Qualitative customer satisfaction surveys or interviews.	3,000	1	30/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	Usability testing/in-person observation testing	1,500	1	30/60

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–24967 Filed 11–14–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–19–0728]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Notifiable Diseases Surveillance System to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 13, 2018 to obtain comments from the public and affected agencies. CDC received 2 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Notifiable Diseases Surveillance System (OMB Control Number: 0920–0728, Exp. Date: February 28, 2021)—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The National Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels as a result of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Infectious disease agents and environmental hazards often cross geographical boundaries. Each year, the Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance and voluntarily submitted to CDC so that information can be shared across jurisdictional boundaries and surveillance and prevention and control activities can be coordinated at regional and national levels.

CDC requests a three-year approval for this Revision which includes (1) receipt of case notification data for *Candida auris* (*C. auris)* which is now nationally notifiable; (2) receipt of case notification data and disease-specific data elements for Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP–CRE) which is now nationally notifiable; (3) receipt of case notification data and disease-specific data elements for *S.* Paratyphi Infection which is now nationally notifiable; (4) renaming Typhoid Fever to ''*S.* Typhi Infection'' on the List of Nationally Notifiable Conditions; (5) receipt of case notification data and disease-specific data elements for Carbon Monoxide (CO) Poisoning; (6) receipt of case notification data and disease-specific data elements for Tuberculosis (TB) Disease; (7) receipt of case notification data and disease-specific data elements for Latent TB Infection which is now under standardized surveillance; (8) receipt of case notification data for Respiratory Syncytial Virus (RSV)-Associated Mortality which is now under standardized surveillance; (9) receipt of disease-specific data elements for Shiga Toxin-Producing Escherichia coli (STEC), Salmonellosis, Shigellosis, Campylobacteriosis, Cryptosporidiosis, Cyclosporiasis, Cholera, Vibriosis, *S.* Typhi Infection, S. Paratyphi Infection, Lyme Disease, Invasive *Haemophilus influenzae* Disease, Meningococcal Disease, Invasive Pneumococcal Disease, Psittacosis, Legionellosis, Tickborne Rickettsial Diseases (TBRD), and Hepatitis; and (10) the extension of the pilot period by two years for receiving sexual orientation and gender identity (SO/GI) data elements for sexually transmitted diseases (STD).

The burden estimates include the number of hours that the public health department uses to process and send case notification data from their jurisdiction to CDC. Specifically, the burden estimates include separate burden hours incurred for automated and non-automated transmissions, separate weekly burden hours incurred

for modernizing surveillance systems as part of NNDSS Modernization Initiative (NMI) implementation, separate burden hours incurred for annual data reconciliation and submission, and separate one-time burden hours incurred for the addition of new diseases and data elements. These estimates are based on information from CDC employees that manage the NMI effort and conduct site visits to provide technical assistance to help the public health departments modernize their surveillance systems. The estimated annual burden is 19,527 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
States	Weekly (Automated)	50	52	20/60
States	Weekly (Non-automated)	10	52	2
States	Weekly (NMI Implementation)	50	52	4
States	Annual	50	1	75
States	One-time Addition of Diseases and Data Elements	50	1	27
Territories	Weekly (Automated)	1	52	20/60
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60
Territories	Weekly (NMI Implementation)	5	52	4
Territories	Annual	5	1	5
Territories	One-time Addition of Diseases and Data Elements	1	1	2
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60
Freely Associated States	Annual	3	1	5
Cities	Weekly (Automated)	2	52	20/60
Cities	Weekly (Non-automated)	2	52	2
Cities	Weekly (NMI Implementation)	2	52	4
Cities	Annual	2	1	75
Cities	One-time Addition of Diseases and Data Elements	2	1	27

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–24968 Filed 11–14–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–19–1235; Docket No. CDC–2018–0100]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth,'' a generic information collection package that supports qualitative and quantitative data collection from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

DATES: CDC must receive written comments on or before January 14, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0100 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov. Please note:* Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth—Revision—Division of Adolescent and School Health, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests three-year OMB approval for the revision of a generic information collection package (OMB #0920–1235) that supports collection of quantitative and qualitative information from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs, and their health risk factors and access to health care are addressed as a primary mission by the Division of Adolescent and School Health (DASH), and adolescents are a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated. Recommendations and guidelines for adolescent sexual risk reduction require that foundation of scientific evidence. Assessment of programmatic practices for adolescents helps to assure effective and evidence-based sexual risk reduction practices and efficient use of resources. Such assessments also help to improve programs through better identification of strategies relevant to adolescents as a population as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored for them.

The information collection requests under this generic package are intended to allow for data collection with two types of respondents:

- Adolescents (11–19 years old) of middle and high school age; and
- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (*e.g.,* food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings; and non-biological parents such as adoptive, foster, or stepparents.

The types of information collection activities included in this generic package are:

(1) Quantitative data collection through electronic, telephone, or paper questionnaires to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age.

(2) Qualitative data collection through electronic, telephone, or paper means to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and in-depth interviewing through group interviews, and cognitive interviewing.

For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels.

For parents and caregivers, data collection instruments will include questions on demographic characteristics as well as parents'/caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined with the information from the collection and will include a cross-walk of data elements to the aspects of the program the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot-tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included. Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children. All data collection procedures will receive review and approval by an Institutional Review Board for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB-approved protocols and these will be described in the individual information collection requests put forward under this generic package.

The table below provides the estimated annualized response burden for up to 15 individual data collections per year. Average burden per response is based on pilot testing and timing of quantitative and qualitative instrument administration during previous studies. Response times include the time to read and respond to consent forms and to read or listen to instructions. The proposed information collections combine for a total estimated annualized burden of up to 57,584 hours for respondents. Participation of respondents is voluntary. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Middle and High School Age Adolescents.	Youth Questionnaire	20,000	1	50/60	16,667
Middle and High School Age Adolescents.	Pre/Post youth questionnaire	10,000	2	50/60	16,667
Middle and High School Age Adolescents.	Youth interview/focus group guide	3,000	2	1.5	9,000
Parents/caregivers of adolescents	Parent/Caregiver questionnaire	7,500	2	25/60	6,250
Parents/caregivers of adolescents	Parent/Caregiver interview/focus group guide.	3,000	2	1.5	9,000
Total					57,584

Jeffery M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–24966 Filed 11–14–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–19–0978; Docket No. CDC–2018–0098]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Emerging Infections Program (EIP). The EIP is a population-based surveillance activity performed via active, laboratory case finding that is used for detecting, identifying, and monitoring emerging pathogens.

DATES: CDC must receive written comments on or before January 14, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0098 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Emerging Infections Program OMB# 0920–0978 Exp. Date: 05/31/2021—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Emerging Infections Programs (EIPs) are population-based centers of excellence established through a network of state health departments collaborating with academic institutions; local health departments; public health and clinical laboratories; infection control professionals; and healthcare providers. EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases.

Activities of the EIPs fall into the following general categories: (1) Active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of

pilot prevention/intervention projects; and (4) flexible response to public health emergencies. Activities of the EIPs are designed to: (1) Address issues that the EIP network is particularly suited to investigate; (2) maintain sufficient flexibility for emergency response and new problems as they arise; (3) develop and evaluate public health interventions to inform public health policy and treatment guidelines; (4) incorporate training as a key function; and (5) prioritize projects that lead directly to the prevention of disease.

A revision is being submitted to make existing collection instruments clearer and to add several new forms specifically surveying laboratory practices. These forms will allow the EIP to better detect, identify, track changes in laboratory testing methodology, gather information about laboratory utilization in the EIP catchment area to ensure that all cases are being captured, and survey EIP staff to evaluate program quality.

The total estimated burden is 40,601 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60	2697
	ABCs Invasive Pneumococcal Disease in Children Case Report Form.	10	22	10/60	37
	ABCs *H.influenzae* Neonatal Sepsis Expanded Surveillance Form.	10	6	10/60	10
	ABCs Severe GAS Infection Supplemental Form	10	136	20/60	453
	ABCs Neonatal Infection Expanded Tracking Form.	10	37	20/60	123
	FoodNet Campylobacter	10	942	21/60	3297
	FoodNet Cyclospora	10	163	10/60	272
	FoodNet Listeria monocytogenes	10	15	20/60	50
	FoodNet Salmonella	10	789	21/60	2761
	FoodNet Shiga toxin producing E. coli	10	205	20/60	683
	FoodNet Shigella	10	213	10/60	355
	FoodNet Vibrio	10	34	10/60	56
	FoodNet Yersinia	10	48	10/60	80
	FoodNet Hemolytic Uremic Syndrome Case Report Form.	10	10	1	100
	FoodNet Clinical Laboratory Practices and Testing Volume—NEW.	10	70	20/60	233
	Influenza Hospitalization Surveillance Network Case Report Form.	10	1000	25/60	4167
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English/Spanish).	10	333	5/60	278
	Influenza Hospitalization Surveillance Project Vaccination Phone Script (English/Spanish).	10	333	5/60	278
	Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults).	10	333	5/60	278
	FluSurv-NET Laboratory Survey—NEW	10	23	10/60	38
	HAIC CDI Case Report Form	10	1650	35/60	9625
	HAIC CDI Annual Laboratory Survey—NEW	10	16	10/60	27
	HAIC CDI Annual Surveillance Officers Survey—NEW.	10	1	15/60	3
	HAIC CDI LTCF Survey—NEW	10	45	5/60	38
	HAIC Multi-site Gram-Negative Bacilli Case Report Form *(MuGSI–CRE/CRAB)*.	10	500	25/60	2083
	HAIC Multi-site Gram-Negative Surveillance Initiative—Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI–ESBL).	10	1200	25/60	5000
	HAIC Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA).	10	474	25/60	1975
	HAIC Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA).	10	754	25/60	3142
	HAIC Invasive *Staphylococcus aureus* Annual Laboratory Survey—NEW.	10	11	8/60	15
	HAIC Invasive *Staphylococcus aureus* Annual Surveillance Officers Survey—NEW.	10	1	10/60	2
	HAIC Candidemia Case Report Form	9	800	20/60	2400
	HAIC Candidemia Periodic Laboratory Survey—NEW.	9	15	20/60	45
Total					40,601

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–24969 Filed 11–14–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10688]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 14, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10688 Home Health (HH) National Provider Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection:* Home Health (HH) National Provider Survey; *Use:* Section 1890A(a)(6) of the Social Security Act (the Act) requires the Secretary of HHS every three years to assess the quality and efficiency effects of the use of endorsed measures in specific Medicare quality reporting and incentive programs. This request is for review and approval of a survey and qualitative interview guide for the home health setting, which CMS proposes to use to address critical needs regarding the impact of use of quality and efficiency measures in the home health setting, including the burden they impose on home health agencies.

CMS plans to use the findings from surveys and qualitative interviews for multiple purposes. The qualitative interviews and standardized survey will inform CMS about the impact of measures used to assess care in HHAs. The surveys will help CMS understand whether the use of performance measures has been associated with changes in HHA behavior—namely, what quality improvements (QI) investments HHAs are making and whether adoption of QI changes is associated with higher performance on the measures. The survey will help CMS identify characteristics associated with high performance, which, if understood, could be used to leverage improvements in care among lower-performing HHAs. The survey and interviews, assuming approval by August 2019, would be fielded from fall 2019 through spring 2020. *Form Number:* CMS–10688 (OMB control number: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 1,040; *Total Annual Responses:* 1,040; *Total Annual Hours:* 1,040. (For policy questions regarding this collection contact Noni Bodkin at 410–786–7837.)

Dated: November 9, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–24951 Filed 11–14–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3692]

Evaluating the Pressor Effects of Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled ''Evaluating the Pressor Effects of Drugs.'' This public workshop is convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA. The purpose of this public workshop is to bring the stakeholder community together to discuss the premarketing assessment of a drug's effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Agency staff will present findings related to the use of ambulatory blood pressure monitoring to assess treatment effects.

DATES: The public workshop will be held on Monday, February 4, 2019 from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at 1777 F Street NW, Washington, DC 20006. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.*

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4166, Silver Spring, MD 20903, 301–796–2240, email: *Norman.Stockbridge@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding FDA's assessment of the pressor effects of drugs. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Following FDA's announcement in the **Federal Register** of the availability of a draft guidance for industry entitled ''Assessment of Pressor Effects of Drugs'' (May 31, 2018, 83 FR 25013), FDA is convening this public meeting in collaboration with the Duke-Margolis Center for Health Policy to discuss the Agency's current thinking with expert stakeholders and to consider public comments.

II. Topics for Discussion at the Public Workshop

Topics for discussion during this meeting include:

- Risk associated with blood pressure change
- Aspects and FDA analyses related to ambulatory blood pressure monitoring
- Evaluating a drug's effect on blood pressure and understanding the optimal regulatory approach to assigning risk

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by Thursday, January 31, 2019, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Duke-Margolis will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (202–791–9561, email: *sarah.supsiri@duke.edu*) no later than November 29, 2018.

Streaming webcast of the public workshop: This public workshop will be webcast live. Persons interested in viewing the live webcast may register ahead of the event by visiting *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.* The live webcast will also be available at the website above on the day of the event without preregistration. Archived video footage will be available at the Duke-Margolis website following the workshop.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.*

Dated: November 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24961 Filed 11–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No.: DHS–2018–0063]

First Responders Community of Practice (FRCoP)

AGENCY: Science and Technology Directorate, Department of Homeland Security.

ACTION: 30-Day Notice of Information Collection; request for comment. (Re-instatement of a Currently Approved Collection, 1640–0016).

SUMMARY: The Department of Homeland Security (DHS), Science and Technology (S&T) is proposing to reinstate OMB 1640–0016, an information collection, by inviting the public to comment on the collection: First Responders Community of Practice (FRCoP) User Registration Page (DHS Form 10059 (9/09)). The FRCoP web based tool collects profile information from first responders and select authorized non-first responder users to facilitate networking and formation of online communities. All users are required to authenticate prior to entering the site. In addition, the tool provides members the capability to create wikis, discussion threads, blogs, documents, etc., allowing them to enter and upload content in accordance with the site's Rules of Behavior. Members are able to participate in threaded discussions and comment on other members' content. The FRCoP program is responsible for providing a collaborative environment for the first responder community to share information, best practices, and lessons learned. The Homeland Security Act of 2002 established this requirement. Interested persons may receive a copy of the collection by contacting the DHS S&T Paperwork Reduction Act (PRA) Coordinator.

DATES: Comments are encouraged and accepted until December 17, 2018.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0063, at:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Mail and hand delivery or commercial delivery:* Science and

Technology Directorate, ATTN: Chief Information Office—Mary Cantey, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0063. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: DHS/S&T/FRG System Owner: Marc Caplan, *Marc.Caplan@HQ.DHS.GOV,* (202) 254–6134 (Not a toll free number).

SUPPLEMENTARY INFORMATION: DHS, in accordance with the PRA (6 U.S.C. 193), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collection of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provides the requested data in the desired format. DHS is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Homeland Security is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: First Responders Community of Practice User Registration Page (DHS Form 10059 (9/09)).

Prior OMB Control Number: 1640–0016.

Prior ***Federal Register*** *Document:* 2018–0035, August 2, 2018.

Type of Review: An extension of an information collection.

Respondents/Affected Public: Federal, State, Local, and Tribal Governments.

Frequency of Collection: Once per respondent.

Average Burden per Response: 30 minutes.

Total Estimated Number of Annual Responses: 2,000.

Total Estimated Number of Annual Burden Hours: 1,000.

Gregg Piermarini,

Deputy Chief Information Officer, Science and Technology Directorate.

[FR Doc. 2018–24907 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–9F–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0038]

Science and Technology Collection of Qualitative Feedback

AGENCY: Science and Technology Directorate (S&T), Department of Homeland Security (DHS).

ACTION: 60-Day notice of information collection; new request for comment.

SUMMARY: S&T will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery.

DATES: Comments are encouraged and accepted until January 14, 2019.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0038, at:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Mail and hand delivery or commercial delivery:* Science and Technology Directorate, ATTN: Chief Information Office—Mary Cantey, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0038. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: DHS/S&T/OCIO Program Manager: Mary Cantey, *Mary.K.Cantey@hq.dhs.gov* or 202–254–5367 (Not a toll free number).

SUPPLEMENTARY INFORMATION: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the S&T's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between S&T and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of S&T's program management. Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. DHS, in accordance with the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. DHS is soliciting comments on the proposed Information Collection Request (ICR) that is described below. DHS is

especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology? Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Science and Technology Collection of Qualitative Feedback.

Type of Review: New.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Frequency of Collection: One per Request.

Estimated Time per Respondent: 30 minutes or under.

Number of Respondents: 215,100.

Total Burden Hours: 34,732.

Dated: October 16, 2018.

Rick Stevens,

Chief Technology Officer, Science and Technology Directorate.

[FR Doc. 2018–24906 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–9F–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6046–N–02]

Family Self-Sufficiency Performance Measurement System (''Composite Score'')

AGENCY: Office of Public and Indian Housing, HUD.

ACTION: Notice of new performance measurement system (''Composite Score'') for the Family Self-Sufficiency Program.

SUMMARY: This notice describes and responds to comments on a performance measurement system that HUD plans to implement for Public Housing Agencies (PHAs) that receive HUD Family Self-Sufficiency (FSS) program coordinator grants. The desired effect of this notice is to notify the public regarding the criteria for evaluating FSS programs.

DATES: *Applicability Date:* December 17, 2018.

FOR FURTHER INFORMATION CONTACT: Questions on this notice may be addressed to *FSS@hud.gov* or by contacting Anice Chenault at 502–618–8163 (email strongly preferred).

Electronic Data Availability. This **Federal Register** notice and a spreadsheet containing scores using the methodology for FSS programs funded in any of the last three years will be available electronically from the HUD FSS web page: *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/fss.* **Federal Register** notices also are available electronically at *https://www.federalregister.gov/,* the U.S. Government Printing Office website.

SUPPLEMENTARY INFORMATION:

I. Background

On December 12, 2017, HUD published a notice in the **Federal Register** (FR–6046–N–01, 82 FR 58434) (2017 Notice) describing and requesting comment on a performance measurement system that HUD plans to implement for public housing agencies (PHAs) that receive HUD Family Self Sufficiency (FSS) program coordinator grants. Through this notice, HUD is implementing the FSS performance measurement system, as proposed in the 2017 Notice. Additionally, in response to public comments, HUD is revising the methodology it uses to compute FSS Performance Scores under the new system; these revisions are described below, in section III of this notice. Henceforth, HUD will use the new system to evaluate the performance of PHAs receiving HUD program coordinator funding in a strictly advisory manner. Beginning with Fiscal Year (FY) 2019 appropriations, HUD intends to use the performance measurement system in the determination of FSS funding awards. The complete, updated methodology can be found on HUD's website at: *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/fss.*

Under section 23(i) of the Housing Act of 1937 (42 U.S.C. 1437u(i)), HUD is required to establish criteria to evaluate eligible entities' implementation of local FSS programs. HUD has developed this new FSS performance measurement system to provide HUD, Congress, public housing agencies (PHAs), and other eligible entities with information on the performance of individual FSS programs. The information will help grantees determine how their programs compare to others across the country in efforts to help participants to successfully graduate from the program and make progress toward economic security. The information will also help HUD understand the extent to which FSS program performance—individually and collectively—improves or declines over time.

Initially, HUD plans to use the performance measures to identify high performing and low performing FSS programs, which could inform its understanding of best practices and its delivery of technical assistance. Toward these goals, at least once per year, HUD will analyze data collected through the Public Housing Information Center (PIC) to calculate FSS performance scores for each FSS program that received an FSS coordinator grant in one or more of the past three fiscal year NOFA competitions. Beginning in Fiscal Year 2019, HUD plans to consider the FSS performance score of an FSS program in determining FSS funding awards.

HUD developed the approach described in this Notice based in part on feedback received on an earlier performance measurement approach proposed in the FY 2014 FSS Notice of Funding Availability (NOFA). In the FY 2014 NOFA, HUD proposed, and asked for feedback on, evaluating FSS programs based on the share of FSS participants that experience an increase in earned income (also known as ''earnings growth'') over a specified time period. Some commenters raised concerns that this approach did not adequately account for differences in local economic conditions and differences in the approaches of local FSS programs. While some FSS programs encourage participants to increase their earnings immediately, others encourage FSS participants to build skills and credentials first and then seek higher paying jobs. The FSS performance measurement system proposed in the December 2017 Notice was developed to address these issues, as well as many others, and to allow for a more nuanced evaluation of the performance of local FSS programs.

A PHA's FSS performance score will be calculated based on three measures, weighted as follows:

A. Earnings Performance Measure (50 percent);

B. FSS Graduation Rate (30 percent);

C. Participation Rate (20 percent).

HUD has selected these measures because they are important indicators of program performance and are verifiable using the data HUD collects through the PIC data system. No outside or additional reporting will be required, which ensures that the system will not increase the reporting burden of PHAs. No new Paperwork Reduction Act (PRA) Information Collection will be required for the scoring, as proposed.

The Earnings Performance Measure represents the difference between the

earnings growth of FSS participants and the earnings growth of similar non-FSS households assisted by the PHA within a specified time frame. This approach, along with a statistical adjustment described below, helps to control for variations in local economic conditions. The program was envisioned and designed for the purpose of increasing employment and earnings for its participants. Therefore, the performance score assigns the Earnings Performance Measure a high weight.

HUD has assigned the next highest weight to the Graduation Rate indicator—which represents the rate of FSS participants who successfully ''graduate'' from the program—to encourage PHAs to work closely with individual FSS participants to increase graduation rates. To graduate from FSS, a participant must be employed, be independent of cash welfare assistance for at least one year, and achieve the other goals set forth in the participant's contract of participation.

Finally, the FSS performance score looks at the local program's Participation Rate, which reflects the extent to which a PHA exceeds the minimum number of households that HUD requires the PHA to serve as a condition of receiving an FSS grant. PHAs with higher Participation Rates are serving more households than required, which is a desired output, provided the PHAs are serving those households effectively. Because the Earnings Performance Measure is weighted more heavily than the Participation Rate, however, PHAs should be careful not to execute more Contracts of Participation than they can serve effectively, because doing so would likely reduce their scores on the Earnings Performance Measure. Together, the Earnings Performance Measure, Graduation Rate, and Participation Rate are expected to provide a balanced measurement of the performance of an individual FSS program.

As indicated in the 2017 Notice soliciting public comment, HUD does not intend to use this performance measurement system for Tribes/Tribally Designated Housing Entities (TDHEs), who do not report into Public and Indian Housing Information Center (PIC), or for PHAs with a Moving to Work (MTW) designation, as they report differently into PIC, using Form HUD–50058–MTW. However, HUD is presently exploring a change to the reporting processes for MTW agencies, in order to include them in the FSS performance scoring process. Nor does HUD intend, after considering public comment, to use this performance measurement system for unfunded PHAs, and PHAs and private owners that serve Project-based Rental Assistance (PBRA) residents at this time.[1] The Agency will continue to explore options for modifying the scoring system for those sub-groups.

II. HUD's Responses to Public Comments

HUD received 68 unique public comments on the planned measures, which are summarized below along with HUD's responses. HUD's responses to comments are organized into five categories: (A) Overall Comments; (B) Comments on Earnings Performance Measure; (C) Comments on FSS Graduation Rate Measure; (D) Comments on Participation Rate Measure; and (E) Comments on Weighting of the Measures. At the conclusion of this Notice, in Section III., Final Thresholds, HUD provides the final FSS performance measurement system thresholds that it intends to adopt to calculate FSS performance scores.

A. Overall Comments

1. *Comment: Data Quality.* Many commenters raised concerns about the quality of data from the PIC system used to calculate the FSS performance scores, particularly with regard to data entered prior to HUD's 2016 guidance. Some requested that PHAs be allowed to examine and correct all data used for calculating their measures prior to HUD calculating the FSS performance measures. Others suggested that this might not be possible or that there would not be resources to correct the data.

HUD Response: Data Quality. On May 6, 2016, HUD issued PIH Notice 2016–08 to help PHAs understand how to submit timely and accurate PIC data regarding FSS, along with a series of webinars to help PHAs apply the guidance to improve their PIC data quality for both current and past participants. Further, HUD has emphasized the importance of PHAs submitting accurate PIC data for many years. HUD believes it is reasonable to rely on existing PIC data in calculating FSS performance scores.

It is important to note that each time the FSS performance scores are calculated, HUD will retrieve a new data report from the PIC system. This ensures that if a PHA has made changes to improve the accuracy of its reporting on any metric, for current or past participants, all of these changes will be reflected in its performance score.

2. *Comment: Limitations on Included Measures.* Many commenters expressed the view that the measures in the planned performance measurement system do not address the variations in participants' goals. Some participants or programs may have interim goals related to addressing barriers to work (*e.g.,* treating psychiatric illness or barriers, accessing medical care, securing childcare, or completing training, or education), which would not immediately result in higher earnings, even if participants make important progress. Several commenters suggested that participation in/provision of services or progress toward Individual Training and Services Plan (ITSP) goals should be included as a measure. Some suggested that changes in educational attainment also be included as a measure.

Several commenters also stated that inputs and outputs should be included in the measures, such as the work associated with serving participants, meeting with participants, connecting participants to services, making referrals, etc. Some indicated that, without these measures, they are not given adequate ''credit'' for serving high-needs participants or that they may be penalized for participant performance issues that are beyond their control (through the earnings and FSS graduation measures).

HUD Response: Limitations on Included Measures. HUD agrees that there is tremendous variety in the ITSP goals of individual FSS participants, which go beyond the statutorily mandated goals of employment and being welfare-free. It is precisely this variety, however, that makes these goals extremely difficult to factor into a performance measurement system. Since each ITSP is set up individually, it would be both impracticable and unwise to standardize ITSP goals across all programs. While HUD could potentially measure the share of ITSP goals achieved for each participant, this would not represent a direct comparison across local FSS programs if some programs set goals that were easy to attain while others set more difficult targets. This approach could also create an incentive for PHAs to change how they are defining individuals' goals to increase their FSS performance scores, without necessarily improving outcomes for participants. Finally, HUD does not currently collect data on the

[1] Section 306 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (Pub. L. 115–174, Approved May 24, 2018) amended the United States Housing Act of 1937. Among various provisions, this law extended FSS program eligibility to tenants of certain privately-owned properties subsidized with project-based rental assistance (PBRA).

goals set nor the share of ITSP goals that participants attain, so the inclusion of ITSP goal data in a performance measurement system for FSS would require additional reporting by PHAs, which would add to their administrative burden.

HUD recognizes the importance and value of setting a range of goals for participants, including goals other than employment. Over time, however, HUD believes the achievement of these goals will support the ultimate goal of the program, which is increased earnings, which will then be captured in the performance measurement system. This is one of the benefits of having five (or more) years to work with participants. The long duration of the FSS program provides PHAs an opportunity to work with participants on a range of issues—including education, training, work readiness, etc.—that will, over time, contribute to earnings gains that can be measured and reflected in the FSS performance measurement system. The earnings and FSS graduation rate measures accommodate this long time-frame, examining data for FSS participants that entered the program as far back as 7.5 to 8 years ago, respectively.

3. *Comment: Homeownership.* A few commenters expressed concern that the measures do not support homeownership goals for FSS participants and stated that progress toward homeownership should be included as a measure in the performance measurement system.

HUD Response: Homeownership. HUD commends PHAs that work with participants on homeownership and recognizes that the achievement of homeownership is an important outcome for many FSS participants. At the same time, it is clear that homeownership is a more realistic goal in some parts of the U.S. than others, due to variations in the local economy. This makes it difficult and inequitable to use homeownership as a performance measure in comparing FSS programs on a national basis.

4. *Comment: Reliance on Past Performance Data.* Some commenters opined that it is unfair to base an assessment of FSS performance on data from prior periods during which FSS coordinators were unaware of the performance measures and could not change their programs accordingly.

HUD Response: Reliance on Past Performance Data. The performance measurement system recognizes that it takes considerable time for an individual FSS participant to make material progress in increasing his or her earnings and to graduate from the program. This requires measurements that span years, rather than months. To implement such a system prospectively, without relying on data from prior periods, would require HUD to wait many years before having valid measures of FSS program performance. Such a delay would undermine HUD's ability to achieve the key purposes of the FSS performance measurement system. In order to ensure that FSS funds are spent responsibly and that FSS participants have access to high-quality programs, HUD needs the ability to recognize the achievements of high-performing FSS programs and identify struggling FSS programs in need of improvement.

The goals of improving earnings and helping FSS participants graduate successfully from the program should not come as a surprise to PHAs administering FSS programs. These goals have been clear since the program's inception and NOFAs have been announcing HUD's intent to use increased earnings as an evaluation metric since FY 2014. The participation rate also should not come as a surprise to PHAs, as HUD has historically based funding decisions on the number of FSS families served by PHAs. HUD's interest in PHAs serving more families (so long as they can do so without undermining earnings growth and FSS graduation rates), as reflected in the participation rate, is a factor that PHAs can influence going forward by adjusting their caseloads.

5. *Comment: Real-Time Data.* Some commenters requested a way to monitor their programs' progress with respect to the measures periodically or in real time.

HUD Response: Real-Time Data. HUD plans to provide updated scores at least once each year so PHAs can track their progress. In addition, PHAs can calculate their own participation rates and FSS graduation rates at any time.

6. *Comment: Small PHAs/Small FSS Programs.* Several commenters raised the concern that the measures could disadvantage small PHAs or small FSS programs because volatility in the data would be more likely and factors beyond the FSS program's control could drive results.

HUD Response: Small PHAs/Small FSS Programs. HUD recognizes that there may be greater volatility in the data for small FSS programs, which could be affected by the outcomes for one or more participants with unusual characteristics or experiences. Accordingly, in assigning earnings scores, HUD has built in protection for small FSS programs by using a test of statistical significance that makes it more difficult for smaller FSS programs than larger programs to receive a zero (0) score on the earnings measure. See the Dec. 12, 2017 **Federal Register** Notice (at page 82 FR 58437) for more details on the statistical test.

HUD has also examined the FSS performance composite scores of PHAs to determine if small programs systematically receive lower composite scores and determined that, there is not a strong relationship between program size and composite FSS performance score. In fact, the decile of PHAs with the second smallest FSS programs (10th through 19th percentile) had the second highest median composite scores of any decile (the highest was the group of PHAs in the 70th through the 79th percentile in size). PHAs with the very smallest FSS programs (0 to 9th percentile) did have the lowest median composite score, but the next lowest score was recorded by PHAs in the 80th to 89th percentile in size. This is an indication that there is not a strong relationship between program size and composite FSS performance score. However, HUD may continue to monitor scores to determine if there are any patterns that might help with the targeting of technical assistance efforts or the interpretation of performance data.

7. *Comment: Joint Applicants.* One commenter suggested that it would be more appropriate to pool joint applicant data for all measures, not just for participation.

HUD Response: Joint Applicants. HUD agrees, and is changing the methodology accordingly.

8. *Comment: Initial Funding Period.* Some commenters thought that FSS programs should not be assessed during their initial 12-month funding period or directly after receiving additional funding for the first time.

HUD Response: Initial Funding Period. HUD agrees with the need to be careful in interpreting the FSS performance scores of newly funded FSS programs and will take this into account in determining how to use the scores. However, HUD believes it is important to measure the performance of all FSS programs that receive HUD coordinator funding so that programs have a way of tracking their performance over time. Also, since HUD has not funded new applicants in several years, all PHAs currently being scored have had programs funded since at least FY2012.

9. *Comment: Minimum Standards.* A few commenters said that HUD should consider setting minimum standards for performance rather than rating FSS programs on a curve.

HUD Response: Minimum Standards. FSS programs will not be graded on a curve, but rather based on whether or not they exceed the specific fixed standards (or thresholds) adopted in the final FSS performance measures. While HUD used percentiles of the distribution to determine the initial thresholds for each score, those thresholds have now been fixed. This means that over time, a PHA's scores may move up or down, based on where the PHA's earnings, FSS graduation, and participation measures fall relative to the thresholds. In other words, a PHA's performance will determine in which performance category the PHA falls, since there is not a set number of ''high'' or ''low'' performers.

10. *Comment: Zero Housing Assistance Payments (HAP).* Some commenters suggested that attainment of a zero HAP amount (either at FSS graduation or in general) should be added as a performance measure.

HUD Response: Zero Housing Assistance Payments (HAP). The ability of an FSS participant to reach a level of earnings at which his or her HAP amount drops to zero will depend to a significant degree on the local labor market and the level of the voucher payment standard, which is a function of the rental housing market as well as a PHA's policies. Since FSS participants in some markets have a much greater likelihood of achieving zero HAP than others, this measure does not provide a useful basis for comparing the performance of PHAs in different labor and housing markets.

11. *Comment: Unfunded PHAs, MTW PHAs, and PHAs that serve PBRA residents.* HUD requested comments on the treatment of these types of PHAs and received many thoughtful comments on the development of performance measures for such PHAs.

HUD Response: Unfunded PHAs, MTW PHAs, and PHAs that serve PBRA residents. HUD appreciates all the thoughtful comments received on these subjects and will be considering these comments as HUD works to determine how best to evaluate the performance of these programs.

12. *Comment: Portability.* Some commenters were concerned about which PHA gets ''credit'' for FSS participants who port out of their PHA or into their PHA, although there was no consensus on how this should be addressed.

HUD Response: Portability. If a family ports, for the Participation Measure, each PHA (the receiving and the initial PHA) will benefit from the family's FSS enrollment. For the earnings and FSS graduation measures, the composite score will count the family as a participant in the FSS program at the PHA who currently administers the FSS contract and thus has final influence on the family's outcomes.

B. Comments on Earnings Performance Measure

1. *Comment: Complexity of Earnings Performance Measure.* Several commenters expressed a concern that the measures (especially the earnings measure) are too complicated or confusing. They indicated that PHAs will not understand them and will not be able to track their own progress. A few asked for information on which comparison households are included for their PHA so that they can track progress and correct data for those comparison households if needed. A few commenters expressed confusion about how comparison households are chosen and who chooses them.

HUD Response: Complexity of Earnings Performance Measure. HUD acknowledges that the methodology for computing the earnings performance score is somewhat complex, but believes the complexity is justified as a means of adjusting for variations in local economic conditions and approaches (*e.g.,* human capital development or ''work first'' or some combination) at different PHAs. Fortunately, however, the measure produces a single clear data point—the earnings performance measure—that PHAs can use to track their progress over time. To the extent that FSS programs are successful in helping participants to increase their earnings—whether in the short-term or in the long-term—they should be able to achieve a strong earnings performance score. For information on how the measure works and how comparison households are selected, see the December 12, 2017 **Federal Register** Notice (at pages 82 FR 58435–37) and comments below.

2. *Comment: Elderly Individuals and Persons with Disabilities.* A few commenters suggested that excluding households headed by elderly persons or persons with disabilities from the earnings performance measure would discourage FSS programs from serving these households.

HUD Response: Elderly Individuals and Persons with Disabilities. This comment provides a good opportunity to clarify that the methodology is designed to achieve the opposite effect. Although program regulations require FSS programs to serve any resident who desires to participate and is able to ''seek and maintain employment,'' see 24 CFR 984.303(b)(4), some FSS programs may be concerned that serving elderly persons and persons with disabilities would lower their earnings performance score because this population may be less likely to experience large earnings gains than other individuals. The methodology excludes households headed by elderly persons or persons with disabilities from the earnings performance measure, which ensures that PHAs can serve these households without worrying about the possibility that this might reduce their earnings performance score. All households served through FSS (regardless of age category or disability status) will be counted in the participation and FSS graduation measures.

3. *Comment: Changes in Elderly or Disability Status.* One commenter asked how HUD will account for FSS participants who age out of the non-elderly category while enrolled in FSS and those that acquire a disability while participating in the program. Will they be included or excluded from the analysis used to calculate the earnings performance measure?

HUD Response: Changes in Elderly or Disability Status. Given the strong interest in and capacity for work of many adults in the 60 to 65 age range, HUD believes it is appropriate to retain in the earnings analysis FSS participants who begin their FSS tenure below the age of 62 but achieve that age during their participation. On the other hand, HUD agrees that a person whose status changes to ''disabled'' during the course of participation in FSS should be excluded from the earnings analysis in order to be consistent with the inclusion of data for other persons with disabilities in the earnings analysis. The methodology for calculating the earnings performance measure has thus been changed to exclude people who are or become disabled while participating in FSS from the analysis.

4. *Comment: Selecting Comparison Households.* Many commenters expressed concern that the variables used to select comparison households were not sufficient to account for important life circumstances that may affect the potential for employment and increased earnings. The most common variables they recommended be included were: Language, education level, childcare availability, family composition (including children of all ages and workable adults or presence of a household member with a disability), mental health, and additional information about household composition. Some commenters also noted that FSS participants are different than non-FSS participants in terms of motivation, resources, or barriers to

employment, though there was disagreement among commenters on whether FSS participants are more likely to have high barriers or low barriers.

HUD Response: Selecting Comparison Households. As described in the December 12, 2017 **Federal Register** Notice, in selecting comparison households for purposes of calculating the earnings performance measure, HUD considered the following household characteristics: Earnings as of the time of the FSS household's entry into FSS, age of head of household, length of time in the voucher or public housing program, number of adults in the household and number of children under age 5. While some of the additional factors recommended by commenters are not available in the PIC dataset used to compute the FSS performance measures, several are, including: presence of children of any age and presence of a household member with a disability.

In response to this comment, HUD has considered whether the increased precision of adding additional comparison factors would outweigh the dilution of the weight of the existing factors and lead to an insufficient number of comparison households. Further analysis has determined that number of children under 18 is better than presence of children under age 5 in predicting whether a household would join FSS and therefore is a better factor in choosing comparison households. HUD will therefore remove presence of children under age 5 from the factors used to match comparison households and instead include number of children under 18.

After further analysis, it has been determined that the presence of a child with a disability and presence of a non-head of household adult with a disability are not substantial factors predicting a household's choice to participate in FSS, but each of these factors is associated with a large and significant difference in a household's future earnings change. As a result, HUD will include both factors in selecting comparison households.

5. *Comment: Location of Comparison Households.* A few commenters stated that households selected as comparisons for purposes of the earnings performance measure should be matched by similar census tract, neighborhood, or other measure of geography, to account for local variations in opportunity.

HUD Response: Location of Comparison Households. HUD agrees that it would be preferable to select comparison households from the same geography as the FSS participants to which they are being compared but notes that this may be impossible to achieve at a very small level of geography, such as census tract or ZIP code, due to an insufficient number of comparison households, especially at small PHAs. Moreover, households in neighboring census tracts or ZIP codes are likely to still be in the same labor market, and thus can still be effective comparators.

In PHAs that serve a very large geographical area, such as statewide PHAs, however, this point may not hold true since the economic conditions may be very different in different parts of the state. Accordingly, HUD plans to modify the protocol to require, under certain circumstances, that comparison households be in the same county and PHA as the FSS participants to which they are being compared. HUD will apply this protocol to all state PHAs and to non-State PHAs serving three or more counties where at least 10 percent of the PHA's housing choice voucher (HCV) or public housing households are leased in each of those counties. To ensure this approach does not unduly dilute the ability to find comparable households, HUD will require that FSS participants be matched to comparison households in the same county only in counties where there are at least four times as many non-FSS households as FSS households being served by the PHA.

6. *Comment: Shifts in Enrollment.* Many commenters were concerned that the performance measures would encourage PHAs to recruit or enroll participants with a high probability of increases in earnings or chances of FSS graduation. This comment arose most often for the earnings measure, though commenters differed on whether this would lead to recruiting minimally employed participants so that they had room to grow or participants who are already somewhat financially successful and have high potential to increase salaries without much intervention. A few commenters raised the concern that FSS programs will stop serving participants with substantial barriers who are riskier for the earnings and FSS graduation measures and require more intensive intervention.

HUD Response: Shifts in Enrollment. HUD appreciates these concerns and would remind PHAs of the requirement to open the program equally to all residents and administer the program for the residents who sign up for it, without trying to adjust enrollment to gain a higher score. As the commenters note, earnings gains among both unemployed participants and already employed participants can help boost a program's earnings performance score. It is also important to note that by regulation, FSS programs may screen families for interest and motivation to participate in the FSS program, but such programs are only permitted to screen for permissible motivational screening factors, *i.e.,* those which solely measure the family's interest and motivation to participate in the FSS program. They may not exclude interested households based on other, prohibited characteristics.[2]

7. *Comment: Variations in Economic Conditions.* Some commenters raised the concern that the earnings measure advantages communities with higher wages and stronger employment opportunities (primarily urban areas) and disadvantages communities with lower wages and weaker employment opportunities (primarily rural and suburban areas).

HUD Response: Variations in Economic Conditions. Because the earnings performance score is calculated based on the difference between the earnings growth of FSS participants and comparison households at the same PHA, it already controls to some extent for difference in economic conditions. Presumably, the comparison households at a PHA in a stronger economic market will experience greater earnings growth than the comparison households at a PHA in a weaker economic market, setting up a higher bar for FSS programs to exceed in the stronger market.

Based on these comments, however, HUD has conducted additional analysis to determine if there are some residual effects of strong economic conditions that are not accounted for in this methodology and therefore a need to account for it in assigning earnings performance scores. This analysis found that there is in fact still a relationship between the earnings performance measures and county median income. Accordingly, HUD has decided to apply an adjustment factor to the earnings performance measure to account for the residual effect of local economic conditions.

To compute this adjustment factor, HUD first used a linear regression model to examine the relationship between the earnings growth of comparison households within a PHA and the average county median income of those households. On average, earnings growth of comparison households was higher in counties with high median incomes, and lower in counties with low median incomes. HUD developed an adjustment factor that eliminated this relationship and then applied this

[2] 24 CFR 984.203(c).

adjustment factor to the earnings performance measure for each PHA, resulting in an adjusted earnings performance measure.

Using these adjusted earnings performance measures, HUD has recalculated the thresholds for awarding a 10, 7.5, or 0 earnings performance score by focusing on the 80th, 60th, and 20th percentile, respectively, of the distribution of adjusted measures. In selecting the revised thresholds, HUD has analyzed the distribution of scores across all funded PHAs, rather than the narrower universe described in the December 12, 2017 **Federal Register** Notice at 82 FR 58437 (the earlier notice included only PHAs whose earnings performance measures have a significant likelihood of being different from $0, per a statistical test). This makes the methodology more consistent with how HUD is calculating thresholds for the FSS graduation rate.

8. *Comment: Interim Earnings.* Many commenters expressed the view that the results of interim reexaminations of income should be included in analyzing earnings growth because they capture seasonal income, and the most recent progress toward higher earnings. Several were also concerned that if participants reach a level of earnings where they no longer receive any HAP, this increase in earnings may only be captured by interim reexaminations and FSS exit reports.

HUD Response: Interim Earnings. As noted in the December 12, 2017 **Federal Register** Notice, HUD did not consider the earnings reported through interim reexaminations of income in the analysis of earnings gains because some PHAs conduct such reexaminations when income increases between annual reexaminations and others do not. Excluding these interim results thus facilitates a direct comparison of local FSS programs. Further, participants' incomes are not reexamined at the time of exit from FSS. While excluding interim reexaminations will mean missing certain earnings changes, such as when a family's earnings increase to the point where they are paying zero HAP, HUD has determined that their inclusion would make it difficult to compare results across PHAs, an essential element of the performance measurement system.

9. *Comment: Other Comments on the Earnings Measure.* Most commenters agreed that averages were more appropriate than medians for the earnings measure. A few commenters stated that new employment and/or employment retention should be included as part of the earnings measure or in addition to the earnings measure. A few commenters suggested that escrow accumulation be included as part of or in addition to the earnings measure.

HUD Response: Other Comments on the Earnings Measure. As noted in the December 12, 2017 **Federal Register** Notice (at page 82 FR 58438–39), HUD chose to focus on average earnings growth rather than median earnings growth to ensure that PHAs received credit for the major, transformative earnings gains experienced by some FSS participants, even if this experience was not typical of the whole population of FSS participants. HUD appreciates that most commenters agreed with this approach. However, HUD disagrees with adding new employment, employment retention, and escrow accumulation as additional measures or as part of the earnings measure. Households that experience new employment and escrow accumulation are likely to also experience increased earnings, since these measures are strongly related. Accordingly, the inclusion of these measures as additional measures would provide even heavier weight to earnings than is already the case, which HUD does not believe to be appropriate. HUD also notes that data on ''new employment'' is not currently collected (though HUD could make inferences about this from the PIC data) and that this measure could disadvantage PHAs that serve a population that generally enters FSS employed. Escrow is driven largely by earnings gains, though it is also affected by the loss of welfare assistance or other non-earnings income and thus is less precise than earnings in measuring earnings growth. Escrow accumulation also does not take into account earnings gains for households above 50 percent of Area Medium Income (AMI), which is taken into consideration by the earnings measure currently in place. Additionally, until HUD has published a regulation or notice that implements Section 102 of Housing Opportunity Through Modernization Act of 2016 (HOTMA), residents who are subject to the Earned Income Disregard will have their escrow affected by that policy (in that escrow will not grow while income is disregarded for rent calculation purposes). While the current measure does not directly measure employment retention, it does factor it in since an FSS participant who retains his or her job while a comparison household does not will experience greater gains in earnings (zero) than the comparison household (a negative number), boosting the PHAs' average earnings performance score.

C. Comments on FSS Graduation Rate Measure

1. *Comment: FSS Graduation Rate.* Many commenters were concerned that the inclusion of an FSS graduation rate measure would encourage PHAs to graduate families quickly instead of encouraging families to set ambitious employment goals in addition to the necessary requirements of maintaining entry level employment and being free of welfare cash assistance for twelve (12) months. Others noted that PHAs define/operationalize some of the FSS graduation standards differently from one another, so this measure would not be consistent across PHAs. A few commenters said that the FSS graduation measure penalizes programs for terminating non-compliant participants.

HUD Response: FSS Graduation Rate. FSS graduation is an important milestone in the FSS program. FSS graduation marks the point at which FSS participants attain both their individual goals and the required program goals of employment and independence from welfare cash assistance. It also is the prerequisite for participants to receive the final disbursement from their escrow accounts.

Together, the Earnings Performance Measure, Graduation Rate, and Participation Rate provide a balanced measurement of the performance of an individual FSS program. Because the Earnings Performance Measure is weighted more heavily than the Graduation Rate, PHAs should balance the need to graduate participants with setting ambitious employment goals so participants can maximize their earnings growth while in the program. In addition, while PHAs have the discretion to terminate the FSS participation of non-compliant participants, HUD would encourage PHAs to first work with participants to determine if their challenges can be addressed so participants can successfully complete the FSS program. Additional guidance can be found in the FSS Promising Practices Guidebook.

D. Comments on Participation Rate Measure

1. *Comment: Top Participation Scores.* Many commenters expressed the view that having the top scores for participation substantially higher than the minimum a PHA is expected to serve with HUD funding is unfair and encourages PHAs to enroll more people than they can effectively serve. A few saw it as an unfunded mandate.

HUD Response: Top Participation Scores. All PHAs that serve the minimum number of participants expected based on the level of HUD coordinator funding will receive at least a 5 as a participation score. If a PHA can attain strong earnings and FSS graduation results while exceeding this minimum, however, HUD wishes to encourage them to do so as this helps to maximize the number of families benefitting from the FSS program. This is the reason for assigning higher participation scores to PHAs that achieve higher participation levels. Since earnings is weighted much more heavily than participation, however, HUD emphasizes that PHAs should only increase their caseloads if and to the extent they can do so without undermining their earnings and FSS graduation results.

HUD examined FSS performance data to determine if there is a correlation between a PHA's participation rate and its earnings and FSS graduation rate, paying particular attention to the participation rate threshold for obtaining a score of 10 points (80th percentile). This analysis did not find a strong relationship between participation rate and earnings performance measure. In fact, PHAs with participation rates between the 80th and 90th percentile had the highest average earnings performance measure of any decile and a median earnings performance measure that was typical for the sample as a whole, confirming that the threshold for obtaining a score of 10 points is not one that leads to lower earnings performance scores.

In terms of FSS graduation rates, the median FSS graduation rate was fairly similar for most deciles of participation rate, except for the very highest and lowest deciles, which both had lower FSS graduation rates than the other deciles. However, the threshold for qualifying for 10 points on the participation rate is set at the 80th percentile and not the 90th percentile (the starting point for the highest decile) and PHAs with participation rates between the 80th and 90th percentile had median and average FSS graduation rates that were typical for the sample as a whole, confirming that this threshold does not inherently lead to sub-par performance.

Based on this analysis, HUD has determined that it is appropriate to encourage PHAs to adopt higher participation rates, so long as they can do so without compromising their earnings performance and FSS graduation rates. However, HUD has decided to change the final scoring so as to reward incremental improvements in participation rates, rather than only participation rates that exceed one of two specific thresholds. Accordingly, HUD will assign PHAs with participation rates above .95 a score of 5, 6, 7, 8, 9 or 10, depending on their participation rate, as specified in Section III of this notice. A score of 10 will be awarded for a participation rate at or above 2.0, which is close to the 80th percentile level HUD previously identified.

2. *Comment: Participation Rate and PHA Size.* A few commenters said that the participation rate measure disadvantages either large PHAs/programs or small ones. For small programs in small PHAs, there may be less opportunity to recruit participants and smaller economies of scale for the coordinator. For large programs, increases in the number of participants enrolled would have to be very large in order to increase the participation score.

HUD Response: Participation Rate and PHA Size. The commenters are split about whether the participation rate calculation benefits smaller or larger PHAs. HUD believes this reflects the reality that all PHAs (regardless of size) have the potential to obtain either a high or a low participation rate, depending on how they manage their FSS program. This is confirmed by the fact that, in the initial spreadsheet of PHA scores, PHAs of all sizes are well represented at each of the participation score levels. While all PHAs must comply with the minimum enrollment requirements associated with the receipt of HUD coordinator funding, each PHA should make a determination of how many families they can serve effectively above this minimum based on their staff capacity, the intensity of participants' needs, and other resources available at the PHA and from partner organizations. HUD encourages PHAs to serve as many households as they can, so long as they do not exceed the level they can effectively support. Additionally, as explained above, there is no clear correlation between a PHA's size and the overall composite score.

E. Comments on Weighting of the Measures

1. *Comment: Weighting.* Several commenters felt that the weights are appropriate and did not comment further. Many commenters expressed the view that the earnings measure is weighted too highly. Commenters who suggested this were often concerned that the earnings measure would not show progress for FSS participants in longer-running education or training programs and so, did not account for variations in participant goals. Some commenters felt that FSS graduation and participation should have the same weight, regardless of the weight of the earnings measure. One reason given for this is that participation is essential for FSS graduation. Another was that weighting FSS graduation rate too highly compared to participation would encourage PHAs to graduate families before they had met ambitious goals.

HUD Response: Weighting. HUD appreciates the range of views expressed on this matter. After considering the comments, HUD plans to retain the weighting specified in the December 12, 2017 **Federal Register** Notice. Earnings represent by far the most powerful and objective measure available to HUD. While there are many goals to which FSS participants aspire, the achievement of most of these should lead to higher earnings which can then be measured through the earnings performance measure. Accordingly, HUD believes that a weight of 50 percent is appropriate.

While there is a case for weighting FSS graduation rate and participation rate equally, HUD believes weights of 30 percent for the FSS graduation rate and 20 percent of the participation rate are appropriate. As noted above, FSS graduation is an important milestone for the FSS program and HUD would like to see PHAs raise FSS graduation rates. HUD would also like to see PHAs serve more families if and to the extent they can do so without jeopardizing their achievement of strong earnings and FSS graduation rates. Weighting FSS graduation rate more heavily than participation rate is consistent with HUD's goal of not creating incentives for PHAs to raise caseloads beyond the point where families can be served effectively.

III. Final Thresholds

A. Summary of Adjustments to FSS Performance Score Methodology

After considering all of the public comments, HUD is adopting the proposed FSS performance measurement system, with the adjustments noted above, which will henceforth be used by HUD to evaluate the performance of PHAs receiving HUD program coordinator funding. These adjustments are summarized in the table below:

CHANGES TO METHODOLOGY FOR COMPUTING FSS PERFORMANCE SCORES

Overall	• Where a family ports, each PHA (the receiving and the initial PHA) will benefit from the family's FSS enrollment as it relates to the PHA's participation measure. For the earnings and FSS graduation measures, HUD will include the family for the PHA who currently administers the FSS contract. • HUD will treat joint applicants as a single PHA for purposes of computing all three components of the FSS performance score.
Earnings Performance Score.	• In calculating the earnings performance score, HUD will exclude FSS participants who become classified as disabled at any point during their participation. • HUD will include within the earnings measure FSS participants that begin the FSS contract below age 62, even if they reach or exceed the age of 62 during their Contract of Participation. • In selecting comparison households, HUD will match FSS families with comparison families based on the number of children under the age of 18, rather than the presence of child under age 5. HUD will also match FSS families with comparison families based on presence of a child with a disability and presence of a non-head of household adult with a disability. • Under certain circumstances, HUD will require that comparison households be in the same county and PHA as the FSS participants to which they are being compared. HUD will apply this protocol to all state PHAs and to any additional PHAs where three or more counties are each home to at least 10 percent of households receiving housing assistance from the PHA (through HCV or public housing). To ensure this approach does not unduly dilute the ability to find comparable households, HUD will require that FSS participants be matched to comparison households in the same county only in counties where there are at least four times as many non-FSS households as FSS households being served by the PHA. • HUD will apply an adjustment factor to the earnings performance measure to account for variations in local economic conditions.

After making these adjustments to the methodology, HUD has recalculated the thresholds for translating the FSS performance measures into individual component scores and the final composite score and notes the final thresholds below.

B. Updated Thresholds for FSS Performance Scores

The following are the updated thresholds HUD will use to compute an FSS Performance Score for each PHA. See the December 12, 2017 **Federal Register** Notice and the updated complete methodology, which can be found on HUD's website at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/fss,* for more information on each of the two steps in this process.

1. Step One: Assigning Scores to Each of the Three Measures

In Step One, HUD will assign a score of 0 to 10 to each PHA's FSS program for each of the three measures. Scores will be assigned using the thresholds and procedures described below. The ranges for awarding points between two values include those values as well as all intermediary values.

a. Earnings Performance Measure (50 percent of final score):

- *10 points:* Earnings performance measure of $8,700 or higher.
- *7.5 points:* Earnings performance measure between $6,950 and $8,699.99.
- *0 points:* Earnings performance measure below $4,050 and a p-value of <.10 on a statistical test measuring the likelihood that a PHA's earnings performance measure is significantly lower than the median measure of $6,302 (see December 12, 2017 **Federal Register** Notice at page 82 FR 58437 for an explanation of this statistical test).
- *5 points:* All PHAs that do not qualify for a 10, 7.5, or a 0.

b. FSS Graduation Rate (30 percent of final score):

- *10 points:* FSS graduation rate of 38 percent or higher.
- *7.5 points:* FSS graduation rate between 28 percent and 37.9 percent.
- *0 points:* FSS graduation rate below 10 percent.
- *5 points:* All PHAs that do not qualify for a 10, 7.5, or a 0

c. Participation Rate (20 percent of final score):

- *10 points:* Participation rate of 2.0 or higher.
- *9 points:* Participation rate between 1.8 and 1.99.
- *8 points:* Participation rate between 1.6 and 1.79.
- *7 points:* Participation rate between 1.4 and 1.59.
- *6 points:* Participation rate between 1.2 and 1.39.
- *5 points:* Participation rate between .96 and 1.19.
- *0 points:* Participation rate of .95 or lower.

2. Step Two: Developing the Final FSS Performance Score and Grade

In Step Two, after computing individual scores for each of the three measures, HUD will aggregate each PHA's scores using the weights noted above to develop a final FSS Performance Score from 0 to 10. Based on this score, HUD will assign the following ranking to the PHA's performance:

- *Category 1:* FSS Performance score of 8.0 or higher.
- *Category 2:* FSS Performance score between 4.26 and 7.99.
- *Category 3:* FSS Performance score between 3.26 and 4.25.
- *Category 4:* FSS Performance score of 3.25 or lower.

IV. Environmental Impact

This notice does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Dated: November 7, 2018.

Dominique Blom,

General Deputy Assistant Secretary, Public and Indian Housing.

[FR Doc. 2018–24949 Filed 11–14–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2018–N115; FXES11130300000–189–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before December 17, 2018.

ADDRESSES: *Document availability and comment submission:* You may, within 30 days of the date of publication of this notice (see **DATES**), submit requests for copies of the applications and related documents, and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TEXXXXXX):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective permit number (*e.g.,* Application No. TEXXXXXX) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, 612–713–5343; *permitsR3ES@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits will allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing such permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE99650C	Dale Dunford II, Rome, OH.	Clubshell (*Pleurobema clava*), fanshell (*Cyprogenia stegaria*), pink mucket (pearly-mussel) (*Lampsilis abrupta*), northern riffleshell (*Epioblasma torulosa rangiana*), purple cat's paw pearlymussel (*E. obliquata obliquata*), snuffbox mussel (*E. triquetra*), rabbitsfoot (*Quadrula cylindrica cylindrica*), sheepnose mussel (*Plethobasus cyphyus*), rayed bean (*Villosa fabalis*).	IN, KY, MI, NY, OH, PA, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, temporary hold, tag, release, relocate.	New.
TE01835D	Mariah Scott, Chicago, IL.	Snuffbox mussel (*Epioblasma triquetra*)	MI	Study growth rate ontogenetic changes, male and female morphology.	Collect dead shells, hold, biosample.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 30, 2018.

Lori H. Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2018–24963 Filed 11–14–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX18DK00GUF0200]

Notice of Request for Nominees for the Advisory Committee on Water Information

AGENCY: United States Geological Survey, Department of the Interior.

ACTION: Notice of request for nominees.

SUMMARY: The U.S. Department of the Interior (Interior) is seeking nominations for individuals to be considered as Committee members and/or alternates to serve on the Advisory Committee on Water Information (ACWI).

FOR FURTHER INFORMATION CONTACT: Ms. Adrienne Bartlewitz, Acting ACWI Executive Secretary, U.S. Geological Survey, 12201 Sunrise Valley Drive, Reston, VA 20192. Telephone: 703–648–4304; Fax: 703–648–5002.

SUPPLEMENTARY INFORMATION: The ACWI was established under the authority of the Office of Management and Budget and Budget Memorandum No. M–92–01 and the Federal Advisory Committee Act, as amended, (5 U.S.C. App. 2), and with the concurrence of the General Services Administration.

Membership represents a wide range of water resources interests and functions. The ACWI has a maximum of 35 members. Members will represent the interests of water oriented organizations and will be selected from among, but not limited to the following groups: Federal agencies, professional water-related associations, State and county water-related associations, academia, private industry, water utility associations, civil engineering societies, watershed and land conservation associations, ecological societies, lake, coastal, and ocean associations, environmental and educational groups.

Member organizations designate their representatives and alternates. Membership rests not with the individual person but rather with the member organization, who names their representative, and sometimes an alternate.

Nominations should include a résumé providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the ACWI and permit the Department of the Interior to contact a potential member. No individual who is currently registered as a Federal lobbyist is eligible to serve as a member of the ACWI.

The Committee functions solely as an advisory body, and in compliance with the provisions of the Federal Advisory Committee Act. Nominations for member organizations should be submitted to the Executive Secretary, at the address listed in **FOR FURTHER INFORMATION CONTACT**.

The purpose of the ACWI is to represent the interests of water-information users and professionals in advising the Federal Government on Federal water-information programs and their effectiveness in meeting the Nation's water-information needs. Member organizations help to foster communications between the Federal and non-Federal sectors on sharing water information.

Dated: October 5, 2018.

Jim Reilly,

Director, United States Geologic Survey.

[FR Doc. 2018–24878 Filed 11–14–18; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0162]

Agency Information Collection Activities; Navajo Partitioned Lands Grazing Permits

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 14, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to the Calvert L. Curley, Office of Trust Services, Branch of Natural Resources, P.O. Box 1060, Gallup, New Mexico 87105; telephone: (505) 863–8221; email: *calvert.curley@bia.gov.* Please reference OMB Control Number 1076–0162 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Calvert L. Curley at telephone: (505) 863–8204, or email: *calvert.curley@bia.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIA; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIA enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIA minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This information collection is authorized under 25 CFR 161, which implements the Navajo-Hopi Indian Relocation Amendments Act of 1980, 94 Stat. 929, and the Federal court decisions of *Healing* v. *Jones,* 174 F. Supp.211 (D Ariz. 1959) (Healing I), *Healing* v. *Jones,* 210 F. Supp. 126 (D. Ariz. 1962), aff'd 363 U.S. 758 (1963) (Healing II), *Hopi Tribe* v. *Watt,* 530 F. Supp. 1217 (D. Ariz. 1982), and *Hopi*

Tribe v. *Watt,* 719 F.2d 314 (9th Cir. 1983).

This information collection allows BIA to receive the information necessary to determine whether an applicant to obtain, modify, or assign a grazing permit on Navajo Partitioned Lands is eligible and complies with all applicable grazing permit requirements. BIA, in coordination with the Navajo Nation, will continue to collect grazing permit information up to and beyond the initial reissuing of the grazing permits, likely within a 1–3 year time period from the date of publication of this notice. The data is collected by electronic global positioning systems and field office interviews by BIA & Navajo Nation staff. The data is maintained by BIA's Navajo Partitioned Lands office. The burden hours for this continued collection of information are reflected in the Estimated Total Annual Hour Burden in this notice.

Title of Collection: Navajo Partitioned Lands Grazing Permits.

OMB Control Number: 1076–0162.

Form Number: 5–5523, 5–5515, and 5–5522.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Tribes, Tribal organizations, and individual Indians.

Total Estimated Number of Annual Respondents: 1,155.

Total Estimated Number of Annual Responses: 2,000.

Estimated Completion Time per Response: On average, two hours.

Total Estimated Number of Annual Burden Hours: 4,000 hours.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: $0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2018–24890 Filed 11–14–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[XXXD5198NI/DS61100000/DNINR0000.000000/DX61104]

Exxon Valdez Oil Spill Public Advisory Committee; Call for Nominations

AGENCY: Office of the Secretary, Interior.

ACTION: Notice to solicit nominations.

SUMMARY: The Exxon Valdez Oil Spill Trustee Council is soliciting nominations for the Public Advisory Committee. The Public Advisory Committee advises the Trustee Council on decisions related to the planning, evaluation, funds allocation, and conduct of injury assessment and restoration activities related to the T/V *Exxon Valdez* oil spill of March 1989. Public Advisory Committee members will be selected and appointed by the Secretary of the Interior to serve a 2-year term.

DATES: All nominations must be received by December 17, 2018.

ADDRESSES: A complete nomination package should be submitted by hard copy or via email to Elise Hsieh, Executive Director, *Exxon Valdez* Oil Spill Trustee Council, 4230 University Drive, Suite 220, Anchorage, Alaska, 99508–4650, or via email at *elise.hsieh@alaska.gov.*

FOR FURTHER INFORMATION CONTACT: Questions should be directed to Cherri Womac, *Exxon Valdez* Oil Spill Trustee Council, 4230 University Drive, Suite 220, Anchorage, Alaska, 99508–4650, (907) 278–8012 or (800) 478–7745 or via email at *cherri.womac@alaska.gov;* or Philip Johnson, Designated Federal Officer, U.S. Department of the Interior, Office of Environmental Policy and Compliance, 1689 C Street, Suite 119, Anchorage, Alaska, 99501–5126, (907) 271–5011.

SUPPLEMENTARY INFORMATION: The *Exxon Valdez* Oil Spill Public Advisory Committee was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska,* Civil Action No. A91–081 CV. The Public Advisory Committee was created to advise the Trustee Council on matters relating to decisions on injury assessment, restoration activities, or other use of natural resource damage recoveries obtained by the Government.

The Trustee Council consists of representatives of the U.S. Department of the Interior, U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, Alaska Department of Fish and Game, Alaska Department of Environmental Conservation, and Alaska Department of Law.

The Public Advisory Committee consists of 10 members to reflect balanced representation from each of the following principal interests: aquaculture/mariculture, commercial tourism, conservation/environmental, recreation, subsistence use, commercial fishing, native landownership, sport hunting/fishing, science/technology, and public-at-large.

Nominations for membership may be submitted by any source.

Nominations should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Public Advisory Committee and permit the Department of the Interior to contact a potential member.

Individuals who are federally registered lobbyists are ineligible to serve on all FACA and non-FACA boards, committees, or councils in an individual capacity. The term ''individual capacity'' refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest.

Authority: 5 U.S.C. Appendix 2.

Michaela Noble,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 2018–24866 Filed 11–14–18; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–D–COS–POL–26719; PPWODIREP0][PPMVSCS1Y.Y00000]

Notice of a Teleconference Meeting of the Made in America Outdoor Recreation Advisory Committee on Friday, November 30, 2018

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service is hereby giving notice that the Made in

America Outdoor Recreation Advisory Committee (Committee) will meet by teleconference as noted below. Members of the public may attend the teleconference meeting in person in Washington, DC to listen to the proceedings.

DATES: The teleconference meeting will be held on Friday, November 30, 2018, from 11:00 a.m. to 1:00 p.m., EST.

ADDRESSES: The teleconference meeting will be conducted in the South Penthouse of the Stewart Lee Udall Department of the Interior Building, 1849 C Street NW, Washington, DC 20240, telephone 202–354–3950.

FOR FURTHER INFORMATION CONTACT: Shirley Sears, Office of Policy, National Park Service, 1849 C Street NW, Mail Stop 2659, Washington, DC 20240, telephone number 202–354–3955, or email *shirley_sears@nps.gov.*

SUPPLEMENTARY INFORMATION: The Committee will meet to receive and deliberate the report of its Subcommittee on Recreation Enhancement Through Reorganization, and to receive status updates from its subcommittees on Partnership and Collaboration, Public Access and Infrastructure, and Technology and the Digital Experience. The Committee meeting will be open to the public in the same way as all committee meetings are open to the public. Space and facilities to accommodate the public are limited and attendees will be accommodated on a first-come basis. Opportunity for oral comment will be limited to no more than 3 minutes per speaker and no more than 15 minutes total. The Committee Chair will determine how time for oral comments will be allocated.

Anyone may file with the Committee a written statement concerning matters to be discussed.

Public Disclosure of Information: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2018–24863 Filed 11–14–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–ACAD–26614; PPNEACADSO, PPMPSPDIZ.YM0000]

Request for Nominations for the Acadia National Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior, is requesting nominations for qualified persons to serve as members of the Acadia National Park Advisory Commission (Commission).

DATES: Written nominations must be postmarked by December 17, 2018.

ADDRESSES: Nominations should be sent to Michael Madell, Deputy Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8701, or email *michael_madell@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Michael Madell, Deputy Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8701, or email *michael_madell@nps.gov.*

SUPPLEMENTARY INFORMATION: The Commission was established by section 103 of Public Law 99–420, as amended, (16 U.S.C. 341 note), and in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16). The Commission advises the Secretary and the NPS on matters relating to the management and development of Acadia National Park, including but not limited to, the acquisition of lands and interests in lands (including conservation easements on islands) and the termination of rights of use and occupancy.

The Commission is composed of 16 members appointed by the Secretary, as follows:

(a) Three members at large; (b) three members appointed from among individuals recommended by the Governor of Maine; (c) four members appointed from among individuals recommended by each of the four towns on the island of Mount Desert; (d) three members appointed from among individuals recommended by each of the three Hancock County mainland communities of Gouldsboro, Winter Harbor, and Trenton, and; (e) three members appointed from among individuals recommended by each of the three island towns of Cranberry Isles, Swans Island, and Frenchboro.

The NPS is seeking nominees for the three members at large. Fifteen member terms will end on February 19, 2019. This notice also informs the public about other opportunities for nominations to represent the Governor of Maine or local municipalities that will have vacancies in February. Nominations received by the park will be sent directly to either the Governor's office or local municipalities for their consideration.

Nominations should be typed and should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Commission and permit the Department to contact a potential member. All documentation, including letters of recommendation, must be compiled and submitted in one complete package. All those interested in membership, including current members whose terms are expiring, must follow the same nomination process. Members may not appoint deputies or alternates.

Members of the Commission serve without compensation. However, while away from their homes or regular places of business in the performance of services for the Committee as approved by the NPS, members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under section 5703 of title 5 of the United States Code.

Public Disclosure of Information: Before including your address, phone number, email address, or other personal identifying information with your nomination, you should be aware that your entire nomination—including your personal identifying information—may be made publicly available at any time. While you can ask us in your nomination to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2018–24865 Filed 11–14–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0025; DS63644200 DRT000000.CH7000 190D1113RT, OMB Control Number 1012–0001]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Accounts Receivable Confirmations Reporting

AGENCY: Office of the Secretary, Office of Natural Resources Revenue, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Office of Natural Resources Revenue (ONRR), is proposing to renew the Accounts Receivable Confirmations Reporting information collection. Every year, under the Chief Financial Officers Act of 1990, mineral lessees are asked to confirm the accuracy of randomly-selected ONRR accounts receivable. Accounts receivable confirmations are a common financial audit practice that require approval under the PRA.

DATES: Interested persons are invited to submit comments on or before December 17, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to Mr. Luis Aguilar, Regulatory Specialist, ONRR, P.O. Box 25165, MS 61030A, Denver, Colorado 80225–0165, or email *Luis.Aguilar@onrr.gov.* Please reference OMB Control Number 1012–0001 in your comments.

FOR FURTHER INFORMATION CONTACT: For questions on technical issues, contact Mr. Hans Meingast, Financial Services, ONRR, at (303) 231–3382, or email to *Hans.Meingast@onrr.gov.* For other questions, contact Mr. Luis Aguilar at (303) 231–3418, or email to *Luis.Aguilar@onrr.gov.* You may also contact Mr. Aguilar to obtain copies (free of charge) of (1) the ICR, (2) any associated form(s), and (3) the regulations that require the subject collection of information. You may also review the ICR online at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format. A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on June 11, 2018 (83 FR 27019). No comments were received.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the ONRR; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the ONRR enhance the quality, utility, and clarity of the information to be collected; and (5) how might the ONRR minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Secretary of the United States Department of the Interior is responsible for collecting royalties from lessees who produce minerals from Federal and Indian lands and the Outer-Continental Shelf (OCS). Under various laws, the Secretary is responsible to manage mineral resources from Federal and Indian lands and the OCS. One of the mineral responsibilities that ONRR performs on behalf of the Secretary is to collect the royalties and other mineral revenues due. These obligations are accounted for as accounts receivables with ONRR's Financial Management group. We have posted the laws pertaining to mineral leases on Federal and Indian lands and the OCS at *http://www.onrr.gov/Laws_R_D/PubLaws/default.htm.*

General Information

When a company or an individual enters into a lease to explore, develop, produce, sell, or otherwise dispose of minerals, from Federal and Indian lands and the OCS, that company or individual agrees to pay the lessor a share in an amount or value of production from the leased lands. For oil, gas, and solid minerals, the lessee is required to report various types of information to ONRR relative to the disposition of the leased minerals. Specifically, companies submit financial information to ONRR on a monthly basis by submitting form ONRR–2014 [Report of Sales and Royalty Remittance for oil and gas reported in OMB Control Number 1012–0004], and form ONRR–4430 [Solid Minerals Production and Royalty Report reported in OMB Control Number 1012–0010]. These royalty reports result in accounts receivables and capture the vast majority of the mineral revenue collected by ONRR.

The basis for the data that companies submit on forms ONRR–2014 and ONRR–4430 is generally available within the records of the lessee or others involved in developing, transporting, processing, purchasing, or selling such minerals. The information that we collect under the ICR includes data necessary to ensure that ONRR's accounts receivables are accurately based on the value of the mineral production, as reported to ONRR on forms ONRR–2014 and ONRR–4430.

Information Collections

Every year, the Chief Financial Officer (CFO) under Chief Financial Officers Act of 1990, the Office of Inspector General, or its agent (agent), audits the accounts receivable portions of the Department's financial statements, which are based on ONRR forms ONRR–2014 and ONRR–4430. Accounts receivable confirmations are a common financial audit practice. A third-party audit provides confirmation of the validity of ONRR's financial records.

As part of the CFO audit, the agent selects a sample of accounts receivable items based on forms ONRR–2014 and ONRR–4430, and provides the sample items to ONRR. ONRR then identifies the company names and addresses for the sample items selected and creates accounts receivable confirmation letters. In order to meet the CFO requirements, the letters must be on ONRR letterhead and the Deputy Director for ONRR, or his or her designee, must sign the letters. The letter requests third-party confirmation responses by a specified date on whether or not ONRR's accounts

receivable records agree with royalty payor records for the following items: (1) Customer identification; (2) royalty invoice number; (3) payor assigned document number; (4) date of ONRR receipt; (5) original amount the payor reported; and (6) remaining balance due to ONRR. The agent mails the letters to the payors, instructing them to respond directly to the agent to confirm the accuracy and validity of selected royalty receivable items and amounts. In turn, it is the responsibility of the payors to verify, research, and analyze the amounts and balances reported on their respective forms ONRR–2014 and ONRR–4430.

OMB Approval

We will request OMB approval to continue to collect this information. Not collecting this information would limit the Secretary's ability to discharge the duties of the office, could result in a violation of the Chief Financial Officers Act of 1990, and may also result in the inability to confirm the accuracy of ONRR's accounts receivables which are based on the accurate reporting of forms ONRR–2014 and ONRR–4430. ONRR protects the proprietary information received and does not collect items of a sensitive nature.

Title of Collections: Accounts Receivable Confirmations.

OMB Control Number: 1012–0001.

Form(s) Number: None.

Type of Review: Extension of a currently approved collection.

Respondent/Affected Public: Businesses.

Total Estimated Number of Annual Respondents: 24 randomly-selected mineral payors from Federal and Indian lands and the OCS.

Total Estimated Number of Annual Responses: 24.

Estimated Completion Time per Response: We estimate that each response will take 15 minutes for payors to complete.

Total Estimated Number of Annual Burden Hours: 6 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annual.

Total Estimated Annual Nonhour Burden Cost: We have identified no ''non-hour cost'' burden associated with this collection of information.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Gregory J. Gould,

Director for Office of Natural Resources Revenue.

[FR Doc. 2018–24877 Filed 11–14–18; 8:45 am]

BILLING CODE 4335–30–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Multi-Stage Fuel Vapor Canister Systems and Activated Carbon Components Thereof, DN 3351*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Ingevity Corp and Ingevity South Carolina, LLC, on November 8, 2018. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain multi-stage fuel vapor canister systems and activated carbon components thereof. The complaint names as respondents: MAHLE Filter Systems North America, Inc. of Murfreesboro, TN; MAHLE Filter Systems Japan Corp. of Japan; MAHLE Sistemas de Filtración de México S.A. de C.V. of Mexico; MAHLE Filter Systems Canada, ULC of Canada; Kuraray Co., Ltd. of Japan; Kuraray America, Inc. of Houston, TX and Nagamine Manufacturing Co., Ltd. of Japan. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond during the 60-day review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues should be filed no later than by close of business nine calendar days after the date of publication of this notice in the **Federal Register**. Complainant may file a reply to any written submission no later than the date on which complainant's reply would be due under § 210.8(c)(2) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(c)(2)).

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3351'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 9, 2018.

Jessica Mullan,

Attorney-Advisor.

[FR Doc. 2018–24955 Filed 11–14–18; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 10–18]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, November 29, 2018:

10:00 a.m.—Issuance of Proposed Decisions in claims against Iraq.

11:00 a.m.—Issuance of Proposed Decisions under the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114–328.

STATUS: Open.

All meetings are held at the Foreign Claims Settlement Commission, 601 D Street NW, Suite 10300, Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 601 D Street NW, Suite 10300, Washington, DC 20579. Telephone: (202) 616–6975.

Brian Simkin,

Chief Counsel.

[FR Doc. 2018–25040 Filed 11–13–18; 11:15 am]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0025]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day notice of information collection under review: Federal Coal Lease Request.

The Department of Justice (DOJ), Antitrust Division (ATR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 83, Number 175, page 45685 on September 10, 2018, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 17, 2018. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments (especially regarding the estimated public burden or associated response time), suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jill Ptacek, Antitrust Division, United States Department of Justice, 450 5th Street NW, Suite 8000, Washington, DC 20530. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—The quality, utility and clarity of the information to be collected; and

—How to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Federal Coal Lease Reserves.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Numbers: ATR–139 and ATR–140, Antitrust Division, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as brief abstract:* Primary: Business or other for Profit. Other: None. The Department of Justice evaluates the competitive impact of issuances, transfers and exchanges of federal coal leases. These forms seek information regarding a prospective coal lessee's existing coal reserves. The Department uses this information to determine whether the issuance, transfer or exchange of the federal coal lease is consistent with the antitrust laws.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond. It is estimated that 10 respondents will complete each form, with each response taking approximately two hours.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 20 annual burden hours associated with this collection, in total.

If additional information is required, contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Washington, DC 20530.

Dated: November 8, 2018.

Jonathan Mueller,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. 2018–24857 Filed 11–14–18; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standard

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before December 17, 2018.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Email: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect a copy of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (voice), *barron.barbara@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor (Secretary) determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2018–019–C.

Petitioner: Knight Hawk Coal, LLC, 1710 State Route 154, Pinckneyville, Illinois 62274.

Mine: Prairie Eagle Underground Mine, MSHA I.D. No. 11–03147, located in Perry County, Illinois.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit the use of nonpermissible, low-voltage or battery-powered electronic testing and diagnostic equipment in or inby the last open crosscut.

The petitioner states that:

(1) The nonpermissible electronic testing and diagnostic equipment would be limited to laptop computers, oscilloscopes, vibration analysis machines, cable fault detectors, point temperature probes, infrared temperature devices, signal analyzer devices, ultrasonic measuring devices, electronic component testers, and electronic tachometers.

(2) Permissible, approved voltage measuring instruments will be used when possible.

(3) All other testing and diagnostic equipment used in or inby the last open crosscut will be permissible

(4) Other testing and diagnostic equipment may be used if approved in advance by MSHA's District office.

(5) All nonpermissible, low-voltage or battery-powered electronic testing and diagnostic equipment to be used in or inby the last open crosscut will be examined prior to use by a certified person to ensure equipment is being maintained in a safe operating condition.

(6) The results of such inspection will be recorded and retained for one year and made available to MSHA on request.

(7) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before

and during the use of nonpermissible electronic testing and diagnostic equipment in or inby the last open crosscut.

(8) Nonpermissible electronic testing and diagnostic equipment will not be used if methane is detected in concentrations at or above one percent. When methane is detected at such levels while the nonpermissible electronic testing and diagnostic equipment is being used, the equipment will be deenergized immediately and withdrawn outby the last open crosscut.

(9) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition as defined in 30 CFR 75.320.

(10) Coal production will cease, except for the time necessary to troubleshoot under actual mining conditions. Coal may remain in or on the equipment in order to test and diagnose the equipment under load. Accumulations of coal and combustible materials referenced in 30 CFR 75.400 will be removed before testing begins to provide additional safety to miners.

(11) Nonpermissible electronic test and diagnostic equipment will not be used to test equipment when float coal dust is in suspension.

(12) All electronic and diagnostic equipment will be used in accordance with the manufacturer's recommended safe use procedures.

(13) Qualified personnel engaged in the use of nonpermissible electronic testing and diagnostic equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(14) The nonpermissible electronic testing and diagnostic equipment will not be put into service until MSHA has inspected the equipment and determined that it is in compliance with all the above terms and conditions.

(15) Cables supplying power to low-voltage testing and diagnostic equipment will only be used when permissible testing and diagnostic equipment is unavailable.

(16) Within 60 days after the Proposed Decision and Order (PDO) becomes final, the petitioner will submit proposed revisions for its approved 30 CFR part 48 training plan to the District Manager. The revisions will specify initial and refresher training regarding the terms and conditions in the PDO.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Roslyn B. Fontaine,

Deputy Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2018–24913 Filed 11–14–18; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice; correction.

SUMMARY: This notice amends a notice published in the **Federal Register** on October 30, 2018, for Affirmative Decisions on Petitions for Modification Granted in Whole or in Part.

FOR FURTHER INFORMATION CONTACT: Roslyn B. Fontaine, 202–693–9440.

Correction

A petition for modification for Docket Number M–2017–019–C, for Marfork Coal Company, LLC, 500 Lee Street East, Suite 701 (25301), Post Office Box 2548, Charleston, West Virginia 25329, referenced in the October 30, 2018 **Federal Register** notice on page 54616 in the 1st column, was inadvertently listed in the notice as granted. The petition was not granted.

Roslyn B. Fontaine,

Deputy Director, Office of Standards, Regulations and Variances.

[FR Doc. 2018–24912 Filed 11–14–18; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Extend an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request a new, one time data collection. The primary purpose of this data collection is to provide critical evidence for the Evaluation of the Centers for Chemical Innovation (CCI) Program. The National Science Foundation (NSF) has submitted this information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register** at 83 FR 27354, and one comments was received. NSF is forwarding the proposed new information collection submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain.*

DATES: Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification.

FOR FURTHER INFORMATION CONTACT: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725—17th Street, NW Room 10235, Washington, DC 20503, and Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission(s) may be obtained by calling 703–292–7556.

SUPPLEMENTARY INFORMATION: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section.

Title of Collection: 2019 National Survey of College Graduates.

OMB Number: 3145–0141.

Summary of Collection: The National Survey of College Graduates (NSCG) has been conducted biennially since the 1970s. The 2019 NSCG sample will be selected from the 2017 American Community Survey (ACS) and the 2017 NSCG, providing coverage of the college graduate population residing in the United States. The purpose of this repeated cross-sectional survey is to collect data that will be used to provide national estimates on the science and engineering workforce and changes in their employment, education, and demographic characteristics.

The National Science Foundation Act of 1950, as subsequently amended, includes a statutory charge to ''. . . provide a central clearinghouse for the collection, interpretation, and analysis of data on scientific and engineering resources, and to provide a source of information for policy formulation by other agencies of the Federal Government.'' The NSCG is designed to comply with these mandates by providing information on the supply and utilization of the nation's scientists and engineers.

The U.S. Census Bureau, as in the past, will conduct the NSCG for NCSES. The survey data collection will begin in February 2019 using web and mail questionnaires. Non-respondents to the web or mail questionnaire will be followed up by computer-assisted telephone interviewing. The individual's response to the survey is voluntary. The survey will be conducted in conformance with Census Bureau statistical quality standards and, as such, the NSCG data will be afforded protection under the applicable Census Bureau confidentiality statutes.

Use of the Information: NCSES uses the information from the NSCG to prepare congressionally mandated reports such as *Women, Minorities and Persons with Disabilities in Science and Engineering* and *Science and Engineering Indicators.* A public release file of collected data, designed to protect respondent confidentiality, will be made available to researchers on the internet.

Expected Respondents: A statistical sample of approximately 148,000 persons will be contacted in 2019. This 148,000 sample is an 18,000 case increase over the sample size listed in the first notice for public comment in the **Federal Register** at 83 FR 27354. The larger sample size is needed to account for non-response in follow-up rounds, to reduce the variance inflation caused when cases thought to be in non-science and engineering (S&E) occupations turn out to be in S&E occupations, and to increase the number of foreign-earned doctorate recipients in the NSCG sample. NCSES estimates the 2019 NSCG response rate to be 70 to 80 percent.

Estimate of Burden: The amount of time to complete the questionnaire may vary depending on an individual's circumstances; however, on average it will take approximately 30 minutes to complete the survey. NCSES estimates that the total annual burden will be no more than 59,200 hours (=148,000 sample persons × 80% response × 30 minutes) during the 2019 survey cycle.

Comments: As required by 5 CFR 1320.8(d), comments on the information collection activities as part of this study were solicited through the publication of a 60-Day Notice in the **Federal Register** on 12 June 2018, at 83 FR 27354. NCSES received one comment on 13 August 2018 from a group representing several organizations. The commenters requested that NCSES include measures of sexual orientation and gender identity on the NSCG and on other NCSES surveys (specifically, the Survey of Doctorate Recipients and the Survey of Earned Doctorates). NCSES informed the commenters that it shares their interest in improving federal data collections and providing reliable measures for important segments of the population. Furthermore, NCSES described its process for evaluating possible questionnaire additions, including the extensive experimentation involved and the time and resources required. Finally, NCSES informed the commenters that it is initiating research to evaluate these measures and does not intend to include them in the 2019 NSCG.

Dated: November 9, 2018.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2018–24928 Filed 11–14–18; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2019–11]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 16, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2019–11; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 7 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* November 8, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* November 16, 2018.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–24916 Filed 11–14–18; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 6, 2018, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 472 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–11, CP2019–10.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–24911 Filed 11–14–18; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, November 15, 2018.

PLACE: The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Stein, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: November 8, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–25021 Filed 11–13–18; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84557; File No. SR–NYSEArca–2018–78]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges To Remove Certain Obsolete Text That References Pillar Phase I Protocols

November 8, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 1, 2018, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to remove certain obsolete text that reference [sic] Pillar phase I protocols now that Pillar phase I protocols are no longer available for ETP Holders to communicate with the NYSE Arca Marketplace. The Exchange proposes to implement the fee changes effective November 1, 2018. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to remove certain obsolete text that reference Pillar phase I protocols now that Pillar phase I protocols are no longer available for ETP Holders to communicate with the NYSE Arca Marketplace. The Exchange proposes to implement the fee changes effective November 1, 2018.

As a general matter, ETP Holders enter orders and order instructions by using communication protocols that map to the order types and modifiers described in Exchange rules. Prior to the implementation of Pillar, ETP Holders communicated with the NYSE Arca Marketplace using Pillar phase I protocols. When the Exchange introduced trading on its Pillar trading platform, the Exchange also introduced new technology to support how ETP Holders communicate with the NYSE Arca Marketplace, referred to in the Exchange's rules as Pillar phase II protocols. During the Pillar implementation, there was a period of time when both Pillar phase I protocols and Pillar phase II protocols were available to ETP Holders. Effective October 1, 2018, Pillar phase I protocols are no longer available to ETP Holders. All ETP Holders now use Pillar phase II protocols to communicate with the NYSE Arca Marketplace. As a result, there is no longer a need to distinguish between Pillar phase I protocols and Pillar phase II protocols in the Exchange's Fee Schedule.

In April 2018, the Exchange filed a proposed rule change to adopt a new pricing tier—BBO Setter Tier.[4] In the BBO Setter Tier Filing, the Exchange adopted the following rule text in the BBO Setter pricing tier: ''For purpose of the BBO Setter Tier, ETP ID means an ETP ID when using Pillar phase I protocols to communicate with the NYSE Arca Marketplace or an MPID when using Pillar phase II protocols to communicate with the NYSE Arca Marketplace.'' The Exchange proposes to remove this text from the Fee Schedule now that Pillar phase I protocols are no longer available and all ETP Holders now communicate with the NYSE Arca Marketplace using Pillar phase II protocols.

Additionally, in August 2017, in connection with the introduction of Pillar phase II protocols, the Exchange amended the Fee Schedule to adopt a cap, for August and September 2017, on monthly fees for the use of ports connecting to the NYSE Arca Marketplace.[5] Given that the months during which the port fee cap was applicable have passed, the Exchange proposes to delete reference to the port fee cap from the Fee Schedule as that rule text is now obsolete.

Finally, in October 2017, the Exchange amended the Fee Schedule to adopt a Decommission Extension Fee applicable to ETP Holders for the use of Pillar phase I protocols to connect with the NYSE Arca Marketplace for a three-month period from March 2018 through May 2018 as an incentive for ETP Holders to fully transition to the use of Pillar phase II protocols to connect with the NYSE Arca Marketplace.[6] In June 2018, the Exchange filed to extend the effectiveness of the Decommission Extension Fee for an additional four months, until September 2018.[7] The Exchange proposes to remove rule text regarding the Decommission Extension Fee from the Fee Schedule as that rule text is now obsolete because the period of time during which the Decommission Extension Fee was applicable has passed.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[9] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to delete reference to obsolete rule text and dates from the Fee Schedule. The Exchange believes that the proposed changes are reasonable because they would result in greater specificity and precision within the Fee Schedule, which would contribute to reasonably ensuring that the fees and credits described there are clear and accurate. Specifically, the proposed changes are reasonable because they would remove obsolete rule text and dates from the Fee Schedule related to the use of ports that are no longer available to connect to the NYSE Arca Marketplace and a Decommission Extension Fee that is no longer charged by the Exchange. The Exchange also believes that the proposed changes are equitable and not unfairly discriminatory because all readers of the Fee Schedule, including all ETP Holders, would benefit from the increased specificity and clarity that this proposed rule change would provide.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[10] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes are not designed to address any competitive issues. Rather, the proposed changes are designed to provide greater specificity and precision within the Fee Schedule, which would contribute to reasonably ensuring that the fees and credits described therein are clear and accurate. In addition, the removal of obsolete text from the Fee Schedule would not have any impact on inter- or intra-market competition because the proposed change would result in a streamlined Fee Schedule without any impact on pricing.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [11] of the Act and subparagraph (f)(2) of Rule 19b–4 [12] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may

[4] *See* Securities Exchange Act Release No. 83032 (April 11, 2017 [sic]), 83 FR 16909 (April 17, 2017 [sic]) (SR–NYSEArca–2018–20) (''BBO Setter Tier Filing'').

[5] *See* Securities Exchange Act Release No. 81573 (September 11, 2017), 82 FR 43430 (September 15, 2017) (SR–NYSEArca–2017–97).

[6] *See* Securities Exchange Act Release No. 81901 (October 19, 2017), 82 FR 49426 (October 25, 2017) (SR–NYSEArca–2017–121).

[7] *See* Securities Exchange Act Release No. 83410 (June 12, 2018), 83 FR 28300 (June 18, 2018) (SR–NYSEArca–2018–42).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4) and (5).

[10] 15 U.S.C. 78f(b)(8).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2018–78 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2018–78. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2018–78 and should be submitted on or before December 6, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–24868 Filed 11–14–18; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(2)(B).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84556; File No. SR–ICEEU–2018–011]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the F&O Guaranty Fund Policy (the "Policy"), Clearing Rules (the "Rules") and Finance Procedures ("Finance Procedures")

November 8, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 29, 2018, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule changes pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b-4(f)(4)(ii) thereunder,[4] so that the proposal was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes to make certain amendments to the Policy, Rules and Finance Procedures relating to the calculation methodology for F&O Clearing Member contributions, the minimum size of the F&O Guaranty Fund and the review cycle and to make various drafting clarifications and improvements.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is generally amending the Policy to address the following aspects of the F&O Guaranty Fund: Changing the calculation methodology for F&O Clearing Member contributions to incorporate an uncollateralized stress loss factor (in addition to a factor based on the intraday original margin requirement), in line with the Clearing House principle of 'polluter pays'; specifying the minimum size of the F&O Guaranty Fund at 2% of the amount of F&O original margin; and changing the review cycle for the F&O Guaranty Fund level from quarterly to every two months, in line with the F&O Risk Committee meeting schedule. Various drafting clarifications and improvements have also been made, and certain descriptions in the Policy that duplicate or describe provisions in other Rules, ICE Clear Europe Procedures and policies have been removed as unnecessary. ICE Clear Europe is also making corresponding amendments to the Rules and Finance Procedures to accommodate the changes being made to the Policy. Set out below are further details regarding the specific proposed amendments.

ICE Clear Europe is proposing to amend its description of the purposes and objectives of the Policy to include a broader statement that the Policy defines how and how often the F&O Guaranty Fund is sized, how Clearing Member contributions are apportioned and the sizing frequency, as well as that the Policy also defines stress margin and its uses, eligible assets covering F&O Guaranty Fund requirement liabilities, the default sequence and powers of assessment. Certain descriptions of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4)(ii).

use of F&O Guaranty Fund that summarize provisions of the Rules have been removed as unnecessary, and a cross reference to the Rules has been added.

The provisions of the Policy relating to the sizing of the F&O Guaranty Fund would be amended to remove details found in other Clearing House policies and documentation, including the methodology used to calculate and allocate the additional guaranty fund apportionment (''AGA'') between the energy and financials & softs segments of the F&O Guaranty Fund. Detail regarding the review of the validity of the stress testing scenario(s) is being removed, as it is covered by other existing stress-testing policies. These changes do not represent a modification to ICE Clear Europe's current practices.

The amendments to the Policy also reflect that the frequency of certain reviews will be changed from a quarterly basis to each time the F&O Risk Committee meets (which is typically every two months). Corresponding amendments to the Rules specify that the Guaranty Fund Period will be set pursuant to the Finance Procedures, instead of being a fixed three month period. The amendments to the Finance Procedures state that the start and end dates of Guaranty Fund Periods will be communicated to F&O Clearing Members.

The amendments change the deadline for Clearing Members to deposit additional funds to comply with an increased F&O Guaranty Fund requirement. Specifically, as amended in section 6.1(i)(iii) of the Finance Procedures and as set out in the amended Policy, the deadline has been reduced from ten business days to five business days.

The proposed amendments define the minimum overall F&O Guaranty Fund size as 2% of the total F&O original margin requirement (averaged over the review period), as compared to the current minimum which is based on the fixed ICE Clear Europe initial contribution to the F&O Guaranty Fund.

The discussion of extraordinary reviews of the F&O Guaranty Fund is being amended to remove certain details relating to actions that will be taken by the clearing risk department when the stress testing results are observed to exceed the level of the relevant F&O Guaranty Fund segment, as this is documented in other Clearing House policies and documentation. The description instead notes that the amber and red limits defined as part of the Board Risk Appetite will potentially trigger an extraordinary review of the F&O Guaranty Fund which would be communicated via the standard process for review.

The requirements of the Policy regarding information presented to the F&O Risk Committee are being simplified such that the following information will be presented to the F&O Risk Committee at each review of the level of the Fund: Historical daily stress-testing results from the Members showing at least the first and second largest uncollateralized losses; details of the stress scenario driving the largest exposures; and any other information supporting a resizing decision. Certain more prescriptive information requirements have been removed, as ICE Clear Europe believes they are unnecessary.

The provisions of the Policy relating to recommendations as to changes in the overall level of the F&O Guaranty Fund have been condensed and simplified. The revised Policy identifies several factors on which the Clearing House will base its recommendations on the level of the Fund (including the level of uncollateralized losses as compared to the F&O Guaranty Fund or relevant segments and the level of stress margin called for relevant F&O product categories), rather than describing specific circumstances under which a 'no change' recommendation or a recommendation to increase a Fund segment will be made. The Clearing House believes the more flexible approach better takes into account the range of factors that may warrant a change in the F&O Guaranty Fund level. In any case, as under the current Policy, a full explanation of the conclusions and related data is to be presented to the F&O Risk Committee and Board Risk Committee.

As noted above, the amendments alter the calculation of F&O Clearing Member contributions to take into account potential uncollateralized, or stress, loss as well as the maximum intraday original margin requirement. The governing principle with respect to this determination is that each Clearing Member's contribution to each of the Fund segments should reflect their relative share of clearing activity as well as their relative share of uncollateralized loss. Under the revised approach, subject to minimum contribution requirements set out in the Policy, an F&O Clearing Member's relative share of the F&O Guaranty Fund requirement will be based 40% on its maximum intraday original margin requirement and 60% on its uncollateralized loss. This will be recalculated at each review (instead of on a quarterly cycle). This two factor contribution model is intended to offer a balanced contribution taking into account clearing activity and stress results. Various conforming and clarifying changes have been made throughout the Policy. As discussed above, F&O Clearing Members will have five (instead of ten) UK business days from notification to cover any increase in their F&O Guaranty Fund requirement. The description of the data validation process is being deleted (as the process is documented in other Clearing House procedures). The proposed amendments to the Policy also specify the minimum fund contribution for an F&O Clearing Member to be the larger of USD 1 million or the calculated member's contribution under the revised methodology. The corresponding proposed amendments to section 14.1(b) of the Finance Procedures accommodate this change, by specifying that the Clearing House will establish from time to time a minimum fund contribution for an F&O Clearing Member based on a methodology adopted by the Clearing House, of not less than USD 1 million.

The proposed amendments also remove a description of the manner in which a drawdown of the F&O Guaranty Fund is made across the different fund segments, as that is covered in greater detail in the existing Rules.

Finally, references to quarterly reviews of stress test results are being replaced with references to general review cycles throughout the Policy and an appendix with an example of a stress margin request is being deleted as unnecessary.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments are consistent with the requirements of Section 17A of the Act[5] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[6] Section 17A(b)(3)(F) of the Act[7] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, to assure the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments are generally intended to enhance the F&O Guaranty Fund allocation methodology to take into account both original margin

[5] 15 U.S.C. 78q–1.

[6] 17 CFR 240.17Ad–22.

[7] 15 U.S.C. 78q–1(b)(3)(F).

requirements and potential stress losses that may exceed normal margin levels. The amendments also clarify the minimum size of the F&O Guaranty Fund, in a manner tied to the original margin requirements and thus the overall level of F&O clearing activity. The amendments further shorten the deadline under which F&O Clearing Members must provide additional F&O Guaranty Fund contributions when required. The Clearing House believes that these changes will more appropriately allocate F&O Guaranty Fund Contributions among F&O Clearing Members, further the risk management of the Clearing House and more generally promote the prompt and accurate clearance and settlement of transactions. The amendments also streamline the Policy to reduce redundancies with other Clearing House policies and the Rules and increase the review cycle from quarterly to every two months, consistent with the cycle of F&O Risk Committee meetings. In ICE Clear Europe's view, enhancing the clarity of the Policy and increasing the oversight of the Policy through more frequent reviews is also expected to better risk management and promote the prompt and accurate clearance and settlement of transactions. As a result, in ICE Clear Europe's view, the amendments are consistent with the requirements of Section 17A(b)(3)(F) of the Act.

The amendments are also consistent with relevant requirements of Rule 17Ad–22.[8] Rules 17Ad–22(e)(4)[9] and 17Ad–22(b)(3)[10] require clearing agencies to maintain certain financial resources at specified levels sufficient to support their clearing operations, including through the use of guaranty funds. The amendments will facilitate compliance with these requirements, through an enhanced approach to allocating F&O Guaranty Fund requirements that takes into account both clearing activity (as indicated through original margin levels) and potential stress losses in extreme but plausible market conditions. The revised Policy also contemplates review of by the F&O Risk Committee of daily stress testing results showing at least the first and second largest uncollateralized losses and details of the stress scenario driving the largest exposures. Taken together, the changes will help the Clearing House ensure that, consistent with regulatory requirements, the F&O Guaranty Fund, together with other financial resources, is sufficient to enable the Clearing House to cover a wide range of foreseeable stress scenarios.

Rule 17Ad–22(e)(2)[11] requires clearing agencies to establish reasonably designed policies and procedures to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. To facilitate compliance with this requirement, the proposed amendments to the Policy more clearly set out the information that will be provided to the F&O Risk Committee at each review of the level of the F&O Guaranty Fund and the factors that will be considered in making recommendations on the appropriate level of the F&O Guaranty Fund.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The changes are being proposed in order to clarify and enhance the Policy and reduce overlap with other Clearing House Rules and policies. The amendments will apply to all F&O Clearing Members. ICE Clear Europe does not believe the amendments will generally affect the overall cost of clearing for F&O Clearing Members or other market participants or otherwise affect access to clearing generally. The amendments may alter the allocation of F&O Guaranty Fund requirements across F&O Clearing Members, which could increase requirements for some members, but such changes are designed to more appropriately take into account potential stress losses as well as clearing activity of such members. In ICE Clear Europe's view, such amendments will enhance the risk management of the Clearing House and tailor the F&O Guaranty Fund requirements to the risks presented by F&O Clearing Members. As a result, any additional burdens placed on F&O Clearing Members will be appropriate in furtherance of that goal. The amendments will provide a transparent and objective methodology for the calculation of F&O Guaranty Fund requirements, and are not intended to disadvantage any particular Clearing Member. As a result, ICE Clear Europe believes that any impact on competition is appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received

[8] 17 CFR 240.17Ad–22.

[9] 17 CFR 240.17Ad–22(e)(4)(i)—(v). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by:

(i) Maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence;

(ii) To the extent not already maintained pursuant to paragraph (e)(4)(i) of this section, for a covered clearing agency providing central counterparty services that is either systemically important in multiple jurisdictions or a clearing agency involved in activities with a more complex risk profile, maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions;

(iii) To the extent not already maintained pursuant to paragraph (e)(4)(i) of this section, for a covered clearing agency not subject to paragraph (e)(4)(ii) of this section, maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the participant family that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions;

(iv) Including prefunded financial resources, exclusive of assessments for additional guaranty fund contributions or other resources that are not prefunded, when calculating the financial resources available to meet the standards under paragraphs (e)(4)(i) through (iii) of this section, as applicable;

(v) Maintaining the financial resources required under paragraphs (e)(4)(ii) and (iii) of this section, as applicable, in combined or separately maintained clearing or guaranty funds;''

[10] 17 CFR 240.17Ad–22(b)(3). The rule states that ''[a] registered clearing agency that performs central counterparty services shall establish, implement, maintain and enforce written policies and procedures reasonably designed to: Maintain sufficient financial resources to withstand, at a minimum, a default by the participant family to which it has the largest exposure in extreme but plausible market conditions.

[11] 17 CFR 240.17 Ad–22(e)(2). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(2) Provide for governance arrangements that:

(i) Are clear and transparent

(ii) Clearly prioritize the safety and efficiency of the covered clearing agency;

(iii) Support the public interest requirements in Section 17A of the Act (15 U.S.C. 78q–1) applicable to clearing agencies, and the objectives of owners and participants;

(iv) Establish that the board of directors and senior management have appropriate experience and skills to discharge their duties and responsibilities;

(v) Specify clear and direct lines of responsibility; and

(vi) Consider the interests of participants' customers, securities issuers and holders, and other relevant stakeholders of the covered clearing agency.''

with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and paragraph (f) of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2018–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2018–011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2018–011 and should be submitted on or before December 6, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–24870 Filed 11–14–18; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15788 and #15789; Georgia Disaster Number GA–00109]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Georgia

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Georgia (FEMA–4400–DR), dated 11/01/2018.

Incident: Hurricane Michael.

Incident Period: 10/09/2018 through 10/23/2018.

DATES: Issued on 11/07/2018.

Physical Loan Application Deadline Date: 12/31/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 08/02/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Georgia, dated 11/01/2018, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Montgomery, Telfair

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator For Disaster Assistance.

[FR Doc. 2018–24891 Filed 11–14–18; 8:45 am]

BILLING CODE 8025–01–P

[12] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Meeting of the Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal Advisory Committee Meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Advisory Committee on Veterans Business Affairs (ACVBA). The meeting is open to the public.

DATES: Thursday, December 6, 2018, from 9:00 a.m. to 4:00 p.m. EST.

ADDRESSES: The meeting will be held at SBA, 409 3rd Street SW, Eisenhower Conference Room B, Washington, DC 20416, and via webinar.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is requested. To RSVP and confirm attendance, the general public should email *veteransbusiness@sba.gov* with subject line—''RSVP for 12/6/18 ACVBA Public Meeting.''

Anyone wishing to make comments to the ACVBA must contact SBA's Office of Veterans Business Development (OVBD) no later than December 1, 2018 via email *veteransbusiness@sba.gov,* or via phone at (202) 205–6773. Comments for the record will be limited to five minutes to accommodate as many participants as possible.

Additionally, special accommodation requests should also be directed to OVBD at (202) 205–6773 or *veteransbusiness@sba.gov.* For more information on veteran owned small business programs, please visit *www.sba.gov/ovbd.*

Security instructions: Those attending the meeting are encouraged to arrive early to allow for security clearance into the building. Attendees should use the main entrance to access SBA headquarters, at 3rd and D Streets SW. For security purposes attendees must:

1. Present a valid photo ID to receive a visitor badge.

2. Know the name of the event being attended: The meeting event is the Advisory Committee on Veterans Business Affairs (ACVBA).

3. Visitor badges are issued by the security officer at the main entrance. Visitors are required to display their visitor badge at all times while inside the building.

4. Laptops and other electronic devices may be inspected and logged for identification purposes.

5. Due to limited parking options, Metro's Federal Center SW station is the easiest way to access SBA headquarters.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The ACVBA is established pursuant to 15 U.S.C. 657(b) note, and serves as an independent source of advice and policy. The purpose of this meeting is to discuss efforts that support veteran-owned small businesses, updates on past and current events, and the ACVBA's objectives for fiscal year 2019.

Dated: November 8, 2018.

Nicole Nelson,

Acting Committee Management Officer.

[FR Doc. 2018–24896 Filed 11–14–18; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Meeting of the Interagency Task Force on Veterans Small Business Development

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time and agenda for the next meeting of the Interagency Task Force on Veterans Small Business Development (Task Force). The meeting is open to the public.

DATES: Wednesday, December 5, 2018, from 1:00 p.m. to 4:00 p.m. EST.

ADDRESSES: The meeting will be held at SBA, 409 3rd Street SW, Eisenhower Conference Room B, Washington, DC 20416, and via webinar.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is requested. To RSVP and confirm attendance, the general public should email *veteransbusiness@sba.gov* with subject line—''RSVP for 12/5/18 IATF Public Meeting.''

Anyone wishing to make comments to the Task Force must contact SBA's Office of Veterans Business Development (OVBD) no later than December 1, 2018 via email *veteransbusiness@sba.gov,* or via phone at (202) 205–6773. Comments for the record will be limited to five minutes to accommodate as many participants as possible.

Additionally, special accommodation requests should also be directed to OVBD at (202) 205–6773 or *veteransbusiness@sba.gov.* For more information on veteran owned small business programs, please visit *www.sba.gov/ovbd.*

Security instructions: Those attending the meeting are encouraged to arrive early to allow for security clearance into the building. Attendees should use the main entrance to access SBA headquarters, at 3rd and D Streets SW. For security purposes attendees must:

1. Present a valid photo ID to receive a visitor badge.

2. Know the name of the event being attended: The meeting event is the Advisory Committee on Veterans Business Affairs (ACVBA).

3. Visitor badges are issued by the security officer at the main entrance. Visitors are required to display their visitor badge at all times while inside the building.

4. Laptops and other electronic devices may be inspected and logged for identification purposes.

5. Due to limited parking options, Metro's Federal Center SW station is the easiest way to access SBA headquarters.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development (Task Force). The Task Force is established pursuant to Executive Order 13540 to coordinate the efforts of Federal agencies to improve capital, business development opportunities, and pre-established federal contracting goals for small business concerns owned and controlled by veterans and service-disabled veterans. The purpose of this meeting is to discuss efforts that support service-disabled veteran-owned small businesses, updates on past and current events, and the Task Force's objectives for fiscal year 2019.

Dated: November 8, 2018.

Nicole Nelson,

Committee Management Officer (Acting).

[FR Doc. 2018–24893 Filed 11–14–18; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15698 and #15699; South Carolina Disaster Number SC–00054]

Presidential Declaration Amendment of a Major Disaster for the State of South Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 5.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of South Carolina (FEMA–4394–DR), dated 09/21/2018.

Incident: Hurricane Florence.

Incident Period: 09/08/2018 through 10/08/2018.

DATES: Issued on 11/05/2018.

Physical Loan Application Deadline Date: 12/05/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 06/21/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of South Carolina, dated 09/21/2018, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 12/05/2018.

All other information in the original declaration remains unchanged.

Catalog of Federal Domestic Assistance Number 59008.

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–24892 Filed 11–14–18; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0064]

Privacy Act of 1974; System of Records

AGENCY: Office of the General Counsel, Social Security Administration (SSA).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act, we are issuing public notice of our intent to establish a new system of records entitled, *Requests for Waiver of Employee Salary Overpayments* (60–0271). This notice publishes details of the system as set forth below under the caption, **SUPPLEMENTARY INFORMATION.**

DATES: The system of records notice (SORN) is applicable upon its publication in today's **Federal Register**, with the exception of the routine uses which are effective December 17, 2018. We invite public comment on the routine uses or other aspects of this SORN. In accordance with 5 U.S.C. 552a(e)(4) and (e)(11), the public is given a 30-day period in which to submit comments. Therefore, please submit any comments by December 17, 2018.

ADDRESSES: The public, Office of Management and Budget (OMB), and Congress may comment on this publication by writing to the Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, or through the Federal e-Rulemaking Portal at *http://www.regulations.gov,* please reference docket number SSA–2018–0064. All comments we receive will be available for public inspection at the above address and we will post them to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Corey Smith, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 966–1768, email: *Corey.D.Smith@ssa.gov.*

SUPPLEMENTARY INFORMATION: We are establishing a new system of records to record agency decisions for requests for waivers of employee overpayments and requests for employee hearings contesting the validity of the debt. Title 31 Section 3711 of the United States Code provides that the head of an executive agency shall try to collect a claim of the United States Government for money or property arising out of the activities of, or referred to, the agency after providing proper notice and explanation of the right to dispute the agency's information regarding the claim or for administrative review of the claim. Title 5 Section 5584 of the United States Code provides that a claim of the United States against a person arising out of an erroneous payment of pay or allowances made on or after July 1, 1960, or arising out of an erroneous payment of travel, transportation or relocation expenses and allowances, to an employee of the agency, the collection of which would be against equity and good conscience and not in the best interests of the United States, may be waived in whole or in part by the authorized official, the head of the agency and the Director of the Administrative Office of the United States Courts. The authority to waive employee salary overpayments has been delegated to the heads of Federal agencies, thus we are establishing this system of records.

In accordance with 5 U.S.C. 552a(r), we have provided a report to OMB and Congress on this new system of records.

Dated: November 5, 2018.

Mary Zimmerman,

Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

SYSTEM NAME AND NUMBER:

Requests for Waiver of Employee Salary Overpayments, 60–0271.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Social Security Administration, Office of the General Counsel, Office of General Law, West High Rise Building, 6401 Security Boulevard, Baltimore, MD 21235.

SYSTEM MANAGER(S):

Associate General Counsel, Social Security Administration, Office of the General Counsel, Office of General Law, West High Rise Building, 6401 Security Boulevard, Baltimore, MD 21235, *ogc.ogl.correspondence@ssa.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 5 Sections 5514 and 5584 and Title 31 Section 3711 of the United States Code and 20 CFR part 422.

PURPOSE(S) OF THE SYSTEM:

We will use the information we collect to make administrative decisions on employee salary overpayment waiver, requests and appeals.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are current or former SSA employees who file administrative requests and appeals with SSA, for waiver of their salary and travel reimbursement overpayments.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains information that we collect for the administrative request and appeals process. This may include contact information; information pertaining to the requestor/employee debtor and appeals, initial request or appeal, personnel records, reports of investigation, recommendations and waiver decision letters.

RECORD SOURCE CATEGORIES:

We obtain information in this system from employees and former employees, personnel, program and component offices, and other Federal agencies as necessary, including our payroll provider.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

We will disclose records pursuant to the following routine uses, however, we will not disclose any information defined as ''return or return information'' under 26 U.S.C. 6103 of the Internal Revenue Service Code, unless authorized by statute, the Internal Revenue Service (IRS), or IRS regulations.

1. To a congressional office in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or a third party acting on the subject's behalf.

2. To the Office of the President in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or a third party acting on the subject's behalf.

3. To Federal, State and local government agencies, private individuals, private attorneys, or other representatives or individuals working on behalf of the employee or former employee in seeking waiver of the overpayment, and other persons or entities with relevant information for the purpose of investigating, settling, or adjudicating claims.

4. To student volunteers, individuals working under a personal services contract, and other workers who technically do not have the status of Federal employees, when they are performing work for SSA, as authorized by law, and they need access to personally identifiable information (PII) in SSA records in order to perform their assigned agency duties.

5. To the National Archives and Records Administration (NARA) under 44 U.S.C. 2904 and 2906.

6. To appropriate agencies, entities, and persons when:

(a) SSA suspects or has confirmed that there has been a breach of the system of records;

(b) SSA has determined that as a result of the suspected or confirmed breach, there is a risk of harm to individuals, SSA (including its information systems, programs, and operations), the Federal Government, or national security; and

(c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with SSA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. To the Department of Justice (DOJ), a court or other tribunal, or another party before such court or tribunal, when:

(a) SSA, or any component thereof; or

(b) any SSA employee in his/her official capacity; or

(c) any SSA employee in his/her individual capacity where DOJ (or SSA when it is authorized to do so) has agreed to represent the employee; or

(d) the United States, or any agency thereof, when SSA determines the litigation is likely to affect the operations of SSA or any of its components,

is a party to the litigation or has an interest in such litigation, and SSA determines that the use of such records by DOJ, a court or other tribunal, or another party before the court or tribunal is relevant and necessary to the litigation, provided, however, that in each case, the agency determines that disclosure of the records to DOJ, court or other tribunal, or another party is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

8. To contractors and other Federal agencies, as necessary, for the purpose of assisting SSA in the efficient administration of its programs. We will disclose information under this routine use only in situations in which SSA may enter into a contractual or similar agreement with a third party to assist in accomplishing an agency function relating to this system of records.

9. To Federal, State, and local law enforcement agencies and private security contractors, as appropriate, information necessary:

(a) to enable them to protect the safety of SSA employees and customers, the security of the SSA workplace, and the operation of SSA facilities, or

(b) to assist in investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupt the operation of SSA facilities.

10. To third parties when an individual involved with the claim needs assistance to communicate because a hearing impairment or a language barrier exists (*e.g.,* interpreters, telecommunications relays system operators, etc.).

11. To the Equal Employment Opportunity Commission when requested in connection with investigation into alleged or possible discriminatory practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with the Uniform Guidelines on Employee Procedures, or other functions vested in the Commission.

12. To the Office of Personnel Management, Merit Systems Protection Board, or the Office of Special Counsel in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigations of alleged or possible prohibited personnel practices, and other such functions promulgated in 5 U.S.C. Chapter 12, or as may be required by law.

13. To the Federal Labor Relations Authority, the Office of the Special Counsel, the Federal Mediation and Conciliation Service, the Federal Service Impasses Panel, or an arbitrator requesting information in connection with the investigations of allegations of unfair practices, matters before an arbitrator or the Federal Service Impasses Panel.

14. To another Federal agency or Federal entity, when SSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(a) responding to a suspected or confirmed breach; or

(b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

We maintain records in this system in paper and electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

We retrieve records by the name of the employee, former employee, or individual requesting the waiver of overpayment.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

We retain the records for a period of six years in accordance with the approved National Archives and Records Schedule N1–47–10–4. The Office of the General Counsel reserves the right to retain for an indefinite period certain records that, in the judgment of that office are of precedential value.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

We retain electronic and paper files containing personal identifiers in secure storage areas accessible only by our authorized employees and contractors who have a need for the information when performing their official duties. Security measures include, but are not limited to, the use of codes and profiles, personal identification number and password, and personal identification verification cards. We restrict access to specific correspondence within the system based on assigned roles and authorized users. We use audit mechanisms to record sensitive transactions as an additional measure to protect information from unauthorized disclosure or modification. We keep paper records in locked cabinets within secure areas, with access limited to only those employees who have an official need for access in order to perform their duties.

We annually provide our employees and contractors with appropriate security awareness training that includes reminders about the need to protect PII and the criminal penalties that apply to unauthorized access to, or disclosure of, PII (5 U.S.C. 552a(i)(1)). Furthermore, employees and contractors with access to databases maintaining PII must sign a sanctions document annually, acknowledging their accountability for inappropriately accessing or disclosing such information.

RECORD ACCESS PROCEDURES:

Individuals may submit requests for information about whether this system contains a record about them by submitting a written request to the system manager at the above address, which includes their name, SSN, or other information that may be in this system of records that will identify them. Individuals requesting notification of, or access to, a record by mail must include: (1) A notarized statement to us to verify their identity; or (2) must certify in the request that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

Individuals requesting notification of or access to, records in person must

provide their name, SSN, or other information that may be in this system of records that will identify them, as well as provide an identity document, preferably with a photograph, such as a driver's license. Individuals lacking identification documents sufficient to establish their identity must certify in writing that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

CONTESTING RECORD PROCEDURES:

Same as record access procedures. Individuals should also reasonably identify the record, specify the information they are contesting, and state the corrective action sought and the reasons for the correction with supporting justification showing how the record is incomplete, untimely, inaccurate, or irrelevant. These procedures are in accordance with our regulations at 20 CFR 401.65(a).

NOTIFICATION PROCEDURES:

Same as record access procedures. These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2018–24908 Filed 11–14–18; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0004]

Privacy Act of 1974; System of Records

AGENCY: Deputy Commissioner for Human Resources, Social Security Administration (SSA).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act, we are issuing public notice of our intent to establish a new system of records entitled, Security and Suitability Files (60–0377). This notice publishes details of the new system as set forth under the caption, **SUPPLEMENTARY INFORMATION.**

DATES: The system of records notice (SORN) is applicable upon its publication in today's **Federal Register**, with the exception of the routine uses, which are effective December 17, 2018. We invite public comment on the routine uses or other aspects of this SORN. In accordance with 5 U.S.C. 552a(e)(4) and (e)(11), the public is given a 30-day period in which to submit comments. Therefore, please submit any comments by December 17, 2018.

ADDRESSES: The public, Office of Management and Budget (OMB), and Congress may comment on this publication by writing to the Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, or through the Federal e-Rulemaking Portal at *http://www.regulations.gov,* please reference docket number SSA–2018–0004. All comments we receive will be available for public inspection at the above address and we will post them to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jasson Seiden, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 597–4307, email: *Jasson.Seiden@ssa.gov.*

SUPPLEMENTARY INFORMATION: Persons appointed to, and under consideration for, Federal service or contract employment are required, with limited exceptions, to submit to a suitability background investigation. In addition, other individuals granted access to agency facilities and records may be required to complete such an investigation. The Deputy Commissioner for Human Resources, Office of Personnel, Center for Suitability and Personnel Security (CSPS) oversees and is responsible for adjudicating these investigations. Suitability and security related information that we collect during the investigations process and send to the Office of Personnel Management (OPM) is covered by OPM/Central-9, Personnel Investigations Records. The new Security and Suitability Files system of records covers suitability and security related information that we generate during the investigation process but that we do not send to OPM. We will use the information we collect to conduct background investigations for the purpose of establishing that individuals employed by us, working under contract for us, or otherwise granted access to our facilities and records are suitable for such employment or access.

In accordance with 5 U.S.C. 552a(r), we have provided a report to OMB and Congress on this new system of records.

Dated: June 5, 2018.

Mary Ann Zimmerman,

Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

Editorial note: This document was received for publication by the Office of the Federal Register on November 8, 2018.

System Name and Number
Security and Suitability Files, 60–0377

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Social Security Administration, Deputy Commissioner for Human Resources, Office of Personnel, Center for Suitability and Personnel Security (CSPS), 6401 Security Boulevard, Baltimore, MD 21235; or the initiating regional office (See Appendix C for address information).

Office of Personnel Management, National Background Investigations Bureau (NBIB), 1137 Branchton Road, PO Box 618, Boyers, PA 16018.

Defense Information Systems Agency (DISA), DISA Defense Enterprise Computing Center (DECC), 3990 E Broad Street, Columbus, OH 43213–1152.

SYSTEM MANAGER(S):

Social Security Administration, Deputy Commissioner for Human Resources, Office of Personnel, Center for Suitability and Personnel Security (CSPS), 6401 Security Boulevard, Baltimore, MD 21235; or the initiating regional office (See Appendix C for address information).

csps.controls.response@ssa.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 205(a) of the Social Security Act, as amended, HSPD–12 (Policy for a Common Identification Standard for Federal Employees and Contractors), Executive Orders 13764 (Amending the Civil Service Rules, Executive Order 13488, and Executive Order 13467 To Modernize the Executive Branch-Wide Governance Structure and Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters) and 12968 (Access to Classified Information), Sections 3301 and 3302 of Title 5, U.S.C., and Parts 5, 731, 732, and 736 of Title 5 of the Code of Federal Regulations; and Fair Credit Reporting Act.

PURPOSE(S) OF THE SYSTEM:

We will use the information in the Security and Suitability Files to determine the suitability of individuals for appointment or retention as an SSA employee, for access to SSA facilities and information systems, to hold sensitive positions, and to perform work or services for or on behalf of SSA as a contractor or volunteer. This will ensure that all of our prospective, current, and former employees, students, contractors, grantees, appointees, cooperative agreement awardees, volunteers, and others granted access to our facilities and records are investigated appropriately for security and suitability, and that the results of the investigations when necessary, are adjudicated based on federal law and regulations and are recorded in the official records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals seeking, or who have sought, to fill an available vacancy with SSA, or to otherwise be granted access to SSA facilities and records. This category of individuals include, but are not limited to, prospective, current, and former employees, students, contractors, grantees, appointees, cooperative agreement awardees, volunteers, and others who perform services for SSA.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains information collected as part of our security and suitability investigative process. This information may include the individual's name, address, date of birth (DOB), Social Security number (SSN), phone number, driver's license information, fingerprints, residential and employment addresses, employment history (*e.g.,* names of supervisors and colleagues), financial and educational background, professional experience information, and information from personal and professional references. We may also collect information about personal and professional conduct that could include disciplinary, criminal, and credit histories. This system may also include determinations of sensitivity and risk level for different positions and information to ensure compliance with security and suitability requirements, and information necessary to monitor and track security and suitability investigations for management workload purposes.

RECORD SOURCE CATEGORIES:

We obtain information in this system primarily from the individuals to whom the record pertains. Information may also be obtained from, but not limited to references, credit reporting agencies, other federal agencies, and educational institutions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

We will disclose records pursuant to the following routine uses; however, we will not disclose any information defined as ''return or return information'' under 26 U.S.C. 6103 of the Internal Revenue Service Code, unless authorized by statute, the Internal Revenue Service (IRS), or IRS regulations.

1. To the Office of the President in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or third party acting on the subject's behalf.

2. To a congressional office in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or a third party acting on the subject's behalf.

3. To the Department of Justice (DOJ), a court or other tribunal, or another party before such court or tribunal, when:

(a) SSA, or any component thereof; or

(b) any SSA employee in his/her official capacity; or:

(c) any SSA employee in his/her individual capacity where DOJ (or SSA where it is authorized to do so) has agreed to represent the employee; or

(d) the United States or any agency thereof where SSA determines the litigation is likely to affect SSA or any of its components,

is a party to the litigation or has an interest in such litigation, and SSA determines that the use of such records by DOJ, a court or other tribunal, or another party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case, the agency determines that disclosure of the records to DOJ, a court or other tribunal, or another party is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

4. To contractors and other Federal agencies, as necessary, for assisting SSA in the efficient administration of its programs. We disclose information under this routine use only in situations in which SSA may enter into a contractual or similar agreement with a third party to assist the accomplishing an agency function relating to this system of records.

5. To student volunteers, individuals working under a personal services contract, and other workers who technically do not have the status of Federal employees, when they are performing work for SSA, as authorized by law, and they need access to personally identifiable information (PII) in SSA records in order to perform their assigned agency functions.

6. To the Equal Employment Opportunity Commission (EEOC or Commission) when requested in connection with investigations into alleged or possible discriminatory practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures, or other functions vested in the Commission.

7. To the Federal Labor Relations Authority, its General Counsel, the Federal Mediation and Conciliation Service, the Federal Service Impasses Panel, or an arbitrator when information is requested in connection with investigations of allegations of unfair practices, matters before an arbitrator or the Federal Service Impasses Panel.

8. To the Office of Personnel Management (OPM), the Merit Systems Protection Board, or the Office of Special Counsel in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigations of alleged or possible prohibited practices, and other such functions promulgated in 5 U.S.C. Chapter 12, or as may be required by law.

9. To Federal, State, and local law enforcement agencies and private security contractors, as appropriate, information necessary:

(a) To enable them to protect the safety of SSA employees and customers, the security of the SSA workplace, and the operation of SSA facilities, or

(b) to assist in investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupt the operation of SSA facilities.

10. To the National Archives and Records Administration (NARA) under 44 U.S.C. 2904 and 2906.

11. To a Federal agency in response to its request, or at SSA's initiative, in connection with decisions to hire or retain an employee, issue a security clearance, conduct a security or suitability investigation, classify a job, award a contract, or regarding the requesting agency's decision to issue a license, grant, or other benefit, to the extent that the information is relevant and necessary to the requesting agency's decision.

12. To officials of labor organizations recognized under 5 U.S.C. Chapter 71 when relevant and necessary to their

duties of exclusive representation concerning personnel policies, practices, and matters affecting conditions of employment.

13. To appropriate agencies, entities, and persons when:

(a) SSA suspects or has confirmed that there has been a breach of the system of records;

(b) SSA has determined that as the result of the suspected or confirmed breach there is a risk of harm to individuals, SSA (including its information systems, programs, and operations), the Federal Government, or national security; and

(c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with SSA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

14. To any source from which information is requested in the course of an investigation, to the extent necessary to identify the individual, inform the source of the nature and purpose of the investigation, and to identify the type of information requested.

15. To another Federal agency or Federal entity, when SSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(a) Responding to a suspected or confirmed breach; or

(b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

16. To the Department of Defense or other Federal agencies in connection with providing approved shared services to subscribing agencies for hiring or retaining an employee; classifying a position; conducting a security, suitability, fitness, or credentialing background investigation (including continuous evaluation/continuous vetting); issuing a security clearance or sensitive position eligibility; making a suitability, fitness, or credentialing decision; or recording the results of any agency decision with respect to these functions.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

We will maintain records in this system in paper and electronic form.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

We will retrieve records in this system by name, SSN, and DOB.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records are temporary. We retain and destroy this information in accordance with the NARA approved General Records Schedules (GRS) 2.0, Human Resources, and GRS 5.6, Security Records. We retain investigative records on employees or applicants for employment, whether or not a security clearance is granted, and other persons, such as those performing work under contract or as volunteers in accordance with the approved records schedules. We retain investigative reports in accordance with OPM Central-9 (81 FR 70191) or successor Records Disposition Authority. Our shared service provider for tracking post-investigation data, the Department of Defense (DoD), retains post-investigative files and the computerized data bases in accordance with the Defense Manpower Data Center (DMDC) retention policies as published in DMDC 24 DoD (81 FR 39032) or successor Records Disposition Authority.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

We retain electronic and paper files with personal identifiers in secure storage areas accessible only by our authorized employees and contractors who have a need for the information when performing their official duties. Security measures include, but are not limited to, the use of codes and profiles, personal identification number and password, and personal identification verification cards. We keep paper records in locked cabinets within secure areas, with access limited to only those employees who have an official need for access in order to perform their duties.

We annually provide our employees and contractors with appropriate security awareness training that includes reminders about the need to protect personally identifiable information (PII) and the criminal penalties that apply to unauthorized access to, or disclosure of, PII (5 U.S.C. 552a(i)(1)). Furthermore, employees and contractors with access to databases maintaining PII must sign a sanctions document annually, acknowledging their accountability for inappropriately accessing or disclosing such information.

The system is protected against compromise of PII and cyberattack by the full suite of defenses and sensors of the DoD cybersecurity perimeter. Data is encrypted where it is stored, and network traffic is encrypted based on the type of user traffic and risk to PII data. User access to data is protected using Identity and Access Management with multifactor authentication that will only allow an authenticated user to access and manipulate the specific records based on user role and permissions. The system audits access to information. Physical entry is restricted by the use of locks, guards, and administrative procedures. All individuals granted access to the system must complete Information Assurance and Privacy Act training before initially accessing the system and annually thereafter, and these users must have also been through the information technology and/or security clearance eligibility process.

RECORD ACCESS PROCEDURES:

This system of records has been exempted from the Privacy Act's access, contesting, and notification provisions as stated below. However, individuals may submit requests for information about whether this system contains a record about them by submitting a written request to the system manager at the above address, which includes their name, SSN, or other information that may be in this system of records that will identify them. Individuals requesting notification of, or access to, a record by mail must include (1) a notarized statement to us to verify their identity or (2) must certify in the request that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

Individuals requesting notification of, or access to, records in person must provide their name, SSN, or other information that may be in this system of records that will identify them, as well as provide an identity document, preferably with a photograph, such as a driver's license. Individuals lacking identification documents sufficient to establish their identity must certify in writing that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

CONTESTING RECORD PROCEDURES:

Same as record access procedures. Individuals should also reasonably

identify the record, specify the information they are contesting, and state the corrective action sought and the reasons for the correction with supporting justification showing how the record is incomplete, untimely, inaccurate, or irrelevant. These procedures are in accordance with our regulations at 20 CFR 401.65(a).

NOTIFICATION PROCEDURES:

Same as record access procedures. These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

This system of records has been exempted from certain provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(5). Rules have been promulgated in accordance with the requirements of 5 U.S.C. 553(b), (c), and (e) and have been published in today's **Federal Register**.

HISTORY:

None.

[FR Doc. 2018–24853 Filed 11–14–18; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 10604]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Vija Celmins: To Fix the Image in Memory'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Vija Celmins: To Fix the Image in Memory,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the San Francisco Museum of Modern Art, San Francisco, California, from on or about December 15, 2018, until on or about March 31, 2019; and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–24957 Filed 11–14–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10602]

Updating the State Department's List of Entities and Subentities Associated With Cuba (Cuba Restricted List)

ACTION: Updated publication of list of entities and subentities.

SUMMARY: The Department of State is publishing an update to its List of Restricted Entities and Subentities Associated with Cuba (Cuba Restricted List) with which direct financial transactions are generally prohibited under the Cuban Assets Control Regulations (CACR). This Cuba Restricted List is also considered during review of license applications submitted to the Department of Commerce's Bureau of Industry and Security (BIS) pursuant to the Export Administration Regulations (EAR).

DATES: The updates to the Cuba Restricted List are effective on November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Benjamin Barron, Office of Economic Sanctions Policy and Implementation, tel.: 202–647–7489; Office of the Coordinator for Cuban Affairs, tel.: 202–453–8456, Department of State, Washington, DC 20520.

SUPPLEMENTARY INFORMATION:

Background

On June 16, 2017, the President signed the National Security Presidential Memorandum on Strengthening the Policy of the United States Toward Cuba (NSPM). As directed by the NSPM, on November 9, 2017, the Department of the Treasury's Office of Foreign Assets Control (OFAC) published a final rule in the **Federal Register** amending the CACR, 31 CFR part 515, and the Department of Commerce's Bureau of Industry and Security (BIS) published a final rule in the **Federal Register** amending, among other sections, the section of the Export Administration Regulations (EAR) regarding Cuba, 15 CFR part 746. The regulatory amendment to the CACR added § 515.209, which generally prohibits direct financial transactions with certain entities and subentities identified on the State Department's Cuba Restricted List, which the State Department is updating as published below, and accessible on the State Department's website. The regulatory amendment to the EAR, specifically § 746.2, notes BIS will generally deny applications to export or reexport items for use by entities or subentities identified on the Cuba Restricted List. (*http://www.state.gov/e/eb/tfs/spi/cuba/cubarestrictedlist/index.htm*). This update includes 26 newly identified subentities and five amendments to previously-listed subentities including three name-changes, one new alias, and one typographical correction (the subentity ''Hotel Palacio del Marqués de San Felipe y Santiago de Bejucal (Habaguanex)'' was incorrectly split between two lines). The State Department will continue to update the Cuba Restricted List periodically.

The publication of the updated Cuba Restricted List further implements the directive in paragraph 3(a)(i) of the NSPM for the Secretary of State to identify the entities or subentities, as appropriate, that are under the control of, or act for or on behalf of, the Cuban military, intelligence, or security services or personnel, and publish a list of those identified entities and subentities with which direct financial transactions would disproportionately benefit such services or personnel at the expense of the Cuban people or private enterprise in Cuba.

Electronic Availability

This document and additional information concerning the Cuba Restricted List are available from the Department of State's website (*http://www.state.gov/e/eb/tfs/spi/cuba/*).

List of Restricted Entities and Subentities Associated With Cuba as of November 15, 2018

Below is the U.S. Department of State's list of entities and subentities under the control of, or acting for or on behalf of, the Cuban military, intelligence, or security services or personnel with which direct financial transactions would disproportionately benefit such services or personnel at the expense of the Cuban people or private

enterprise in Cuba. For information regarding the prohibition on direct financial transactions with these entities, please see section 515.209 of the Cuban Assets Control Regulations (31 CFR part 515). All entities and subentities were listed effective November 9, 2017, unless otherwise indicated.

* * * *Entities or subentities owned or controlled by another entity or subentity on this list are not treated as restricted unless also specified by name on the list.* * * *

Ministries

MINFAR—Ministerio de las Fuerzas Armadas Revolucionarias
MININT—Ministerio del Interior

Holding Companies

CIMEX—Corporación CIMEX S.A.
Compañía Turística Habaguanex S.A.
GAESA—Grupo de Administración Empresarial S.A.
Gaviota—Grupo de Turismo Gaviota
UIM—Unión de Industria Militar

Hotels in Havana and Old Havana

Aparthotel Montehabana (Habaguanex)
Gran Hotel Manzana Kempinski (Gaviota)
H10 Habana Panorama (Gaviota)
Hostal Valencia (Habaguanex)
Hotel Ambos Mundos (Habaguanex)
Hotel Armadores de Santander (Habaguanex)
Hotel Beltrán de Santa Cruz (Habaguanex)
Hotel Conde de Villanueva (Habaguanex)
Hotel del Tejadillo (Habaguanex)
Hotel el Bosque (Habaguanex)
Hotel el Comendador (Habaguanex)
Hotel el Mesón de la Flota (Habaguanex)
Hotel Florida (Habaguanex)
Hotel Habana 612 (Habaguanex)
Hotel Kohly (Habaguanex)
Hotel Los Frailes (Habaguanex)
Hotel Marqués de Prado Ameno (Habaguanex)
Hotel Palacio del Marqués de San Felipe y Santiago de Bejucal (Habaguanex)
Hotel Palacio O'Farrill (Habaguanex)
Hotel Park View (Habaguanex)
Hotel Raquel (Habaguanex)
Hotel San Miguel (Habaguanex)
Hotel Telégrafo (Habaguanex)
Hotel Terral (Habaguanex)
Iberostar Grand Packard Hotel (Gaviota) *Effective* November 15, 2018
Memories Miramar Havana (Gaviota)
Memories Miramar Montehabana (Gaviota)
SO/Havana Paseo del Prado (Gaviota) *Effective* November 15, 2018

Hotels in Santiago de Cuba

Villa Gaviota Santiago (Gaviota)

Hotels in Varadero

Blau Marina Varadero Resort (Gaviota) (also Fiesta Americana Punta Varadero *Effective November 15, 2018*)
Grand Memories Varadero (Gaviota)
Hotel Las Nubes (Gaviota) *Effective* November 15, 2018
Hotel Oasis (Gaviota) *Effective* November 15, 2018
Iberostar Bella Vista (Gaviota) *Effective* November 15, 2018
Iberostar Laguna Azul (Gaviota)
Iberostar Playa Alameda (Gaviota)
Meliá Marina Varadero (Gaviota)
Meliá Peninsula Varadero (Gaviota)
Memories Varadero (Gaviota)
Naviti Varadero (Gaviota)
Ocean Varadero El Patriarca (Gaviota)
Ocean Vista Azul (Gaviota)
Paradisus Princesa del Mar (Gaviota)
Paradisus Varadero (Gaviota)
Sol Sirenas Coral (Gaviota)

Hotels in Pinar del Rio

Hotel Villa Cabo de San Antonio (Gaviota)
Hotel Villa Maria La Gorda y Centro Internacional de Buceo (Gaviota)

Hotels in Baracoa

Hostal 1511 (Gaviota)
Hostal La Habanera (Gaviota)
Hostal La Rusa (Gaviota)
Hostal Rio Miel (Gaviota)
Hotel El Castillo (Gaviota)
Hotel Porto Santo (Gaviota)
Villa Maguana (Gaviota)

Hotels in Cayos de Villa Clara

Angsana Cayo Santa María (Gaviota) *Effective* November 15, 2018
Dhawa Cayo Santa María (Gaviota)
Golden Tulip Aguas Claras (Gaviota) *Effective* November 15, 2018
Hotel Cayo Santa María (Gaviota)
Hotel Playa Cayo Santa María (Gaviota)
Iberostar Ensenachos (Gaviota)
Las Salinas Plana & Spa (Gaviota) *Effective* November 15, 2018
La Salina Noreste (Gaviota) *Effective* November 15, 2018
La Salina Suroeste (Gaviota) *Effective* November 15, 2018
Meliá Buenavista (Gaviota)
Meliá Cayo Santa María (Gaviota)
Meliá Las Dunas (Gaviota)
Memories Azul (Gaviota)
Memories Flamenco (Gaviota)
Memories Paraíso (Gaviota)
Ocean Casa del Mar (Gaviota)
Paradisus Los Cayos (Gaviota) *Effective* November 15, 2018
Royalton Cayo Santa María (Gaviota)
Sercotel Experience Cayo Santa María (Gaviota) *Effective* November 15, 2018
Sol Cayo Santa María (Gaviota)
Starfish Cayo Santa María (Gaviota) *Effective* November 15, 2018
Valentín Perla Blanca (Gaviota) *Effective* November 15, 2018
Villa Las Brujas (Gaviota)
Warwick Cayo Santa María (Gaviota) (also Labranda Cayo Santa María Hotel *Effective* November 15, 2018)

Hotels in Holguín

Blau Costa Verde Beach & Resort (Gaviota) (also Fiesta Americana Holguín Costa Verde *Effective* November 15, 2018)
Hotel Playa Costa Verde (Gaviota)
Hotel Playa Pesquero (Gaviota)
Memories Holguín (Gaviota)
Paradisus Río de Oro Resort & Spa (Gaviota)
Playa Costa Verde (Gaviota)
Playa Pesquero Premium Service (Gaviota)
Sol Rio de Luna y Mares (Gaviota)
Villa Cayo Naranjo (Gaviota)
Villa Cayo Saetia (Gaviota)
Villa Pinares de Mayari (Gaviota)

Hotels in Jardines del Rey

Grand Muthu Cayo Guillermo (Gaviota) *Effective* November 15, 2018
Hotel Playa Coco Plus (Gaviota)
Iberostar Playa Pilar (Gaviota)
Meliá Jardines del Rey (Gaviota)
Memories Caribe (Gaviota)
Pestana Cayo Coco (Gaviota)

Hotels in Topes de Collantes

Hostal Los Helechos (Gaviota)
Kurhotel Escambray (Gaviota) *Effective* November 15, 2018
Los Helechos (Gaviota)
Villa Caburni (Gaviota)

Tourist Agencies

Crucero del Sol
Gaviota Tours

Marinas

Marina Gaviota Cabo de San Antonio (Pinar del Rio)
Marina Gaviota Cayo Coco (Jardines del Rey)
Marina Gaviota Las Brujas (Cayos de Villa Clara)
Marina Gaviota Puerto Vita (Holguín)
Marina Gaviota Varadero (Varadero)

Stores in Old Havana

Casa del Abanico (Habaguanex)
Colección Habana (Habaguanex)
Florería Jardín Wagner (Habaguanex)
Joyería Coral Negro (CIMEX)—Additional locations throughout Cuba
La Casa del Regalo (Habaguanex)
San Ignacio 415 (Habaguanex)
Soldadito de Plomo (Habaguanex)
Tienda El Navegante (Habaguanex)
Tienda Muñecos de Leyenda (Habaguanex)
Tienda Museo El Reloj Cuervo y Sobrinos (Habaguanex)

Entities Directly Serving the Defense and Security Sectors

ACERPROT—Agencia de Certificación y Consultoría de Seguridad y Protección (alias Empresa de Certificación de Sistemas de Seguridad y Protección *Effective* November 15, 2018)
AGROMIN—Grupo Empresarial Agropecuario del Ministerio del Interior
APCI—Agencia de Protección Contra Incendios
CAHOMA—Empresa Militar Industrial Comandante Ernesto Che Guevara
CASEG—Empresa Militar Industrial Transporte Occidente
CID NAV—Centro de Investigación y Desarrollo Naval
CIDAI—Centro de Investigación y Desarrollo de Armamento de Infantería
CIDAO—Centro de Investigación y Desarrollo del Armamento de Artillería e Instrumentos Ópticos y Ópticos Electrónicos
CORCEL—Empresa Militar Industrial Emilio Barcenas Pier
CUBAGRO—Empresa Comercializadora y Exportadora de Productos Agropecuarios y Agroindustriales
DATYS—Empresa Para El Desarrollo De Aplicaciones, Tecnologías Y Sistemas
DCM TRANS—Centro de Investigación y Desarrollo del Transporte
DEGOR—Empresa Militar Industrial Desembarco Del Granma
DSE—Departamento de Seguridad del Estado
EMIAT—Empresa Importadora Exportadora de Abastecimientos Técnicos
Empresa Militar Industrial Astilleros Astimar
Empresa Militar Industrial Astilleros Centro
Empresa Militar Industrial Yuri Gagarin
ETASE—Empresa de Transporte y Aseguramiento
Ferretería TRASVAL
GELCOM—Centro de Investigación y Desarrollo Grito de Baire
Impresos de Seguridad
MECATRONICS—Centro de Investigación y Desarrollo de Electrónica y Mecánica
NAZCA—Empresa Militar Industrial Granma
OIBS—Organización Integración para el Bienestar Social
PLAMEC—Empresa Militar Industrial Ignacio Agramonte
PNR—Policía Nacional Revolucionaria
PROVARI—Empresa de Producciones Varias
SEPSA—Servicios Especializados de Protección
SERTOD—Servicios de Telecomunicaciones a los Órganos de la Defensa; *Effective* November 15, 2018
SIMPRO—Centro de Investigación y Desarrollo de Simuladores
TECAL—Empresa de Tecnologías Alternativas
TECNOPRO—Empresa Militar Industrial ''G.B. Francisco Cruz Bourzac''
TECNOTEX—Empresa Cubana Exportadora e Importadora de Servicios, Artículos y Productos Técnicos Especializados
TGF—Tropas de Guardafronteras
UAM—Unión Agropecuaria Militar
ULAEX—Unión Latinoamericana de Explosivos
XETID—Empresa de Tecnologías de la Información Para La Defensa
YABO—Empresa Militar Industrial Coronel Francisco Aguiar Rodríguez

Additional Subentities of CIMEX

ADESA/ASAT—Agencia Servicios Aduanales (Customs Services)
Cachito (Beverage Manufacturer)
Contex (Fashion)
Datacimex
ECUSE—Empresa Cubana de Servicios
Inmobiliaria CIMEX (Real Estate)
Inversiones CIMEX
Jupiña (Beverage Manufacturer)
La Maisón (Fashion)
Najita (Beverage Manufacturer)
Publicitaria Imagen (Advertising)
Residencial Tarara S.A. (Real Estate/ Property Rental) *Effective* November 15, 2018
Ron Caney (Rum Production)
Ron Varadero (Rum Production)
Telecable (Satellite Television)
Tropicola (Beverage Manufacturer)
Zona Especializada de Logística y Comercio (ZELCOM)

Additional Subentities of GAESA

Almacenes Universales (AUSA)
ANTEX—Corporación Antillana Exportadora
Compañía Inmobiliaria Aurea S.A. (GAESA) *Effective* November 15, 2018
Dirección Integrada Proyecto Mariel (DIP)
Empresa Inmobiliaria Almest (Real Estate)
GRAFOS (Advertising)
RAFIN S.A. (Financial Services)
Sociedad Mercantin Inmobiliaria Caribe (Real Estate)
TECNOIMPORT
Terminal de Contenedores de la Habana (TCH)
Terminal de Contenedores de Mariel, S.A.
UCM—Unión de Construcciones Militares
Zona Especial de Desarrollo Mariel (ZEDM)
Zona Especial de Desarrollo y Actividades Logísticas (ZEDAL)

Additional Subentities of Gaviota

AT Comercial
Manzana de Gomez (Shopping Mall)
PhotoService
Plaza La Estrella *Effective* November 15, 2018
Plaza Las Dunas *Effective* November 15, 2018
Plaza Las Morlas *Effective* November 15, 2018
Plaza Las Salinas *Effective* November 15, 2018
Plaza Las Terrazas del Atardecer *Effective* November 15, 2018
Plaza Los Flamencos *Effective* November 15, 2018
Plaza Pesquero *Effective* November 15, 2018
Producciones TRIMAGEN S.A. (Tiendas Trimagen)

Additional Subentities of Habaguanex

Sociedad Mercantil Cubana Inmobiliaria Fenix S.A. (Real Estate)

Peter D. Haas,

Senior Bureau Official, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2018–24904 Filed 11–14–18; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice: 10611]

Notice of Meeting: U.S. Advisory Commission on Public Diplomacy

The U.S. Advisory Commission on Public Diplomacy will hold a public meeting from 10:00 a.m. until 12:00 p.m., Tuesday, December 4, 2018, at the U.S. Capital Visitor Center in Room SVC 201–00 (First St. NE, Washington, DC 20515). The public meeting will focus on the release of the Commission's 2018 Comprehensive Annual Report.

This meeting is open to the public, including the media and members and staff of governmental and non-governmental organizations. Any requests for reasonable accommodation should be sent by email to Michelle Bowen at *BowenMC1@state.gov* by 5:00 p.m. on Tuesday, November 27, 2018. Attendees should plan to arrive for the meeting by 9:45 a.m. to allow for a prompt start.

The U.S. Advisory Commission on Public Diplomacy appraises U.S. government activities intended to understand, inform, and influence foreign publics. The Advisory Commission may conduct studies, inquiries, and meetings, as it deems necessary. It may assemble and disseminate information and issue reports and other publications, subject to the approval of the Chairperson, in

consultation with the Executive Director. The Advisory Commission may undertake foreign travel in pursuit of its studies and coordinate, sponsor, or oversee projects, studies, events, or other activities that it deems desirable and necessary in fulfilling its functions.

For more information on the U.S. Advisory Commission on Public Diplomacy, please visit *www.state.gov/pdcommission.* For more information on the upcoming public meeting, contact the Commission's Designated Federal Official, Jeff Daigle, at *DaigleJJ@state.gov.*

John J. Daigle,

Designated Federal Official, Advisory Commission on Public Diplomacy, Department of State.

[FR Doc. 2018–24958 Filed 11–14–18; 8:45 am]

BILLING CODE 4710–11–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2018–0035]

Request for Comments on Negotiating Objectives for a U.S.-European Union Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments and notice of public hearing.

SUMMARY: On October 16, 2018, the United States Trade Representative notified Congress of the Administration's intention to enter into negotiations on a trade agreement with the European Union (EU). The Office of the United States Trade Representative (USTR) is seeking public comments on a proposed U.S.-EU trade agreement, including U.S. interests and priorities, in order to develop U.S. negotiating positions. You can provide comments in writing and orally at a public hearing. The Administration's aim in negotiations with the EU is to address both tariff and non-tariff barriers and to achieve fairer, more balanced trade.

DATES:

December 10, 2018: Deadline for the submission of written comments and for written notification of your intent to testify, as well as a summary of your testimony at the public hearing.

December 14, 2018: The Trade Policy Staff Committee (TPSC) will hold a public hearing beginning at 9:30 a.m., at the Auditorium of the Herbert C. Hoover Building, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

ADDRESSES: You should submit notifications of intent to testify and written comments through the Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting comments in parts 2 and 3 below. For alternatives to on-line submissions, please contact Yvonne Jamison at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning written comments, please contact Yvonne Jamison at (202) 395–3475. Direct all other questions to David Weiner, Deputy Assistant U.S. Trade Representative for Europe, at (202) 395–9679.

SUPPLEMENTARY INFORMATION:

1. Background

The decision to launch negotiations for a U.S.-EU trade agreement is an important step toward achieving fairer, more balanced trade with the EU and follows the July 25, 2018 meeting between President Trump and European Commission President Jean-Claude Juncker. In the joint statement issued following their July 25th meeting, President Trump and President Juncker affirmed the intention of the United States and the EU to address both tariff and non-tariff barriers in their trading relationship.

On October 16, 2018, following consultations with relevant Congressional committees, the United States Trade Representative informed Congress that the President intends to commence negotiations with the EU for a U.S.-EU Trade Agreement.

2. Public Comment and Hearing

The TPSC invites interested parties to submit comments and/or oral testimony to assist USTR as it develops negotiating objectives and positions for the agreement, including with regard to objectives identified in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4201). In particular, the TPSC invites interested parties to comment on issues including, but not limited to, the following:

a. General and product-specific negotiating objectives for the proposed agreement.

b. Relevant barriers to trade in goods and services between the U.S. and the EU that should be addressed in the negotiations.

c. Economic costs and benefits to U.S. producers and consumers of removal or reduction of tariffs and removal or reduction of non-tariff barriers on articles traded with the EU.

d. Treatment of specific goods (described by HTSUS numbers) under the proposed agreement, including comments on:

i. Product-specific import or export interests or barriers.

ii. Experience with particular measures that should be addressed in the negotiations.

iii. Ways to address export priorities and import sensitivities in the context of the proposed agreement.

e. Customs and trade facilitation issues that should be addressed in the negotiations.

f. Sanitary and phytosanitary measures and technical barriers to trade that should be addressed in the negotiations.

g. Other measures or practices that undermine fair market opportunities for U.S. businesses, workers, farmers, and ranchers that should be addressed in the negotiations.

USTR must receive written comments no later than Monday, December 10, 2018.

USTR requests that small businesses, generally defined by the Small Business Administration as firms with fewer than 500 employees, or organizations representing small business members, which submit comments to self-identify as such, so that we may be aware of issues of particular interest to small businesses.

The TPSC will hold a hearing on December 14, 2018, in the Auditorium of the Herbert C. Hoover Building, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. If necessary, the hearing will continue on the next business day. Persons wishing to testify at the hearing must provide written notification of their intention by December 10, 2018. The notification of intent to testify must be made in the 'type comment' field under docket number USTR–2018–0035 on the *www.regulations.gov* website and should include the name, address, and telephone number of the person presenting the testimony. You should attach a summary of the testimony by using the 'upload file' field. The file name also should include who will be presenting the testimony. The TPSC limits remarks at the hearing to no more than five minutes to allow for possible questions.

3. Requirements for Submissions

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *www.regulations.gov* website. Persons submitting a notification of intent to testify and/or written comments must do so in English and must identify (on the first page of the submission) the ''U.S.-EU Trade Agreement.''

To submit comments via *www.regulations.gov,* enter docket number USTR–2018–0035 on the home page and click 'search.' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled 'comment now!' For further information on using the *www.regulations.gov* website, please consult the resources provided on the website by clicking on 'How to Use This Site' on the left side of the home page.

The *www.regulations.gov* website allows users to provide comments by filling in a 'type comment' field, or by attaching a document using an 'upload file' field. USTR prefers that you provide comments in an attached document. If a document is attached, it is sufficient to type 'see attached' in the 'type comment' field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the 'type comment' field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters 'BC.' Any page containing business confidential information must be clearly marked BUSINESS CONFIDENTIAL on the top of that page. Filers of submissions containing business confidential information also must submit a public version of their comments. The file name of the public version should begin with the character 'P.' The 'BC' and 'P' should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

As noted, USTR strongly urges submitters to file comments through *www.regulations.gov.* You must make any alternative arrangements before transmitting a comment and in advance of the applicable deadline with Yvonne Jamison at (202) 395–3475.

USTR will place comments in the docket for public inspection, except business confidential information. General information concerning USTR is available at *www.ustr.gov.*

Edward Gresser,

Chair of the Trade Policy Staff Committee, Office of the United States Trade Representative.

[FR Doc. 2018–24979 Filed 11–14–18; 8:45 am]

BILLING CODE 3290–F9–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Results of the 2017/2018 Annual Generalized System of Preferences Review

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is announcing the results of the 2016/2017 Annual Generalized System of Preferences (GSP) Review with respect to: Products considered for addition to the list of eligible products for GSP; products considered for removal from the list of eligible products for certain beneficiary countries; decisions related to competitive need limitations (CNLs), including petitions for waivers of CNLs; and requests to reinstate/redesignate products previously excluded from GSP eligibility for certain countries.

FOR FURTHER INFORMATION CONTACT: Lauren Gamache, Director for GSP at (202) 395–2974 or *lauren.m.gamache@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The GSP program provides for the duty-free treatment of designated articles when imported from beneficiary developing countries (BDCs). The GSP program is authorized by title V of the Trade Act of 1974 (19 U.S.C. 2461–2467), as amended, and is implemented in accordance with Executive Order 11888 of November 24, 1975, as modified by subsequent Executive Orders and Presidential Proclamations.

Each year, USTR leads the interagency Trade Policy Staff Committee (TPSC) in reviewing the list of products eligible for GSP benefits. After completion of a process that includes public hearings, USTR provides recommendations to the President on appropriate actions based on statutory criteria, including exclusions from duty-free treatment of products from certain countries when they have reached the statutory CNL thresholds.

The GSP statute (19 U.S.C. 2463(c)(2)) establishes CNLs as a basis for withdrawing duty-free treatment. The statute provides that when the President determines that a GSP beneficiary has exported to the United States during any calendar year a quantity of an eligible article that either is greater than a specified amount ($180 million for 2017), or exceeds 50 percent of the appraised value of the total U.S. imports of that article, the President ''shall, not later than November 1 of the next calendar year, terminate the duty-free treatment for that article'' from that beneficiary, unless a waiver is granted.[1]

The statute provides that the President may waive either CNL if, before November 1 of the calendar year following the year in which imports exceeded CNLs, the President (1) receives advice from the U.S. International Trade Commission (USITC) on whether any industry in the United States is ''likely to be adversely affected by such waiver''; (2) determines, based on certain statutory considerations,[2] that such a waiver is in the national economic interest; and (3) publishes that determination in the **Federal Register**. The statute further provides that the President may disregard the 50 percent CNL if total imports of an article did not exceed a *de minimis* amount ($23.5 million in 2017), or if the product was not produced in the United States in any of the three preceding calendar years.

As part of the 2017/2018 GSP Annual Review, the TPSC reviewed three types of actions related to the CNLs: (1) Whether to grant CNL waivers for products from certain countries, (2) whether to redesignate products from certain countries previously excluded from GSP eligibility based on CNLs; and (3) whether to grant *de minimis* CNL waivers for products from certain countries.

B. Results of the 2017/2018 Annual GSP Review

In the 2017/2018 Annual GSP Review, the TPSC reviewed (1) petitions to add nine products to the list of those eligible for duty-free treatment under GSP; (2) petitions to remove the GSP eligibility of two products; (3) petitions to waive CNLs for five products from beneficiary countries; (4) 92 products eligible for one-year *de minimis* waivers of CNLs; and (5) petitions to redesignate products previously excluded from GSP

[1] CNLs do not apply to least-developed or sub-Saharan African beneficiaries (19 U.S.C. 2463(c)(2)(D)).

[2] These include the general statutory considerations for granting duty-free treatment for any article from any beneficiary under 19 U.S.C. 2461, as well as the country eligibility criteria set forth in 19 U.S.C. 2462(c).

eligibility for certain beneficiary countries.

Presidential Proclamation 9813 of October 30, 2018, implements the President's decisions regarding the 2017/2018 Annual GSP Review, including CNL waivers and product redesignations. The modifications to the GSP program that were implemented by Presidential Proclamation 9813 became effective on November 1, 2018. This notice provides a summary of the results of the 2017/2018 Annual GSP Review. You can also view the results, comprising six lists, at *https://www.regulations.gov* using docket number USTR–2017–0014, under ''Supporting and Related Materials'' and on the USTR website at *https://ustr.gov/sites/default/files/IssueAreas/gsp/Decisions%20on%202017_2018%20%20product%20review.pdf.*

As described in List I, the President denied all petitions to add products to the list of GSP-eligible products for all BDCs. The products in List I, however, remain eligible for duty-free preferences for least-developed beneficiary countries only. For ease of reference, a brief description and the U.S. Harmonized Tariff Schedule (HTS) categories of the nine products included in List I follows:

1. Certain fresh pears (HTS 0808.30.40)
2. certain melon and citrus fruit peel (HTS 0814.00.80)
3. cottonseed (HTS 1207.29.00)
4. crude sunflower-seed or safflower oil (HTS 1512.11.00)
5. certain prepared or preserved apples (HTS 2008.99.05)
6. p-Anisic acid, clofibrate, and 3-phenoxybenzoic acid (HTS 2918.99.05)
7. certain aromatic carboxylic acids and their derivatives described in U.S. Note 3 (HTS 2918.99.43)
8. certain aromatic carboxylic acids and their derivatives not covered in U.S. Note 3 (HTS 2918.99.47)
9. certain rubber transmission V-belts (HTS 4010.33.30)

A complete description of the nine products is included in List I. By statute (19 U.S.C. 2463(a)(1)(C)), these products may not be reconsidered for addition to GSP for the next three years.

As described in List II, the President granted the petition to remove tart cherry juice concentrate and other cherry juice (HTS 2009.89.6011 and HTS 2009.89.6019) from GSP eligibility for Turkey. To reflect this change, cherry juice imported into the United States now falls under a new HTS category, 2009.89.65. Cherry juice from Turkey now enters the United States at the Normal Trade Relations (NTR) duty rate in column 1 of the HTS. In addition, the President denied the petition to remove nonadhesive plates and sheets (HTS 3920.51.50) from GSP for Indonesia and Thailand. These products will continue to enter the United States duty-free.

As described in List III, the President granted a petition to redesignate ammonium perrhentate (HTS 2841.90.20) from Kazakhstan to GSP. This product now enters the United States duty-free. The remaining redesignation petitions were denied: Apple, quince and pear pastes and purees (HTS 2007.9948) from Argentina; sunflower seed oilcake (HTS 2306.30.00) from Argentina; certain odoriferous or flavoring compounds (HTS 2909.50.40) from Indonesia; fancy bovine leather (full grain, whole, unsplit) (HTS 4107.11.80) from Argentina; certain tropical plywood (HTS 4412.31.41) from Indonesia; granite monumental or building stone (HTS 6802.93.00) from India; and certain ferroniobium (HTS 7202.93.80) from Brazil. These products will continue to enter the United States at NTR duty rates and, by statute (19 U.S.C. 2463(a)(1)(C)), may not be reconsidered for addition to GSP for the next three years.

As described in List IV, three articles exceeded the CNLs in 2017 for which no petition was received and now enter the United States at the NTR duty rates. These products are ethers of acyc monohydric alcohols (HTS 2909.19.18) and refined copper (HTS 7403.19.00) from Brazil, and washing machines (HTS 8450.20.00) from Thailand.

As described in List V, the President granted three petitions for CNL waivers: (1) Edible birds' nests (HTS 0410.00.00) from Thailand; (2) lithium carbonates (HTS 2836.91.00) from Argentina; and (3) ferrosilicon chromium (HTS 7202.50.00) from Kazakhstan. These three products will continue to enter the United States duty-free. The following products did not receive a CNL waiver and are therefore subject to the NTR duty rates: Essential oils of lemon (HTS 3301.03.00) from Argentina, and monumental or building stone (HTS 6802.99.00) from Brazil.

As described in List VI, the President did not grant *de minimis* waivers to 92 products that exceeded the 50 percent import share CNL but for which the aggregate value of all U.S. imports of that article was below the 2017 *de minimis* level of $23.5 million. These products now enter the United States at the NTR duty rate.

Erland Herfindahl,

Deputy Assistant U.S. Trade Representative for the Generalized System of Preferences, Office of the U.S. Trade Representative.

[FR Doc. 2018–24919 Filed 11–14–18; 8:45 am]

BILLING CODE 3290–F9–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on request to release airport property at the St. Louis Lambert International Airport (STL), St. Louis, Missouri.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at the St. Louis Lambert International Airport, St. Louis, Missouri, under the provisions of 49 U.S.C. 47107(h)(2).

DATES: Comments must be received on or before December 17, 2018.

ADDRESSES:

Comments on this application may be mailed or delivered to the FAA at the following address: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust, Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Dana Ryan, Planning Manager, St. Louis Lambert International Airport, 10701 Lambert International Blvd., St. Louis, MO 3145–0212, 314–551–5027.

FOR FURTHER INFORMATION CONTACT: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust, Room 364, Kansas City, MO 64106, (816) 329–2644, *lynn.martin@faa.gov.*

The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release approximately 1.389 acres of airport property, at the St. Louis Lambert International Airport (STL) under the provisions of 49 U.S.C. 47107(h)(2). On June 13, 2018, the Director of Airports for the City of St. Louis, MO requested from the FAA that approximately 1.389 acres of property, be released for sale to Union Electric

(dba Ameron Missouri) for use as substation. On October 22, 2018, the FAA determined that the request to release property at the St. Louis Lambert International Airport (STL) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this Notice.

The following is a brief overview of the request:

St. Louis Lambert International Airport (STL) is proposing the release of two parcels, one parcel on Monroe Avenue contains 0.826 acres and Parcel 2 on Jefferson Avenue containing 0.563 acres for a total containing 1.389 acres. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at the St. Louis Lambert International Airport (STL) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for aviation at the St. Louis Lambert International Airport.

In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at the St. Louis Lambert International Airport.

Issued in Kansas City, MO, on November 5, 2018.

Ed Hyatt,

Acting Director, Airports Division.

[FR Doc. 2018–24875 Filed 11–14–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (the ''SDN List'') based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: *OFAC:* Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treas.gov/ofac*).

Notice of OFAC Actions

On October 16, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Entities

1. TADBIRGARAN ATIYEH IRANIAN INVESTMENT COMPANY, No. 48, 14th Street, Ahmad Ghasir Avenue, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 10102867151 (Iran); Registration Number 246077 (Iran) [SDGT] [IFSR] (Linked To: MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by MEHR EQTESAD IRANIAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

2. TAKTAR INVESTMENT COMPANY, Number 10, Seventh Fath Highway, 65 Metri Fath Highway, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 10103804463 (Iran); Registration Number 263015 (Iran) [SDGT] [IFSR] (Linked To: TECHNOTAR ENGINEERING COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by TECHNOTAR ENGINEERING COMPANY, a person determined to be subject to E.O. 13224.

3. CALCIMIN (a.k.a. KALSIMIN), No. 12, St. Bilal Habashi, Khorramshahr Ave., Zanjan 4516773541, Iran; Second Floor, No. 13, Street 8th, Ghaem Magham Farahari Ave., Tehran 1586868513, Iran; website *www.calcimin.com;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: IRAN ZINC MINES DEVELOPMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by IRAN ZINC MINES DEVELOPMENT COMPANY, a person determined to be subject to E.O. 13224.

4. QESHM ZINC SMELTING AND REDUCTION COMPANY (a.k.a. QESHM ZINC SMELTING AND REDUCTION COMPLEX), 20 Km Dargahan-to-Loft Road, Qeshm Island, Hormozgan, Iran; website *www.gzsc.ir;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: CALCIMIN).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by CALCIMIN, a person determined to be subject to E.O. 13224.

5. BANDAR ABBAS ZINC PRODUCTION COMPANY, No. 15, Zarir Alley, Turkmenistan Street, Motahhari Avenue, Tehran 1565613115, Iran; website *www.bzpc.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 1080000606618 (Iran); Registration Number 3249 (Iran) [SDGT] [IFSR] (Linked To: CALCIMIN).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by CALCIMIN, a person determined to be subject to E.O. 13224.

6. ZANJAN ACID PRODUCTION COMPANY (a.k.a. ZANJAN ACID MAKERS; a.k.a. ZANJAN ACID MAKERS AND ALVAND ROUINKARAN; a.k.a. ZANJAN ACID SAZAN), The end of the Tenth Bahrevari Street, Zinc Industrial Town, 5 km off Bijar Road, Zanjan, Iran; website *www.acidsazan.ir;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: CALCIMIN).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by CALCIMIN, a person determined to be subject to E.O. 13224.

7. NEGIN SAHEL ROYAL INVESTMENT COMPANY (a.k.a. NEGIN SAHEL ROYAL CO.), No. 48, 14th Street, Ahmad Ghasir Avenue, Argentina Square, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 10103589144 (Iran); Registration Number 322430 (Iran) [SDGT] [IFSR] (Linked To: MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by MEHR EQTESAD IRANIAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

8. IRAN ZINC MINES DEVELOPMENT COMPANY, No. 13, 8th Street, Ghaem Maghame Farahani Ave., Tehran, Iran; No. 45, 4th Street, Amir Alame Ghazanfarian Avenue, Etemadiyeh, Zanjan, Iran; website *www.IZMDC.com;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: TAKTAR INVESTMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by

TAKTAR INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

9. TECHNOTAR ENGINEERING COMPANY, Number 10, Seventh Fath Street, 65 Metri Fath Highway, Tehran, Iran; website *www.tecnotar.com;* Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 1086165880 (Iran); Registration Number 13807 (Iran) [SDGT] [IFSR] (Linked To: MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by MEHR EQTESAD IRANIAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

10. IRAN TRACTOR MANUFACTURING COMPANY (a.k.a. IRAN TRACTOR MANUFACTURING), Sephabod Gharani Avenue, Km 9/5 Karaj Special Road, Corner of Yazar Zarin Street, Opposite Shahab Khodro, Office of The Tractor Engineering, Tehran, Iran; website *www.itm.co.ir;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY; Linked To: NEGIN SAHEL ROYAL INVESTMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by MEHR EQTESAD IRANIAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by NEGIN SAHEL ROYAL COMPANY, a person determined to be subject to E.O. 13224.

11. PARSIAN CATALYST CHEMICAL COMPANY, Sixth Bahrevari Street, Zinc Special Town, 5 km of Bijar Road, Zanjan 453515357, Iran; website *www.catalistparsian.com;* Additional Sanctions Information—Subject to Secondary Sanctions; Registration Number 6181 (Iran) [SDGT] [IFSR] (Linked To: CALCIMIN).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by CALCIMIN, a person determined to be subject to E.O. 13224.

12. ANDISHEH MEHVARAN INVESTMENT COMPANY, No. 13, 8th Street, Ghaem Magham Farahani Ave, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: IRAN ZINC MINES DEVELOPMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by IRAN ZINC MINES DEVELOPMENT COMPANY, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, IRAN ZINC MINES DEVELOPMENT COMPANY, a person determined to be subject to E.O. 13224.

13. BAHMAN GROUP, No. 37, Saba Boulevard, Africa Street, P.O. Box 14335–835, Tehran 1917773844, Iran; website *www.bahmangroup.com;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: ANDISHEH MEHVARAN INVESTMENT COMPANY).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, ANDISHEH MEHVARAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

14. ESFAHAN'S MOBARAKEH STEEL COMPANY (a.k.a. MOBARAKEH STEEL COMPANY), P.O. Box 161–84815, Mobarakeh, Esfahan 11131–84881, Iran; Mobarakeh Steel Company, Sa'adat Abad St., Azadi SQ., Esfahan, Esfahan, Iran; Mobarakeh Steel Company, No. 2, Gol Azin Alley, Kouhestan St., Ketah SQ., Sa'adat Abad, Tehran, Iran; website *www.en.msc.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 10260289464 (Iran); Commercial Registry Number 411175869887 (Iran) [SDGT] [IFSR] (Linked To: MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, MEHR EQTESAD IRANIAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

15. MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY (a.k.a. MEHR EGHTESAD IRANIAN INVESTMENT COMPANY; a.k.a. MEHR IRANIAN ECONOMY COMPANY; a.k.a. MEHR IRANIAN ECONOMY INVESTMENTS; a.k.a. MEHR EQTESAD IRANIAN INVESTMENT COMPANY; f.k.a. TEJARAT TOSE'E EQTESADI IRANIAN), No. 18, Iranian Building, 14th Alley, Ahmad Qassir Street, Argentina Square, Tehran, Iran; No. 48, 14th Alley, Ahmad Qassir Street, Argentina Square, Tehran, Iran; website *www.mebank.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; Phone Number 982188526300; alt. Phone Number 982188526301; alt. Phone Number 982188526302; alt. Phone Number 982188526303; alt. Phone Number 9821227700019; Business Registration Document # 103222 (Iran); National ID No. 10101863528 (Iran); Fax: 982188526337; Alt. Fax: 9221227700019 [SDGT] [NPWMD] [IRGC] [IFSR] (Linked To: MEHR EQTESAD BANK).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by MEHR EQTESAD BANK, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, MEHR EQTESAD BANK, a person determined to be subject to E.O. 13224.

16. BASIJ RESISTANCE FORCE (a.k.a. BASEEJ; a.k.a. BASIJ; a.k.a. BASIJ–E MELLI; a.k.a. MOBILIZATION OF THE OPPRESSED ORGANIZATION; f.k.a. SAZMAN BASIJ MELLI; a.k.a. SAZMAN–E MOGHAVEMAT–E BASIJ; f.k.a. VAHED–E BASIJ–E MOSTAZAFEEN; f.k.a. ''NATIONAL MOBILIZATION ORGANIZATION''; a.k.a. ''NATIONAL RESISTANCE MOBILIZATION''; a.k.a. ''RESISTANCE MOBILIZATION FORCE''), Iran; Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IRGC] [IFSR] [IRAN–HR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)–QODS FORCE; Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by Iran's ISLAMIC REVOLUTIONARY GUARD CORPS, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, Iran's ISLAMIC REVOLUTIONARY GUARD CORPS–QODS FORCE, a person determined to be subject to E.O. 13224.

17. BONYAD TAAVON BASIJ (a.k.a. BASIJ COOPERATIVE FOUNDATION), Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: BASIJ RESISTANCE FORCE).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by Iran's BASIJ RESISTANCE FORCE, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, Iran's BASIJ RESISTANCE FORCE, a person determined to be subject to E.O. 13224.

18. BANK MELLAT, Head Office Bldg, 276 Taleghani Ave, Tehran, Iran; SWIFT/BIC BKMTIRTH; website *www.bankmellat.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; All Branches Worldwide [IRAN] [SDGT] [IFSR] (Linked To: MEHR EQTESAD BANK).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, MEHR EQTESAD BANK, a person determined to be subject to E.O. 13224.

19. MEHR EQTESAD BANK (a.k.a. MEHR INTEREST–FREE BANK), No. 182, Shahid Tohidi St, 4th Golsetan, Pasdaran Ave, Tehran 1666943, Iran; website *www.mebank.ir;* Additional Sanctions Information—Subject to Secondary Sanctions [SDGT] [IFSR] (Linked To: BONYAD TAAVON BASIJ; Linked To: BASIJ RESISTANCE FORCE).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by BONYAD TAAVON BASIJ, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, BONYAD TAAVON BASIJ, a person determined to be subject to E.O. 13224.

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological

support for, or financial or other services to or in support of, Iran's BASIJ RESISTANCE FORCE, a person determined to be subject to E.O. 13224.

20. MEHR EQTESAD FINANCIAL GROUP, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 10101471388 (Iran) [SDGT] [IFSR] (Linked To: MEHR–E EQTESAD–E IRANIAN INVESTMENT COMPANY).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by MEHR EQTESAD IRANIAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

21. SINA BANK (a.k.a. SINA FINANCE AND CREDIT INSTITUTE), Between Miremad Street and Mofateh Street, Motahari Avenue, Tehran 15888–6457, Iran; SWIFT/BIC SINAIRTH; website *www.sinabank.ir;* Additional Sanctions Information—Subject to Secondary Sanctions [IRAN] [SDGT] [IFSR] (Linked To: ANDISHEH MEHVARAN INVESTMENT COMPANY).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, ANDISHEH MEHVARAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

22. PARSIAN BANK, No. 4, Zarafshan Street, Shahid Farahzadi Boulevard, Sharak Ghods, Tehran, Iran; SWIFT/BIC BKPAIRTH; website *www.parsian-bank.com;* Additional Sanctions Information—Subject to Secondary Sanctions; All Branches Worldwide [IRAN] [SDGT] [IFSR] (Linked To: ANDISHEH MEHVARAN INVESTMENT COMPANY).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, techological support for, or financial or other services to or in support of, ANDISHEH MEHVARAN INVESTMENT COMPANY, a person determined to be subject to E.O. 13224.

In light of their designations, the following entities no longer are blocked solely pursuant to Executive Order 13599 of February 5, 2012 and Section 560.211 of the Iranian Transactions and Sanctions Regulations (ITSR), 31 CFR part 560, and, thus, they have been removed from the List of Persons Identified as Blocked Solely Pursuant to Executive Order 13599 (the E.O. 13599 List) and placed on the SDN List:

1. BANK MELLAT, Head Office Bldg, 276 Taleghani Ave, Tehran, Iran; SWIFT/BIC BKMTIRTH; website *www.bankmellat.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; All Branches Worldwide [IRAN] [SDGT] [IFSR] (Linked To: MEHR EQTESAD BANK).

2. SINA BANK (a.k.a. SINA FINANCE AND CREDIT INSTITUTE), Between Miremad Street and Mofateh Street, Motahari Avenue, Tehran 15888–6457, Iran; SWIFT/BIC SINAIRTH; website *www.sinabank.ir;* Additional Sanctions Information—Subject to Secondary Sanctions [IRAN] [SDGT] [IFSR] (Linked To: ANDISHEH MEHVARAN INVESTMENT COMPANY).

3. PARSIAN BANK, No. 4, Zarafshan Street, Shahid Farahzadi Boulevard, Sharak Ghods, Tehran, Iran; SWIFT/BIC BKPAIRTH; website *www.parsian-bank.com;* Additional Sanctions Information—Subject to Secondary Sanctions; All Branches Worldwide [IRAN] [SDGT] [IFSR] (Linked To: ANDISHEH MEHVARAN INVESTMENT COMPANY).

Dated: October 16, 2018.

Andrea M. Gacki,

Director, Office of Foreign Assets Control U.S. Department of the Treasury.

[FR Doc. 2018–22881 Filed 11–14–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one individual and seven entities that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of this person and these entities are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action

On October 4, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following individual and entities are blocked under the relevant sanctions authority listed below.

Individual

1. AL–AMIN, Muhammad 'Abdallah (a.k.a. AL AMEEN, Mohamed Abdullah; a.k.a. AL AMIN, Mohammad; a.k.a. AL AMIN, Muhammad Abdallah; a.k.a. AL AMIN, Muhammed; a.k.a. AL–AMIN, Mohamad; a.k.a. ALAMIN, Mohamed; a.k.a. AMINE, Mohamed Abdalla; a.k.a. EL AMINE, Muhammed), Yusif Mishkhas T: 3 Ibn Sina, Bayrut Marjayoun, Lebanon; Beirut, Lebanon; DOB 11 Jan 1975; POB El Mezraah, Beirut, Lebanon; nationality Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Gender Male (individual) [SDGT] (Linked To: TABAJA, Adham Husayn).

Designated pursuant to section 1(d)(i) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of TABAJA, Adham Husayn, an individual determined to be subject to E.O. 13224.

Entities

1. IMPULSE INTERNATIONAL S.A.L. OFFSHORE (a.k.a. STATURA S.A.L. OFFSHORE), Unesco Center, 4th Floor, Office No. 19, Verdun, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1801124 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

2. IMPULSE S.A.R.L., Floor 4, Unesco Center, Verdun, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1003871 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

3. LAMA FOODS INTERNATIONAL OFFSHORE S.A.L. (a.k.a. LAMA FOOD INTERNATIONAL OFF SHORE S.A.L.; a.k.a. LAMA FOODS INTERNATIONAL S.A.R.L.), Unesco Center, 4th Floor, Office No. 19, Verdun, Beirut, Lebanon; Additional

Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1012499 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

4. LAMA FOODS S.A.R.L., Airport Road, Dahieh Area, Cocodi sector, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1005341 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

5. M. MARINE S.A.L. OFFSHORE, Unesco Center, 4th Floor, Office No. 19, Verdun, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1804696 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

6. SIERRA GAS S.A.L. OFFSHORE (a.k.a. SIRRA GAS S.A.L. OFF SHORE), Unesco Center, 4th Floor, Office No. 19, Verdun, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1804895 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

7. THAINGUI S.A.L. OFFSHORE (a.k.a. ''SHANGHAI S.A.L. OFFSHORE COMPANY''), Unesco Center, 4th Floor, Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; Commercial Registry Number 1804869 (Lebanon) [SDGT] (Linked To: AL–AMIN, Muhammad 'Abdallah).

Designated pursuant to section 1(c) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for being owned or controlled by AL–AMIN, Muhammad 'Abdallah, an individual determined to be subject to E.O. 13224.

Dated: October 4, 2018.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2018–21979 Filed 11–14–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On November 8, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. BASOV, Aleksandr Vasilevich (a.k.a. BASOV, Alexander; a.k.a. BASOV, Oleksandr), Ukraine; DOB 16 Oct 1971; Gender Male (individual) [CAATSA—RUSSIA] (Linked To: MINISTRY OF STATE SECURITY).

Designated pursuant to section 11(a)(3) of Support for the Sovereignty, Integrity, Democracy, and Economic Stability of Ukraine Act, as amended by the section 228(a) of the Countering America's Adversaries Through Sanctions Act, Public Law 115–44, (SSIDES), 22 U.S.C. 8910(a)(3) for acting or purporting to act for or on behalf of, directly, or indirectly, the MINISTRY OF STATE SECURITY, a person whose property and interests in property are blocked pursuant to Section 11(a)(1) of SSIDES.

2. SUSHKO, Andriy Volodymyrovych (a.k.a. SUSHKO, Andrey; a.k.a. SUSHKO, Andrey Vladimirovich; a.k.a. SUSHKO, Andrii), Bldg. 78, Apt. 74, ulitsa Generala Petrova, city of Kerch, Crimea; DOB 23 Jan 1976; POB Village of Leninskoe, Leninskiy Region, Autonomous Region of Crimea; Gender Male (individual) [CAATSA—RUSSIA].

Designated pursuant to section 11(a)(1) of SSIDES, 22 U.S.C. 8910(a)(1), for being responsible for, complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses in any territory forcibly occupied or otherwise controlled by the Government of the Russian Federation.

3. ZARITSKY, Vladimir Nikolaevich (a.k.a. ZARITSKY, Vladimir Nikolayevich), Russia; DOB 15 Jun 1948; POB Ostany Village, Korosten District, Zhitomir region, Ukraine; Gender Male (individual) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of Executive Order 13685 of December 19, 2014, ''Blocking Property of Certain Persons and Prohibiting Certain Transactions With Respect to the Crimea Region of Ukraine'' (E.O. 13685) for operating in the Crimea region of Ukraine.

Entities

1. JOINT STOCK COMPANY SANATORIUM AY–PETRI (a.k.a. JOINT STOCK COMPANY AI–PETRI SANATORIUM; a.k.a. JSC SANATORIUM AY–PETRI), House 15, Alupkinskoye shosse, Urban Village Koreiz, City of Yalta, Crimea 298671, Ukraine; Tax ID No. 9103082749 (Russia); Registration Number 1169102093797 (Russia) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

2. JOINT STOCK COMPANY SANATORIUM DYULBER (a.k.a. JOINT STOCK COMPANY DIULBER SANATORIUM; a.k.a. JSC SANATORIUM DYULBER), House 19, Alupkinskoye shosse, Koreiz, Yalta, Crimea 298671, Ukraine; Tax ID No. 9103084143 (Russia); Registration Number 1179102009525 (Russia) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

3. JOINT STOCK COMPANY SANATORIUM MISKHOR (a.k.a. JSC SANATORIUM MISKHOR), House 9, Alupkinskoye shosse, Koreiz, Yalta, Crimea 298671, Ukraine; Tax ID No. 9103082756 (Russia); Registration Number 1169102093930 (Russia) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

4. KRYMTETS, AO (a.k.a. AKTSIONERNOE OBSHCHESTVO KRYMTEPLOELEKTROTSENTRAL; a.k.a. AO, KRIMTETS; f.k.a. KRYMTEPLOELEKTROTSENTRAL, AO), 1, ul. Montazhnaya Pgt. Gresovski, Simferopol, Crimea 295493, Ukraine; website *www.krimtec.com;* Email Address *e.hmelnitskiy@krimtec.com;* Tax ID No. 9102070194 (Russia); Government Gazette Number 00828288 (Russia); Registration Number 1159102014169 (Russia) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

5. LIMITED LIABILITY COMPANY GARANT–SV (a.k.a. GARANT–SV; a.k.a. GARANT–SV LIMITED LIABILITY COMPANY; a.k.a. GARANT–SV LLC; a.k.a. GARANT–SV, OOO; a.k.a. LLC GARANT–SV; a.k.a. OOO GARANT–SV), House 9, Generala Ostryakova Street, Opolznevoye Village, Yalta, Crimea 298685, Ukraine; 9, Generala Ostryakova St., Opolznevoye, Yalta, Crimea 298685, Ukraine; website *http://mriyaresort.com;* Tax ID No. 9103007830 (Russia); Registration Number 1149102066740 (Russia) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

6. LIMITED LIABILITY COMPANY INFRASTRUCTURE PROJECTS MANAGEMENT COMPANY (a.k.a. MANAGEMENT COMPANY FOR INFRASTRUCTURE PROJECTS; a.k.a. UPRAVLYAYUSHCHAYA KOMPANIYA INFRASTRUKTURNYKH PROEKTOV; a.k.a. ''LLC UKIP''; a.k.a. ''UKIP''; a.k.a. ''UKIP, OOO''), Sevastopolskaya Street, House 4½, Simferopol, Crimea 295024, Ukraine; Email Address *fnatali@mail.ru;* Tax ID No. 9102045582 (Russia); Government Gazette Number 00742767 (Russia); Registration Number 1149102091654 (Russia) [UKRAINE—E.O. 13685].

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

7. LIMITED LIABILITY COMPANY SOUTHERN PROJECT (a.k.a. LLC SOUTHERN PROJECT; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU YUZHNY PROEKT; a.k.a. YUZHNY PROEKT, OOO), Room 15–H, Litera A, House 2, Rastrelli Place, City of St. Petersburg 191124, Russia; Tax ID No. 7842144503 (Russia); Registration Number 1177847378279 (Russia) [UKRAINE—E.O. 13661] [UKRAINE—E.O. 13685] (Linked To: BANK ROSSIYA; Linked To: KOVALCHUK, Yuri Valentinovich).

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

Designated pursuant to section 1(a)(ii)(C)(2) of Executive Order 13661 of March 16, 2014, ''Blocking Property of Additional Persons Contributing to the Situation in Ukraine'' (E.O. 13661) for being owned or controlled by BANK ROSSIYA, a person whose property and interests in property are blocked pursuant to E.O. 13661.

Designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for being owned or controlled by Yuri Valentinovich KOVALCHUK, a person whose property and interests in property are blocked pursuant to E.O. 13661.

8. MINISTRY OF STATE SECURITY (a.k.a. ''MGB''), Luhansk People's Republic, Luhansk City, Ukraine [CAATSA—RUSSIA].

Designated pursuant to section 11(a)(1) of SSIDES, 22 U.S.C. 8910(a)(1), for being responsible for, complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses in any territory forcibly occupied or otherwise controlled by the Government of the Russian Federation.

9. MRIYA RESORT & SPA (a.k.a. MRIYA RESORT; a.k.a. MRIYA RESORT AND SPA; a.k.a. MRIYA SANATORIUM COMPLEX; a.k.a. MRIYA SANATORIUM RESORT COMPLEX; a.k.a. SANATORIUM–RESORT COMPLEX MRIYA), 9, Generala Ostryakova Street, Opolznevoye Village, Yalta, Crimea 298685, Ukraine; website *http://mriyaresort.com;* Email Address *info@mriyaresort.com* [UKRAINE–E.O. 13685] (Linked To: LIMITED LIABILITY COMPANY GARANT–SV).

Designated pursuant to section 2(a)(i) of E.O. 13685 for operating in the Crimea region of Ukraine.

Designated pursuant to section 2(a)(iii) of E.O. 13685 for being owned or controlled by, directly or indirectly, LIMITED LIABILITY COMPANY GARANT–SV, a person whose property and interests in property are blocked pursuant to E.O. 13685.

Additionally, OFAC is updating the listing on the Specially Designated Nationals and Blocked Persons List of seven entities that are identified pursuant to Executive Order 13599. The entities' listings will be updated from:

1. HEKMAT IRANIAN BANK (a.k.a. BANK–E HEKMAT IRANIAN), Argentine Circle, beginning of Africa St., Corner of 37th St., (Dara Cul-de-sac), No.26, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions [IRAN].

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1. HEKMAT IRANIAN BANK (a.k.a. BANK–E HEKMAT IRANIAN), Argentine Circle, beginning of Africa St., Corner of 37th St., (Dara Cul-de-sac), No.26, Tehran, Iran [IRAN].

2. KHAVARMIANEH BANK (a.k.a. MIDDLE EAST BANK), No. 22, Second Floor Sabounchi St., Shahid Beheshti Ave., Tehran, Iran; SWIFT/BIC KHMIIRTH; Additional Sanctions Information—Subject to Secondary Sanctions; All offices worldwide [IRAN].

-to-

2. KHAVARMIANEH BANK (a.k.a. MIDDLE EAST BANK), No. 22, Second Floor Sabounchi St., Shahid Beheshti Ave., Tehran, Iran; SWIFT/BIC KHMIIRTH; All offices worldwide [IRAN].

3. KISH INTERNATIONAL BANK (a.k.a. KISH INTERNATIONAL BANK OFFSHORE COMPANY PJS), NBO–9, Andisheh Blvd., Sanayi Street, Kish Island, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; All offices worldwide [IRAN].

-to-

3. KISH INTERNATIONAL BANK (a.k.a. KISH INTERNATIONAL BANK OFFSHORE COMPANY PJS), NBO–9, Andisheh Blvd., Sanayi Street, Kish Island, Iran; All offices worldwide [IRAN].

4. MEHR IRAN CREDIT UNION BANK (a.k.a. BANK–E GHARZOLHASANEH MEHR IRAN; a.k.a. GHARZOLHASANEH MEHR IRAN BANK), Taleghani St., No.204, Before the intersection of Mofateh, across from the former U.S. embassy, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions [IRAN].

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4. MEHR IRAN CREDIT UNION BANK (a.k.a. BANK–E GHARZOLHASANEH MEHR IRAN; a.k.a. GHARZOLHASANEH MEHR IRAN BANK), Taleghani St., No.204, Before the intersection of Mofateh, across from the former U.S. embassy, Tehran, Iran [IRAN].

5. CREDIT INSTITUTION FOR DEVELOPMENT, 53 Saanee, Jahan-e Koodak, Crossroads Africa St., Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions [IRAN].

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5. CREDIT INSTITUTION FOR DEVELOPMENT, 53 Saanee, Jahan-e Koodak, Crossroads Africa St., Tehran, Iran [IRAN].

6. NATIONAL IRANIAN TANKER COMPANY (a.k.a. NITC), NITC Building, 67–88, Shahid Atefi Street, Africa Avenue, Tehran, Iran; website *www.nitc.co.ir;* Email Address *info@nitc.co.ir;* alt. Email Address *administrator@nitc.co.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; Telephone (98)(21)(66153220); Telephone (98)(21)(23803202); Telephone (98)(21)(23803303); Telephone (98)(21)(66153224); Telephone (98)(21)(23802230); Telephone (98)(9121115315); Telephone (98)(9128091642); Telephone (98)(9127389031); Fax (98)(21)(22224537); Fax (98)(21)(23803318); Fax (98)(21)(22013392); Fax (98)(21)(22058763) [IRAN] [IFCA].

-to-

6. NATIONAL IRANIAN TANKER COMPANY (a.k.a. NITC), NITC Building, 67–88, Shahid Atefi Street, Africa Avenue, Tehran, Iran; website *www.nitc.co.ir;* Email Address *info@nitc.co.ir;* alt. Email Address *administrator@nitc.co.ir;* IFCA Determination—Involved in the Shipping Sector ; Additional Sanctions Information—Subject to Secondary Sanctions; Telephone (98)(21)(66153220); Telephone (98)(21)(23803202); Telephone (98)(21)(23803303); Telephone (98)(21)(66153224); Telephone (98)(21)(23802230); Telephone (98)(9121115315); Telephone (98)(9128091642); Telephone

(98)(9127389031); Fax (98)(21)(22224537); Fax (98)(21)(23803318); Fax (98)(21)(22013392); Fax (98)(21)(22058763) [IRAN] [IFCA].

7. NATIONAL IRANIAN OIL COMPANY (a.k.a. NIOC), Hafez Crossing, Taleghani Avenue, P.O. Box 1863 and 2501, Tehran, Iran; National Iranian Oil Company Building, Taleghani Avenue, Hafez Street, Tehran, Iran; website *www.nioc.ir;* Additional Sanctions Information—Subject to Secondary Sanctions; all offices worldwide [IRAN] [IFCA].

-to-

7. NATIONAL IRANIAN OIL COMPANY (a.k.a. NIOC), Hafez Crossing, Taleghani Avenue, P.O. Box 1863 and 2501, Tehran, Iran; National Iranian Oil Company Building, Taleghani Avenue, Hafez Street, Tehran, Iran; website *www.nioc.ir;* IFCA Determination—Involved in Energy Sector; Additional Sanctions Information—Subject to Secondary Sanctions; all offices worldwide [IRAN] [IFCA].

Dated: November 8, 2018.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2018–24889 Filed 11–14–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, November 29, 2018.

FOR FURTHER INFORMATION CONTACT: Otis Simpson at 1–888–912–1227 or 202–317–3332.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be held Thursday, November 29, 2018, at 10:00 a.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Otis Simpson. For more information please contact Otis Simpson at 1–888–912–1227 or 202–317–3332, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

The agenda will include a discussion on various letters, and other issues related to written communications from the IRS.

Dated: November 8, 2018.

Antoinette Ross,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2018–24879 Filed 11–14–18; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

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No. 221 November 15, 2018

Part II

Department of the Treasury

Internal Revenue Service

Department of Labor

Employee Benefits Security Administration

Department of Health and Human Services

26 CFR Part 54

29 CFR Part 2590

45 CFR Part 147

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–F2]

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Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, interim final rules concerning religious exemptions and accommodations regarding coverage of certain preventive services issued in the **Federal Register** on October 13, 2017. These rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an ''accommodation'' process as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline, 1–866–444–EBSA (3272) or visit the Department of Labor's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47792), ''Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (the Religious IFC). The rules are necessary to expand the protections for the sincerely held religious objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, a requirement that was created by HHS through guidance promulgated by the Health Resources and Services Administration (HRSA) (hereinafter ''Guidelines''), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules maintain a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's Guidelines. The changes being finalized to these rules will ensure that proper respect is afforded to sincerely held religious objections in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement

These rules finalize exemptions provided in the Religious IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held religious beliefs opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's Guidelines. The rules finalize exemptions to the same types of organizatons and individuals for which exemptions were provided in the Religious IFC: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals. The rules also finalize the regulatory restatement in the Religious IFC of language from section 2713(a) and (a)(4) of the Public Health Service Act.

In response to public comments, various changes are made to clarify the intended scope of the language in the Religious IFC. The prefatory language to the exemptions is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to clarify that, where an exemption encompasses a plan or coverage established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, the exemption applies to each employer, organization, or plan sponsor that adopts the plan. Language is also added to clarify that the exemptions apply to non-governmental entities, including as the exemptions apply to institutions of higher education. The Departments revise the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement. The Departments also restructure the provision describing the religious objection for entities. That provision specifies that the entity objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for either: coverage or payments for some or all contraceptive services; or, a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The final rule specifies that the individual exemption ensures that the HRSA Guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. Optional Accommodation

These rules also finalize provisions from the Religious IFC that maintain the accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation process so that contraceptive coverage to which they object is omitted from their plan, but their issuer or third party administrator, as applicable, will arrange for the persons covered by their plan to receive contraceptive coverage or payments.

In response to public comments, these final rules make technical changes to the accommodation regulations maintained in parallel by HHS, the Department of Labor, and the Department of the Treasury. The Departments modify the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional

rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days notice pursuant to Public Health Service Act section 2715(d)(4) and 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), and 29 CFR 2590.715–2715(b). The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

The Departments also modify the Religious IFC by adding a provision that existed in rules prior to the Religious IFC, namely, that if an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable contraceptive coverage requirement from HRSA's Guidelines if the issuer complies with the obligations under this section applicable to such issuer. Likewise, the rule adds pre-existing ''reliance'' language deeming an issuer serving an accommodated organization compliant with the contraceptive coverage requirement if the issuer relies reasonably and in good faith on a representation by an organization as to its eligibility for the accommodation and the issuer otherwise complies with the accommodation regulation, and likewise deeming a group health plan compliant with the contraceptive coverage requirement if it complies with the accommodation regulation.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	The purpose of this provision is to ensure that the regulatory language that restates section 2713(a) and (a)(4) of the Public Health Service Act mirrors the language of the statute. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.
Expanded religious exemptions.	Expanding religious exemptions to the contraceptive coverage requirement will relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their religious beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage or using the accommodation in violation of their sincerely held religious beliefs.	We estimate there will be transfer costs where women previously receiving contraceptive coverage from employers will no longer receive that coverage where the employers use the expanded exemptions. Even after the public comment period, we have very limited data on what the scale of those transfer costs will be. We estimate that in no event will they be more than $68.9 million. We estimate that, where entities using the accommodation revoke it to use the exemption, the cost to industry of sending notices of revocation to their policy holders will be $112,163.
Optional accommodation regulations.	Maintaining the accommodation as an optional process will ensure that contraceptive coverage is made available to many women covered by plans of employers that object to contraceptive coverage but not to their issuers or third party administrators arranging for such coverage to be provided to their plan participants.	We estimate that, by expanding the types of organizations that may use the accommodation, some entities not currently using it will opt into it. When doing so they will incur costs of $677 to send a self-certification or notice to their issuer or third party administrator, or to HHS, to commence operation of the accommodation. We estimate that entities that newly make use of the accommodation as the result of these rules, or their issuers or third party administrators, will incur costs of $311,304 in providing their policy holders with notices indicating that contraceptive coverage or payments are available to them under the accommodation process.

B. Background

Over many decades, Congress has protected conscientious objections, including those based on religious beliefs, in the context of health care and human services including health coverage, even as it has sought to promote and expand access to health services.[1] In 2010, Congress enacted the

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *id.* at Div. E, Sec. 808 (regarding any requirement for ''the provision of contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *id.* at Div. I, (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide-related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations

Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended the PPACA. As amended by HCERA, the PPACA is known as the Affordable Care Act (ACA).

The ACA reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter ''section 2713(a)(4)''), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, ''with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by'' HRSA's Guidelines.

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same time period, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, ''the Departments'') [3] have promulgated regulations to guide HRSA in exercising its discretion to allow exemptions to those requirements, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments defined the scope of permissible exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Many individuals and entities brought legal challenges to the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate'') as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1 (''RFRA''). Several of those cases went to the Supreme Court. *See, for example, Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751 (2014); *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016).

The Departments most recently solicited public comments on these issues again in two interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017: the regulations (82 FR 47792) that are being finalized with changes here, and regulations (82 FR 47838) concerning moral objections (the Moral IFC), which are being finalized with changes in companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Religious IFC, the Departments explained several reasons why it was appropriate to reevaluate the religious exemptions and accommodations for the contraceptive Mandate and to take into account the religious beliefs of certain employers concerning that Mandate. The Departments also sought public comment on those modifications. The Departments considered, among other things, Congress's history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; protection of the free exercise of religion in the First Amendment and, by Congress, in RFRA; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); previously submitted public comments;

and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice (now Medicare Advantage) managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in state law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); see also 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] The references in this document to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to ''Contraceptive Methods and Counseling'' as ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header ''Contraception,'' to: ''the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,'' ''contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),'' and ''instruction in fertility awareness-based methods, including the lactation amenorrhea method.'' *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

and the extensive litigation over the contraceptive Mandate.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Religious IFC, with changes based on comments as indicated herein.[5]

II. Overview, Analysis, and Response to Public Comments

We provided a 60-day public comment period for the Religious IFC, which closed on December 5, 2017. The Departments received over 56,000 public comment submissions, which are posted at *www.regulations.gov*.[6] Below, the Departments provide an overview of the general comments on the final regulations, and address the issues raised by commenters.

These rules expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules finalize the accommodation process, which was previously established in response to objections of religious organizations that were not protected by the original exemption, as an optional process for any exempt entities. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[7]

A. The Departments' Authority To Mandate Coverage and Provide Religious Exemptions

The Departments received conflicting comments on their legal authority to provide the expanded exemptions and accommodation for religious beliefs. Some commenters agreed that the Departments are legally authorized to provide the expanded exemptions and accommodation, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing religious exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the exemptions that existed prior to the Religious IFC, but not to expand them.

Some commenters who argued that section 2713(a)(4) does not allow for exemptions said that the previous exemptions for houses of worship and integrated auxiliaries, and the previous accommodation process, were set forth in the ACA itself, and therefore were acceptable while the expanded exemptions in the Religious IFC were not. This is incorrect. The ACA does not prescribe (or prohibit) the previous exemptions for house of worship and the accommodation processes that the Departments issued through regulations.[8] The Departments, therefore, find it appropriate to use the regulatory process to issue these expanded exemptions and accommodation, to better address concerns about religious exercise.

The Departments conclude that legal authority exists to provide the expanded exemptions and accommodation for religious beliefs set forth in these final rules. These rules concern section 2713 of the PHS Act, as also incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes.[9]

Where it applies, section 2713(a)(4) requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' Guidelines developed by HHS through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS, as the administering agency of HRSA, and to all three agencies, as the administering agencies of the statutes by which the Guidelines are enforced, to shape that development. *See* 26 U.S.C. 9834; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38,409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable Guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must ''provide for'' and ''support'' the application of Guidelines that it chooses to adopt. HRSA's authority to support ''comprehensive guidelines'' involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only ''as provided for in comprehensive guidelines supported by [HRSA].'' That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word ''as'' in the phrase ''as provided for,'' it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase ''as you like it.'' [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See, e.g.*, 42 U.S.C. 1395x (''The Secretary shall establish procedures to make beneficiaries and providers aware

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[5] The Department of the Treasury and the Internal Revenue Service (IRS) published proposed and temporary regulations as part of the joint rulemaking of the Religious IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules. The Department of the Treasury and IRS are finalizing their proposed regulations.

[6] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2014-0115* and *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=7525&dct=PS&D=IRS-2017-0016.* Some of those submissions included form letters or attachments that, while not separately tabulated at *regulations.gov*, together included comments from, or were signed by, hundreds of thousands of separate persons. The Departments reviewed all of the public comments and attachments.

[7] *See, for example,* Family Planning grants in 42 U.S.C. 300 *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), and 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), and (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[8] The ACA also does not require that contraceptives be covered under the preventive services provisions.

[9] 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92.

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (''[u]sed to indicate by comparison the way something happens or is done'').

of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.'') (emphasis added). Thus, the inclusion of ''as'' in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has been granted discretion in supporting how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word ''as'' is missing from the other three provisions in PHS Act section 2713(a). Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require ''evidence-based'' or ''evidence-informed'' coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The religious objections at issue here, and in regulations providing exemptions from the inception of the Mandate in 2011, are considerations that, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines ''exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,'' and ''it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.'' *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a specific statutory mandate that contraceptives must be covered or that they be covered without any exemptions or exceptions, supports the conclusion that the Departments are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The conclusions on which these final rules are based are consistent with the Departments' interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4)'s grant of authority to include broad discretion regarding the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrators of self-insured church plans. *See* 80 FR 41323. Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. During prior rulemakings, the Departments also disagreed with commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or as incorporated into ERISA and the Code, and who contended instead that we must enforce the Guidelines on the broadest spectrum of group health plans as possible. *See, e.g.,* 2012 final regulations at 77 FR 8726.

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require coverage of preventive services for every type of plan that is subject to the ACA. *See, e.g.,* 76 FR 46623. On the contrary, Congress carved out an exemption from PHS Act section 2713 (and from several other provisions) for grandfathered plans. In contrast, grandfathered plans do have to comply with many of the other provisions in Title I of the ACA—provisions referred to by the previous Administration as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime and annual dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group health insurance markets, and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Hobby Lobby,* 134 S. Ct. at 2764 n.10.

Some commenters argue that Executive Order 13535's reference to

[11] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' Henry J Kaiser Family Foundation (Sept. 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions to the Mandate in the Guidelines. The Departments, however, believe these final regulations are consistent with Executive Order 13535. Issued upon the signing of the ACA, Executive Order 13535 specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs from certain requirements in health care contexts. While the Executive Order 13535 does not require the expanded exemptions in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws that protect religious beliefs, and are consistent with the Executive Order's intent that the ACA would be implemented in accordance with the conscience protections set forth in those laws.

The extent to which RFRA provides authority for these final rules is discussed below in section II.C., The First Amendment and the Religious Freedom Restoration Act.

B. Availability and Scope of Religious Exemptions

Some commenters supported the expanded exemptions and accommodation in the Religious IFC, and the entities and individuals to which they applied. They asserted the expanded exemptions and accommodation are appropriate exercises of discretion and are consistent with religious exemptions Congress has provided in many similar contexts. Some further commented that the expanded exemptions are necessary under the First Amendment or RFRA. Similarly, commenters stated that the accommodation was an inadequate means to resolve religious objections, and that the expanded exemptions are needed. They objected to the accommodation process because it was another method to require compliance with the Mandate. They contended its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and that such coverage flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to the religious objections that organizations would not have with an expanded exemption.

Several other commenters asserted that the exemptions in the Religious IFC are too narrow and called for there to be no mandate of contraceptive coverage. Some of them contended that HRSA should not include contraceptives in their women's preventive services Guidelines because fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of preventive health services. They also contended that contraceptives can pose medical risks for women and that studies do not show that contraceptive programs reduce abortion rates or rates of unintended pregnancies. Some commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacients and, therefore, violate federal conscience protections such as the Weldon Amendment, *see* section 507(d) of Public Law 115–141.

Other commenters contended that the expanded exemptions are too broad. In general, these commenters supported the inclusion of contraceptives in the Guidelines, contending they are a necessary preventive service for women. Some said that the Departments should not exempt various kinds of entities such as businesses, health insurance issuers, or other plan sponsors that are not nonprofit entities. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318). Some commenters said the Departments should not expand the exemptions, but simply expand or adjust the accommodation process to resolve religious objections to the Mandate and accommodation. Some commenters contended that even the previous regulations allowing an exemption and accommodation were too broad, and said that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible.

After consideration of the comments, the Departments are finalizing the provisions of the Religious IFC without contracting the scope of the exemptions and accommodation set forth in the Religious IFC. Since HRSA issued its Guidelines in 2011, the Departments have recognized that religious exemptions from the contraceptive Mandate are appropriate. The details of the scope of such exemptions are discussed in further detail below. In general, the Departments conclude it is appropriate to maintain the exemptions created by the Religious IFC to avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals. The Departments do not believe the previous exemptions are adequate, because some religious objections by plan sponsors and individuals were favored with exemptions, some were not subjected to contraceptive coverage if they fell under the indirect exemption for certain self-insured church plans, and others had to choose between the Mandate and the accommodation even though they objected to both. The Departments wish to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage. The lack of a congressional mandate that contraceptives be covered, much less that they be covered without religious exemptions, has also informed the Departments' decision to expand the exemptions. And Congress's decision not to apply PHS Act section 2713 to grandfathered plans has likewise informed the Departments' decision whether exemptions to the contraceptive Mandate are appropriate.

Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements of the Religious Freedom Restoration Act. And Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive coverage Mandate by the exercise of agency discretion, that we also include exemptions for the protection of religious beliefs in certain cases. The expanded exemptions finalized in these rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. They are also consistent with the intent of Executive Order 13535 (March 24, 2010), which was issued upon the signing of the ACA and declared that, ''[u]nder the Act, longstanding federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Public Law 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.''

Some commenters argued that Congress's failure to explicitly include

religious exemptions in PHS Act section 2713 itself is indicative of an intent that such exemptions not be included, but the Departments disagree. As noted above, Congress also failed to require contraceptive coverage in PHS Act section 2713. And the commenters' argument would negate not just these expanded exemptions, but the previous exemptions for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting religious beliefs in the context of certain federal health care requirements.

If there is to be a federal contraceptive mandate that fails to include some—or, in the views of some commenters, any—religious exemptions, the Departments do not believe it is appropriate for us to impose such a regime through discretionary administrative measures. Instead, such a serious imposition on religious liberty should be created, if at all, by Congress, in response to citizens exercising their rights of political participation. Congress did not prohibit religious exemptions under this Mandate. It did not even require contraceptive coverage under the ACA. It left the ACA subject to RFRA, and it specified that additional women's preventive services will only be required coverage as provided for in Guidelines supported by HRSA. Moreover, Congress legislated in the context of the political consensus on conscientious exemptions for health care that has long been in place. Since *Roe* v. *Wade* in 1973, Congress and the states have consistently offered religious exemptions for health care providers and others concerning issues such as sterilization and abortion, which implicate deep disagreements on scientific, ethical, and religious (and moral) concerns. Indeed over the last 44 years, Congress has repeatedly expanded religious exemptions in similar cases, including to contraceptive coverage. Congress did not purport to deviate from that approach in the ACA. Thus, we conclude it is appropriate to specify in these final rules, that, if the Guidelines continue to maintain a contraceptive coverage requirement, the expanded exemptions will apply to those Guidelines and their enforcement.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for religious beliefs in the context of certain Federal health care requirements. Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held religious beliefs to the extent the Guidelines otherwise include contraceptive coverage.[12] These exemptions do not prohibit any services, nor do they authorize employers to prohibit employees from obtaining any services. The Religious IFC and these final rules simply refrain from imposing the federal Mandate that employers and health insurance issuers cover contraceptives in their health plans where compliance with the Mandate would violate their sincerely held religious beliefs. And though not necessary to the Departments' decision here, the Departments note that the Church Amendments explicitly protect entities and that several subsequent federal conscience statutes have protected against federal mandates in health coverage.

The Departments note that their decision is also consistent with state practice. A significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[13] Although the practice of states is not a limit on the discretion delegated to HRSA by the ACA, nor is it a statement about what the federal government may do consistent with RFRA or other limitations or protections embodied in federal law, such state practices can inform the Departments' view that it is appropriate to protect religious liberty as an exercise of agency discretion.

The Departments decline to adopt the suggestion of some commenters to use these final rules to revoke the contraceptive Mandate altogether, such as by declaring that HHS through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). Although previous regulations were used to authorize religious exemptions and accommodations to the imposition of the Guidelines' coverage of contraception, the issuance of the Guidelines themselves in 2011 describing what items constitute recommended women's preventive services, and the update to those recommendations in December 2016, did not occur through the regulations that preceded the 2017 Religious IFC and these final rules. The Guidelines' specification of which women's preventive services were recommended were issued, not by regulation, but directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The Departments decline to accept the invitation of some commenters to use these rules to specify whether HRSA includes contraceptives in the Guidelines at all. Instead the Departments conclude it is appropriate for these rules to continue to focus on restating the statutory language of PHS Act section 2713 in regulatory form, and delineating what exemptions and accommodations apply if HRSA lists contraceptives in its Guidelines. Some commenters said that if contraceptives are not removed from the Guidelines entirely, some entities or individuals with religious objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in the Religious IFC and these final rules cover a broad range of entities and individuals. The Departments are not aware of specific groups or individuals whose religious beliefs would still be substantially burdened by the Mandate after the issuance of these final rules.

Some commenters asserted that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

[13] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'', The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These rules focus on what religious exemptions and accommodations shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacients.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content of, and the process for developing and updating, the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov.*

The Departments conclude that it would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption. In the past, the Departments had stated in our regulations and court briefs that the previous accommodation process required contraceptive coverage or payments in a way that is ''seamless'' with the coverage provided by the objecting employer. As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued. The Departments have attempted to identify an accommodation process that would eliminate the religious objections of all plaintiffs, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but we stated in January 2017 that we were unable to develop such an approach at that time.[14] The Departments continue to believe that, because of the nature of the accommodation process, merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate. Instead, we conclude that the most appropriate approach to resolve these concerns is to expand the exemptions as set forth in the Religious IFC and these final rules, while maintaining the accommodation as an option for providing contraceptive coverage, without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.

Comments considering the appropriateness of exempting certain specific kinds of entities or individuals are discussed in more detail below.

C. The First Amendment and the Religious Freedom Restoration Act

Some commenters said that the Supreme Court ruled that the exemptions to the contraceptive Mandate, which the Departments previously provided to houses of worship and integrated auxiliaries, were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but exemptions beyond those are not. But in *Hobby Lobby* and *Zubik,* the Supreme Court did not decide whether the exemptions previously provided to houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate to other organizations unless RFRA prohibits the Departments from doing so. Moreover, the previous church exemption, which applied automatically to all churches whether or not they had even asserted a religious objection to contraception, 45 CFR 147.141(a), is not tailored to any plausible free-exercise concerns. The Departments decline to adopt the view that RFRA does not apply to other religious organizations, and there is no logical explanation for how RFRA could require the church exemption but not this expanded religious exemption, given that the accommodation is no less an available alternative for the former than the latter.

Commenters disagreed about the scope of RFRA's protection in this context. Some commenters said that the expanded exemptions and accommodation are consistent with RFRA. Some also said that they are required by RFRA, as the Mandate imposes substantial burdens on religious exercise and fails to satisfy the compelling-interest and least-restrictive-means tests imposed by RFRA. Other commenters, however, contended that the expanded exemptions and accommodation are neither required by, nor consistent with, RFRA. In this vein, some argued that the Departments have a compelling interest to deny religious exemptions, that there is no less restrictive means to achieve its goals, or that the Mandate or its accommodation process do not impose a substantial burden on religious exercise.

For the reasons discussed below, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden. Here, after further consideration of these issues and review of the public comments, the Departments have determined that a broader exemption, rather than a mere accommodation, is the appropriate response.

In addition, with respect to religious employers, the Departments conclude that, without finalizing the expanded exemptions, and therefore requiring certain religiously objecting entities to choose between the Mandate, the accommodation, or penalties for noncompliance—or requiring objecting individuals to choose between purchasing insurance with coverage to which they object or going without insurance—the Departments would violate their rights under RFRA.

1. Discretion To Provide Religious Exemptions

In the Religious IFC, we explained that even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised.

The Departments received conflicting comments on this issue. Some commenters agreed that the Departments have administrative discretion to address the religious objections even if the Mandate and accommodation did not violate RFRA. Other commenters expressed the view that RFRA does not provide such discretion, but only allows exemptions when RFRA requires exemptions. They contended that RFRA does not require exemptions for entities covered by the expanded exemptions of the Religious IFC, but that subjecting those entities to the accommodation satisfies RFRA, and therefore RFRA provides the Departments with no additional authority to exempt those entities. Those commenters further contended that because, in their view, section 2713(a)(4) does not authorize the

[14] *See* Departments of Labor, Health and Human Services, and the Treasury, ''FAQs About Affordable Care Act Implementation Part 36,'' (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

expanded exemptions, no statutory authority exists for the Departments to finalize the expanded exemptions.

As discussed above, the Departments disagree with the suggestions of commenters that section 2713(a)(4) does not authorize the Departments to adopt the expanded exemptions. Nevertheless, the Departments note that the expanded exemptions for religious objectors also rest on an additional, independent ground: The Departments have determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*. Indeed, with respect to at least some objecting entities, an expanded exemption, as opposed to the existing accommodation, is required by RFRA. The Departments disagree with commenters who contend RFRA does not give the Departments discretion to offer these expanded exemptions.

The Departments' determination about their authority under RFRA rests in part on the Departments' reassessment of the interests served by the application of the Mandate in this specific context. Although the Departments previously took the position that the application of the Mandate to objecting employers was narrowly tailored to serve a compelling governmental interest, as discussed below the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Particularly under those circumstances, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement or instead to attempt to create an accommodation that would mitigate the burden. And here, the Departments have determined that a broader exemption rather than the existing accommodation is the appropriate response. That determination is informed by the Departments' reassessment of the relevant interests, as well as by their desire to bring to a close the more than five years of litigation over RFRA challenges to the Mandate.

Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive Mandate, pursuant to *Hobby Lobby*—neither RFRA nor the ACA *prescribes* the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent (on the view of some commenters, with which the Departments disagree, that section 2713(a)(4) does not itself authorize the Departments to recognize exceptions). The prior administration *chose* to do so through the complex accommodation it created, but nothing in RFRA or the ACA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. After all, on the theory that section 2713(a)(4) allows for no exemptions, the accommodation also departed from section 2713(a)(4) in the sense that employers were not themselves offering contraceptive coverage, and the ACA did not require the Departments to choose that departure rather than the expanded exemptions as the exclusive method to satisfy their obligations under RFRA to eliminate the substantial burden imposed by the Mandate. The agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA. *See* 82 FR at 47798; *see also Ricci* v. *DeStefano,* 557 U.S. 586, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban). Indeed, if the Departments had simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result now based merely on path dependence.

Although the foregoing analysis is independently sufficient, additional support for this view is provided by the Departments' conclusion, as explained more fully below, that an expanded exemption is required by RFRA for at least some objectors. In the Religious IFC, the Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation, (82 FR at 47800), a conclusion that was confirmed by some commenters (and the continued litigation over the accommodation).[15] Some commenters agreed the religious objections could not be satisfied by amending the accommodation without expanding the exemptions, because if the accommodation requires an objecting entity's issuer or third party administrator to provide or arrange contraceptive coverage for persons covered by the plan because they are covered by the plan, this implicates the objection of entities to the coverage being provided through their own plan, issuer, or third party administrator. Other commenters contended the accommodation could be modified to satisfy RFRA concerns without extending exemptions to objecting entities, but they did not propose a method of modifying the accommodation that would, in the view of the Departments, actually address the religious objections to the accommodation.

In the Departments' view, after considering all the comments and the preceding years of contention over this issue, it is appropriate to finalize the expanded exemptions rather than merely attempt to change the accommodation to satisfy religious objections. This is because if the accommodation still delivers contraceptive coverage through use of the objecting employer's plan, issuer, or third party administrator, it does not address the religious objections. If the accommodation could deliver contraceptive coverage independent and separate from the objecting employer's plan, issuer, and third party administrator, it could possibly address the religious objections, but there are two problems with such an approach. First, it would effectively be an exemption, not the accommodation as it has existed, so it would not be a reason not to offer the expanded exemptions finalized in these rules. Second, although (as explained above) the Departments have authority to provide exemptions to the Mandate, the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided

[15] *See* RFI, 81 FR 47741 (July 26, 2016); Departments of Labor, Health and Human Services, and the Treasury, ''FAQs, About Affordable Care Act Implementation Part 36,'' (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections. The Departments are aware of ways in which certain persons covered by an objecting employer might obtain contraceptive coverage through other governmental programs or requirements, instead of through objecting employers' plans, issuers, or third party administrators, and we mention those elsewhere in this rule. But those approaches do not involve the accommodation, they involve the expanded exemptions, plus the access to contraceptives through separate means.

2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances

Before the Religious IFC, the Departments had previously contended that the Mandate did not impose a substantial burden on entities and individuals under RFRA; that it was supported by a compelling government interest; and that it was, in combination with the accommodation, the least restrictive means of advancing that interest. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with sincerely held religious objections, that argument was rejected in *Hobby Lobby,* which held that the Mandate imposes a substantial burden and was not the least restrictive means of achieving any compelling governmental interest. *See* 134 S. Ct. at 2775–79. In the Religious IFC, the Departments revisited its earlier conclusions and reached a different view, concluding that requiring compliance through the Mandate or accommodation constituted a substantial burden on the religious exercise of many entities or individuals with religious objections, did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest, so that requiring such compliance led to the violation of RFRA in many instances. (82 FR at 47806).

In general, commenters disagreed about this issue. Some commenters agreed with the Departments, and with some courts, that requiring entities to choose between the contraceptive Mandate and its accommodation violated their rights under RFRA, because it imposed a substantial burden on their religious exercise, did not advance a compelling government interest, and was not the least restrictive means of achieving such an interest. Other commenters contended that requiring compliance either with the Mandate or the accommodation did not violate RFRA, agreeing with some courts that have concluded the accommodation does not substantially burden the religious exercise of organizations since, in their view, it does not require organizations to facilitate contraceptive coverage except by submitting a self-certification form or notice, and requiring compliance was the least restrictive means of advancing the compelling interest of providing contraceptive access to women covered by objecting entities' plans.

The Departments have examined further, including in light of public comments, the issue of whether requiring compliance with the combination of the contraceptive Mandate and the accommodation process imposes a substantial burden on entities that object to both, and is the least restrictive means of advancing a compelling government interest. The Departments now reaffirm the conclusion set forth in the Religious IFC, that requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.

a. Substantial Burden

The Departments concur with the description of substantial burdens expressed recently by the Department of Justice:

> A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.
>
> Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion.[16]

The Mandate and accommodation under the previous regulation forced certain non-exempt religious entities to choose between complying with the Mandate, complying with the accommodation, or facing significant penalties. Various entities sincerely contended, in litigation or in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion, either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice. To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings,* 801 F.3d at 942. Likewise, reconsideration of these issues has also led the Departments to conclude that the Mandate imposes a substantial burden on the religious beliefs of an individual employee who opposes coverage of some (or all) contraceptives in his or her plan on the basis of his or her religious beliefs, and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because the Mandate requires that employer or issuer to provide a plan that covers all FDA-approved contraceptives. The Departments disagree with commenters that contend the accommodation did not impose a substantial burden on religiously objecting entities, and agree with other commenters and some courts and judges that concluded the accommodation can be seen as imposing a substantial burden on religious exercise in many instances.

b. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have concluded, after reassessing the relevant interests and, in light of the public comments received, that it does not. This is based on several independent reasons.

First, as discussed above, the structure of section 2713(a)(4) and the ACA evince a desire by Congress to

[16] *See* Federal Law Protections for Religious Liberty, 82 FR 49668, 49669 (Oct. 26, 2017).

grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4). This informs the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling interest, as doing so imposes a substantial burden on religious exercise. As the Department of Justice has explained, ''[t]he strict scrutiny standard applicable to RFRA is exceptionally demanding,'' and ''[o]nly those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent.'' [17]

Second, since the day the contraceptive Mandate came into effect in 2011, the Mandate has not applied in many circumstances. To begin, the ACA does not apply the Mandate, or any part of the preventive services coverage requirements, to grandfathered plans. To continue, the Departments under the last Administration provided exemptions to the Mandate and expanded those exemptions through multiple rulemaking processes. Those rulemaking processes included an accommodation that effectively left employees of many non-exempt religious nonprofit entities without contraceptive coverage, in particular with respect to self-insured church plans exempt from ERISA. Under the previous accommodation, once a self-insured church plan filed a self-certification or notice, the accommodation relieved it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would generally have transferred the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments recognized that they lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to health insurance issuers, but does not apply to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs of those plans to provide such coverage, led to significant disparity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

Third party administrators for some, but not all, religious nonprofit organizations were subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they administer a self-insured church plan. Notably, many of those nonprofit organizations were not houses of worship or integrated auxiliaries. Under section 3(33)(C) of ERISA, organizations whose employees participate in self-insured church plans need not be churches so long as they are controlled by or ''share[ ] common religious bonds and convictions with'' a church or convention or association of churches. The effect is that many similar religious organizations were being treated differently with respect to their employees receiving contraceptive coverage based solely on whether organization employees participate in a church plan.

This arrangement encompassed potentially hundreds of religious non-profit organizations that were not covered by the exemption for houses of worship and integrated auxiliaries. For example, the Departments were sued by two large self-insured church plans—Guidestone and Christian Brothers.[18] Guidestone is a plan organized by the Southern Baptist convention that covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not. Christian Brothers is a plan that covers Catholic churches and integrated auxiliaries and has said in litigation that it covers about 500 additional entities that are not exempt as churches. In several other lawsuits challenging the Mandate, the previous Administration took the position that some plans established and maintained by houses of worship but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government ''has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time.'' *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

Third, the Departments now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. The Mandate is not narrowly tailored to advance the government's interests and appears both overinclusive and underinclusive. It includes some entities where a contraceptive coverage requirement seems unlikely to be effective, such as religious organizations of certain faiths, which, according to commenters, primarily hire persons who agree with their religious views or make their dedication to their religious views known to potential employees who are expected to respect those views. The Mandate also does not apply to a significant number of entities encompassing many employees and for-profit businesses, such as grandfathered plans. And it does not appear to target the population defined, at the time the Guidelines were developed, as being the most at-risk of unintended pregnancy, that is, ''women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority.'' [19] Rather than focusing on this group, the Mandate is a broad-sweeping requirement across employer-provided coverage and the individual and group health insurance markets.

The Department received conflicting comments on this issue. Some commenters agreed that the government does not have a compelling interest in applying the Mandate to objecting religious employers. They noted that the expanded exemptions will impact only a small fraction of women otherwise affected by the Mandate and argued that refusing to provide those exemptions would fail to satisfy the compelling interest test. Other commenters, however, argued that the government has a broader interest in the Mandate because all women should be considered at-risk of unintended pregnancy. But the Institute of Medicine (IOM), in discussing whether contraceptive coverage is needed, provided a very specific definition of the population of women most at-risk of unintended pregnancy.[20] The Departments believe it is appropriate to consider the government's interest in

[17] *Id.* at 49670.

[18] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[19] Institute of Medicine, ''Clinical Preventive Services for Women: Closing the Gaps'' at 102 (2011).

[20] Id.

the contraceptive coverage requirement using the definition that formed the basis of that requirement and the justifications the Departments have offered for it since 2011. The Mandate, by its own terms, applies not just to women most at-risk of unintended pregnancy as identified by the IOM, but applies to any non-grandfathered ''group health plan and a health insurance issuer offering group or individual health insurance coverage.'' PHS Act section 2713(a). Similarly, the exemptions and accommodation in previous rules, and the expanded exemptions in these rules, do not apply only to coverage for women most at-risk of unintended pregnancy, but to plans where a qualifying objection exists based on sincerely held religious beliefs without regard to the types of women covered in those plans. Seen in this light, the Departments believe there is a serious question whether the administrative record supports the conclusion that the Mandate, as applied to religious objectors encompassed by the expanded exemptions, is narrowly tailored to achieve the interests previously identified by the government. Whether and to what extent it is certain that an interest in health is advanced by refraining from providing expanded religious exemptions is discussed in more detail below in section II.F., Health Effects of Contraception and Pregnancy.

Fourth, the availability of contraceptive coverage from other possible sources—including some objecting entities that are willing to provide some (but not all) contraceptives, or from other governmental programs for low-income women—detracts from the government's interest to refuse to expand exemptions to the Mandate. The Guttmacher Institute recently published a study that concluded, ''[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,'' and ''there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.'' [21] In discussing why they did not see such an effect from the Mandate, the authors suggested that ''[p]rior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use. In addition, cost is not the only barrier to accessing a full range of method options,'' and ''[t]he fact that income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings may reflect broader access to affordable and/or free contraception made possible through programs such as Title X.''

Fifth, the Departments previously created the accommodation, in part, as a way to provide for payments of contraceptives and sterilization in a way that is ''seamless'' with the coverage that eligible employers provide to their plan participants and their beneficiaries. (80 FR 41318). As noted above, some commenters contended that seamlessness between contraceptive coverage and employer sponsored insurance is important and is a compelling governmental interest, while other commenters disagreed. Neither Congress, nor the Departments in other contexts, have concluded that seamlessness, as such, is a compelling interest in the federal government's delivery of contraceptive coverage. For example, the preventive services Mandate itself does not require contraceptive coverage and does not apply to grandfathered plans, thereby failing to guarantee seamless contraceptive coverage. The exemption for houses of worship and integrated auxiliaries, and the application of the accommodation to certain self-insured church plans, also represents a failure to achieve seamless contraceptive coverage. HHS's Title X program provides contraceptive coverage in a way that is not necessarily seamless with beneficiaries' employer sponsored insurance plans. After reviewing the public comments and reconsidering this issue, the Departments no longer believe that if a woman working for an objecting religious employer receives contraceptive access in ways that are not seamless to her employer sponsored insurance, a compelling government interest has nevertheless been undermined. Therefore the Departments conclude that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides employers' religious objections to the contraceptive Mandate.

Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result. This is discussed in more detail in following section, II.D., Burdens on Third Parties.

D. Burdens on Third Parties

The Departments received a number of comments on the question of burdens that these rules might impose on third parties. Some commenters asserted that the expanded exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might not otherwise receive contraceptive coverage with no cost-sharing. These included commenters agreeing with the Departments' explanations in the Religious IFC, stating that unintended pregnancies were decreasing before the Mandate was implemented, and asserting that any benefit that third parties might receive in getting contraceptive coverage does not justify forcing religious persons to provide such products in violation of their beliefs. Other commenters disagreed, asserting that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies,[22] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as those found in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as

[21] M.L. Kavanaugh et al., Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[22] Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.

prioritizing religious liberty of exempted entities over the religious liberty, conscience, or choices of women who would not receive contraceptive coverage where an exemption is used.

The Departments note that the exemptions in the Religious IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these final rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. HHS exercised discretion granted to HRSA by the Congress to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits. But Congress did not create a right to receive contraceptive coverage from other private citizens through PHS Act section 2713, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Religious IFC and these rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third-party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae,* 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the Government refrain from requiring private citizens, in violation of their religious beliefs, to cover contraception for other citizens. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.''). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting religious objections to such governmental mandates, especially where, as here, the mandate is not an explicit statutory requirement.[23] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these final rules.

As the Department of Justice has observed, the fact that exemptions may relieve a religious adherent from conferring a benefit on a third party ''does not categorically render an exemption unavailable,'' and RFRA still applies.[24] The Departments conclusion on this matter is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants ''to confer benefits on third parties.'' *See Hobby Lobby,* 134 S. Ct. at 2781 n.37. Here, no law contains such a requirement, but the Mandate is derived from an administrative exercise of discretion that Congress charged HRSA and the Departments with exercising. Burdens that may affect third parties as a result of revisiting the exercise of agency discretion may be relevant to the RFRA analysis, but they cannot be dispositive. ''Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).'' *Id.*

When government relieves burdens on religious exercise, it does not violate the Establishment Clause; rather, ''it follows the best of our traditions.'' *Zorach* v. *Clauson,* 343 U.S. 306, 314 (1952). The Supreme Court's cases ''leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.'' *Board of Educ. of Kiryas Joel Village Sch. Dist.* v. *Grumet,* 512 U.S. 687, 705 (1994). Rather, the Supreme Court ''has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause.'' *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 334 (1987) (quoting *Hobbie* v. *Unemployment Appeals Comm'n of Fla.,* 480 U.S. 136, 144–45 (1987)). ''[T]here is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.'' *Cutter* v. *Wilkinson,* 544 U.S. 709, 713 (2005) (internal quotation omitted). Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII's prohibition against discrimination in employment on the basis of religion, *see Amos,* 483 U.S. at 335–39; a state property tax exemption for religious organizations, *see Walz* v. *Tax Comm'n of City of New York,* 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach,* 343 U.S. at 315.

Before 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under PHS

[23] *See, for example, Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (''[A] woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'').

[24] See Federal Law Protections for Religious Liberty, 82 FR at 49670.

Act section 2713 to be covered by grandfathered plans. Many States do not impose contraceptive coverage mandates, or they offer religious exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or State courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters said that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others said that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to states or local governments. We are not aware of instances where the various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage (other than through the Religious and Moral IFCs), have been determined to cause a cognizable injury to state or local governments. Some states that were opposed to the IFCs submitted comments objecting to the potential impacts on their programs resulting from the expanded exemptions, but they did not adequately demonstrate that such impacts would occur, and they did not explain whether, or to what extent, they were impacted by the other kinds of instances mentioned above in which no federal mandate of contraceptive coverage has applied to certain plans. The Departments find no legal prohibition on finalizing these rules based on the speculative suggestion of an impact on state or local governments, and we disagree with the suggestion that once we have exercised our discretion to deny exemptions—no matter how recently or incompletely—we cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, these expanded exemptions apply only to a small fraction of entities to which the Mandate would otherwise apply—those with qualifying religious objections. Public comments did not provide reliable data on how many entities would use these expanded religious exemptions, in which states women in such plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would have to cover. As mentioned above, at least one study, published by the Guttmacher Institute, concluded the Mandate has caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the expanded exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates.

In the discussion below concerning estimated economic impacts of these rules, the Departments explain there is not reliable data available to accurately estimate the number of women who may lose contraceptive coverage under these rules, and the Departments set forth various reasons why it is difficult to know how many entities will use these exemptions or how many women will be impacted by those decisions. Solely for the purposes of determining whether the rules have a significant economic impact under Executive Order 12,866, and in order to estimate the broadest possible impact so as to determine the applicability of the procedures set forth in that Executive Order, the Departments propose that the rules will affect no more than 126,400 women of childbearing age who use contraceptives covered by the Guidelines, and conclude the economic impact falls well below $100 million. As explained below, that estimate assumes that a certain percentage of employers which did not cover contraceptives before the ACA will use these exemptions based on sincerely held religious beliefs. The Departments do not actually know that such entities will do so, however, or that they operate based on sincerely held religious beliefs against contraceptive coverage. The Departments also explain that other exemptions unaffected by these rules may encompass many or most women potentially affected by the expanded exemptions. In other words, the houses of worship and integrated auxiliaries exemption, the accommodation's failure to require contraceptive coverage in certain self-insured church plans, the non-applicability of PHS Act section 2713 to grandfathered plans, and the permanent injunctive relief many religious litigants have received against section 2713(a)(4), may encompass a large percentage of women potentially affected by religious objections, and therefore many women in those plans may not be impacted by these rules at all. In addition, even if 126,400 women might be affected by these rules, that number constitutes less than 0.1% of all women in the United States.[25] This suggests that if these rules have any impact on state or local governments, it will be statistically de minimus. The Departments conclude that there is insufficient evidence of a potential negative impact of these rules on state and local governments to override the appropriateness of deciding to finalize these rules.

Some commenters contended that the expanded exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions

[25] U.S. Census Bureau, ''Quick Facts: Population Estimates, July 1, 2017'' (estimating 325,719,178 persons in the U.S., 50.8% of which are female), available at *https://www.census.gov/quickfacts/fact/table/US/PST045217.*

would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these final rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The expanded exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead they allow entities that have sincerely held religious objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

These commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.,* 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII ''does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women''). Second, these rules create no disparate impact. The women's preventive services mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inures to the specific benefit of women—men are denied any benefit from that section. Both before and after these final rules, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or male contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions are expanded to encompass religious objections. The previous regulations, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that few women of childbearing age in the country will be affected by these expanded exemptions.[26] In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters observed that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some objected to the suggestion in the Religious IFC that many forms of contraceptives are available for around $50 per month and other forms, though they bear a higher one-time cost, cost a similar amount over the duration of use. But some of those commenters cited sources maintaining that birth control pills can cost up to $600 per year (that is, $50 per month), and said that IUDs, which can last three to six years or more,[27] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters said that, for lower income women, contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately insured individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, pointing out that some government programs that provide family planning have income and eligibility thresholds, so that women earning certain amounts above those levels would need to pay full cost for contraceptives if they were no longer covered in their health plans.

The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules. In addition, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed regulation to amend the regulations governing its Title X family planning program. The proposed regulation would amend the definition of ''low income family''—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions (see 83 FR 25502). If that regulation is finalized as proposed, it could further reduce any potential effect of these final rules on women's access to contraceptives. That proposal also demonstrates that the government has other means available to it for increasing women's access to contraception. Some of those means are less restrictive of religious exercise than imposition of the contraceptive Mandate on employers with sincerely held religious objections to providing such coverage.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS ''shall not promulgate any regulation'' that ''creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,'' ''impedes timely access to health care services,'' ''interferes with communications regarding a full range of treatment options between the patient and the provider,'' ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,'' ''violates the principles of informed consent and the ethical standards of health care professionals,'' or ''limits the

[26] Below, the Departments estimate that no more than 126,400 women of childbearing age will be affected by the expanded exemptions. As noted above, this is less than 0.1% of the over 165 million women in the United States. The Departments previously estimated that, at most 120,000 women of childbearing age would be affected by the expanded exemptions. *See* Religious IFC, 82 FR 47,823–84.

[27] *See, for example,* Planned Parenthood, ''IUD,'' *https://www.plannedparenthood.org/learn/birth-control/iud.*

availability of health care treatment for the full duration of a patient's medical needs.'' 42 U.S.C. 18114. Such commenters urged, for example, that the Religious IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections. The Departments, which administer both ACA section 1554 and PHS Act section 2713, did not conclude that the exemptions or accommodations in those regulations violated section 1554. Moreover, the decision not to impose a governmental mandate is not the ''creation'' of a ''barrier,'' especially when that mandate requires private citizens to provide services to other private citizens. Nor, in any event, are the exemptions from the Mandate unreasonable. Section 1554 of the ACA does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 prohibit the Departments from providing exemptions for burdens on religious exercise, or, as is the case here, from refraining to impose the Mandate in cases where religious exercise would be burdened by it. In light of RFRA and the First Amendment, providing religious exemptions is a reasonable administrative response in the context of this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts. Religious exemptions from federal mandates in sensitive health contexts have existed in federal laws for decades, and President Obama referenced them when he issued Executive Order 13535 (March 24, 2010), declaring that, under the ACA, ''longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact,'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.'' While the text of Executive Order 13535 does not require the expanded exemptions issued in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect religious beliefs.

In short, the Departments do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

Members of the public have widely divergent views on whether expanding the exemptions is good public policy. Some commenters said the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind expanding the exemptions and arguing that the exemptions would not interfere with the physician-patient relationship. For all the reasons explained at length in this preamble, the Departments have determined that these rules are good policy. Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

E. Interim Final Rulemaking

The Departments received several comments about their decision to issue the Religious IFC as interim final rules with requests for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Religious IFC in that way, agreeing that the Departments had explicit statutory authority to do so, good cause under the Administrative Procedure Act (APA), or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe legal authority existed to issue the Religious IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Religious IFC, the Departments issued three interim final rules implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Religious IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Religious IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules are being issued after receiving and thoroughly considering public comments as requested in the Religious IFC. These final rules therefore comply with the APA's notice and comment requirements.

F. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause or are associated with an increased risk of depression,[28] venous thromboembolic

[28] Commenters cited Charlotte Wessel Skovlund et al., ''Association of Hormonal Contraception with Depression,'' 73 *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) (''Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression,

disease,[29] fatal pulmonary embolism,[30] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[31] hypertension,[32] HIV–1 acquisition and transmission,[33] and breast, cervical, and liver cancers.[34] Some commenters also observed that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that contraceptive access does not reduce unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 IOM Report's discussions of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality.[35] Commenters also said studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer,[36] and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[37] Some commenters said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters said that, in the Religious IFC, the Departments made incorrect statements concerning scientific studies. For example, some commenters argued there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Religious IFC for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality Report No.: 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR at 47804, the 2013 Agency for Healthcare Research and Quality study, and others, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to take into account both of those studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[38] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or, more specifically, the part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some

suggesting depression as a potential adverse effect of hormonal contraceptive use.'').

[29] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception: Recent Advances and Controversies,'' 82 *Fertility and Sterility* S20, S26 (2004); V.A. Van Hylckama et al., ''The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,'' 339 *Brit. Med. J.* 339b2921 (2009); Y. Vinogradova et al., ''Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,'' 350 *Brit. Med. J.* 350h2135 (2015) (''Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.''); Ø. Lidegaard et al., ''Hormonal contraception and risk of venous thromboembolism: national follow-up study,'' 339 *Brit. Med. J.* b2890 (2009): M. de Bastos et al., ''Combined oral contraceptives: venous thrombosis,'' Cochrane Database Syst. Rev. (no. 3, 2014). CD010813. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* and Robert A. Hatcher et al., *Contraceptive Technology* 405–07 (Ardent Media 18th rev. ed. 2004).

[30] Commenters cited N.R. Poulter, ''Risk of Fatal Pulmonary Embolism with Oral Contraceptives,'' 355 *Lancet* 2088 (2000).

[31] Commenters cited Ø. Lidegaard et al., ''Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception,'' 366 *N. Eng. J. Med.* 2257, 2257 (2012) (risks ''increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg''); Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception''; M. Vessey et al., ''Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,'' 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, ''Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,'' 349 *Lancet* 1202, 1202–09(1997); K.M. Curtis et al., Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review, 73 Contraception 73179, 179–88 (2006); L.A. Gillum et al., ''Ischemic stroke risk with oral contraceptives: A meta analysis,'' 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[32] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology* 407, 445 (Ardent Media 18th rev. ed. 2004).

[33] Commenters cited Renee Heffron et al., ''Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study,'' 12 *Lancet Infectious Diseases 19, 24* (2012) (''Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men.''); and ''Hormonal Contraception Doubles HIV Risk, Study Suggests,'' *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[34] Commenters cited ''Oral Contraceptives and Cancer Risk'' (Mar. 21, 2012, National Cancer Institute (reviewed Feb. 22, 2018), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* S.N. Bhupathiraju et al., ''Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study,'' 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, ''The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment'', World Health Organization (Sept. 2005), *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, ''Known and Probably Human Carcinogens,'' American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

[35] Citing, *e.g.,* Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809–23, and John Hopkins Bloomberg Public Health School of Health, Contraception Use Averts 272,000 Maternal Deaths Worldwide, *https://www.jhsph.edu/news/news-releases/2012/ahmed-contraception.html.*

[36] Citing, *e.g.,* Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. International Journal of Endocrinology and Metabolism, 11 (1), 41–47.

[37] Citing, *e.g.,* id., and American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. (2015, January). Committee Opinion Number 615: Access to Contraception. As discussed below, to the extent that contraceptives are prescribed to treat existing health conditions, and not for preventive purposes, the Mandate would not be applicable.

[38] 82 FR at 47803–04.

commenters agreed with the quotation, in the Religious IFC, of FDA materials [39] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Religious IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Religious IFC that some persons believe those possible effects are ''abortifacient.''

The objection on this issue appears to be partially one of semantics. People disagree about whether to define ''conception'' or ''pregnancy'' to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items ''abortifacient''—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 (''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.'').

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere religious objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief under RFRA.[40] Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer expanded religious exemptions with respect to this Mandate.

The Departments also received comments about their discussion of the uncertain effects of the expanded exemptions on teen sexual activity. In this respect, the Departments stated, ''With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that '[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.' '' [41] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that denying expanded exemptions to the Mandate is not a narrowly tailored way to advance the Government's interests in reducing teen pregnancy, and suggesting there are means of doing so that are less restrictive of religious exercise.[42] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[43]

Many commenters opposing the Religious IFC misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, we note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments' conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including but not limited to reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline), and concluded ''that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.'' [44] One

[39] FDA's guide ''Birth Control: Medicines To Help You,'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

[40] ''Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.'' *Hobby Lobby,* 134 S. Ct. at 2762–63. ''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.'' *Id.* at 2765–66.

[41] Citing J.S. Santelli & A.J. Melnikas, ''Teen fertility in transition: recent and historic trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at *http://public.econ.duke.edu/~psarcidi/addicted13.pdf. See also* K. Buckles & D. Hungerman, ''The Incidental Fertility Effects of School Condom Distribution Programs,'' *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* (''access to condoms in schools increases teen fertility by about 10 percent'' and increased sexually transmitted infections).

[42] *See* Helen Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[43] *See, for example,* Lindberg L., Santelli J., ''Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,'' 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[44] Kearney MS and Levine PB, ''Investigating recent trends in the U.S. birth rate,'' 41 *J. Health*

study found that during the teen pregnancy decline between 2007–2012, teen sexual activity was also decreasing.[45] One study concluded that falling unemployment rates in the 1990s accounted for 85% of the decrease in rates of first births among 18–19 year-old African Americans.[46] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[47] One study concluded that an ''increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.'' [48] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[49] Some commenters also cited studies, which are not limited to the issue of teen pregnancy, that have found many women who have abortions report that they were using contraceptives when they became pregnant.[50]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing religious exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments for implementing the ACA.

G. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promotes the health and equality of women, especially low income women and promotes female participation and equality in the workforce. Other commenters contended that there was insufficient evidence that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed the study quoted above, published and revised by the Guttmacher Institute in October 2017, concluding that through 2014 there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy, that there was no significant shift from less effective to more effective methods, and that it was ''unclear'' whether this Mandate impacted contraceptive use because there was no significant increase in the use of contraceptive methods the Mandate covered.[51] These commenters also noted that, in the 29 States where contraceptive coverage mandates have been imposed statewide,[52] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[53] Other commenters, however, disputed the significance of these state statistics, noting that of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the expanded exemptions in these rules might have on the Mandate more broadly. The state mandates apply to a very large number of plans and plan participants, notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups are, and have been, exempt from the federal Mandate prior to the Religious IFC. The exemptions as set forth in the Religious IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might

Econ. 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[45] *See, for example,* K. Ethier et al., ''Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,'' 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* (''Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall. . . .'').

[46] Colen CG, Geronimus AT, and Phipps MG, ''Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,'' 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[47] Atkins DN and Wilkins VM, ''Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,'' 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[48] E. Collins & B. Herchbein, ''The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,'' *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* (''[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women'').

[49] *See* D. Paton & L. Wright, ''The effect of spending cuts on teen pregnancy,'' 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* (''Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates'').

[50] Commenters cited, for example, Guttmacher Institute, ''Fact Sheet: Induced Abortion in the United States'' (Jan. 2018) (''Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant''), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

[51] Kavanaugh, 97 *Contraception* at 14–21.

[52] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (June 11, 2018); Kaiser Family Foundation, ''State Requirements for Insurance Coverage of Contraceptives,'' Henry J Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[53] *See* Michael J. New, ''Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,'' 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

result from a broad contraceptive coverage mandate.

Some commenters expressed concern that providing exemptions to the Mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, PHS Act section 2713(a)(2) requires coverage of ''immunizations,'' and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting religious beliefs from certain health care mandates concerning issues such as sterilization, abortion and birth control.

Some commenters took issue with the conclusion set forth in the Religious IFC, which is similar to that asserted in the 2017 Guttmacher study, that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.'' They observed that more women have coverage of contraceptives and contraception counseling under the Mandate and that more contraceptives are provided without co-pays than before. Still other commenters argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [54] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also argued that studies show that decreases in unintended pregnancies are due to broader access of contraceptives. Finally, some commenters argued that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on our review, it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. We also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, are an appropriate exercise of the Departments' discretion.

Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise. The Departments view the provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for religious exercise set forth in the Religious IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

[54] Citing, for example, Adelle Simmons et al., ''The Affordable Care Act: Promoting Better Health for Women,'' Table 1, Assistant Secretary for Planning and Evaluation (June 14, 2016), *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

III. Description of the Text of the Regulations and Response to Additional Public Comments

Here, the Departments describe the regulatory text set forth prior to the Religious IFC, the regulations from that IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. As noted above, various members of the public provided comments that were supportive, or critical, of the Religious IFC overall, or of significant policies pertaining to those regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified these restatements to more closely align them with the text of PHS Act section 2713(a) and (a)(4).

Previous versions of these rules had varied from the statutory language. PHS Act section 2713(a) and (a)(4) require group health plans and health insurance issuers offering coverage to provide coverage without cost sharing for ''such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines'' supported by HRSA. In comparison, the previous version of regulatory restatements of this language (as drawn from 45 CFR 147.130(a)(1)

and (a)(1)(iv)) stated the coverage must include ''evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by'' HRSA. The Religious IFC amended this language to state, parallel to the language in section 2713(a)(4), that the coverage must include ''such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by'' HRSA.

These rules adopt as final, without change, the provisions in the Religious IFC amending 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). In this way, the regulatory text better conforms to the statutory language. In paragraph (a)(1) of the final regulations, instead of saying ''must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements . . . with respect to those items and services:'', the regulation now tracks the statutory language by saying ''must provide coverage for and must not impose any cost-sharing requirements . . . for—''. By eliminating the language ''coverage for all of the following items and services,'' and ''with respect to those items and services,'' the Departments do not intend that coverage for specified items and services will not be required, but we simply intend to simplify the text of the regulation to track the statute and avoid duplicative language.

By specifying that paragraph (a)(1)(iv) concerning the women's preventive services Guidelines encompasses ''such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132,'' the regulatory text also better tracks the statutory language that the Guidelines are for ''such additional'' preventive services as HRSA may ''provide[ ] for'' and ''support[ ].'' This text also eliminates language, not found in the statute, that the Guidelines are ''evidence-informed'' and ''binding.'' Congress did not include the word ''binding'' in PHS Act section 2713, and did include the words ''evidence-based'' or ''evidence-informed'' in section 2713(a)(1) and (a)(3), but omitted such terms from section 2713(a)(4). In this way, the regulatory text better comports with the scope of the statutory text. This text of paragraph (a)(1)(iv) also acknowledges that the Departments have decided Guidelines issued under section 2713(a)(4) will not be provided for or supported to the extent they exceed the exemptions and accommodation set forth in 45 CFR 147.131 and 147.132. Previous versions of the regulation placed that limit in 45 CFR 147.130(a)(1), but did not reiterate it in § 147.130(a)(1)(iv). To clearly set forth the applicability of the exemptions and accommodation, the Departments adopt as final the Religious IFC language, which included the language ''subject to §§ 147.131 and 147.132'' in both § 147.130(a)(1) and § 147.130(a)(1)(iv). Because these final rules adopt as final the Religious IFC language which includes the exemptions and accommodation in both §§ 147.131 and 147.132, and not just in § 147.131 as under the previous rules, the Departments correspondingly included references to both sections in this part.

Some commenters supported restoring the statutory language from PHS Act section 2713(a) and (a)(4) in the regulatory restatements of that language. Other commenters opposed doing so, asserting that Guidelines issued pursuant to section 2713(a)(4) must be ''evidence-informed'' and ''binding.'' The Departments disagree with the position that, even though Congress omitted those terms from section 2713(a)(4), their regulatory restatement of the statutory requirement should include those terms. Instead, the Departments conclude that it is more appropriate for the regulatory restatements of section 2713(a)(4) to track the statutory language in this regard, namely, ''as provided for in comprehensive guidelines supported by [HRSA] for purposes of'' that paragraph.

B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))

These final rules adopt as final, with changes based on comments as set forth below, the regulatory provision in the Religious IFC that moved the religious exemption from 45 CFR 147.131(a) to 45 CFR 147.132.

In the previous regulations, the exemption stated, at § 147.131(a), that HRSA's Guidelines ''may establish an exemption'' for the health plan or coverage of a ''religious employer,'' defined as ''an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.'' The Religious IFC moved the exemption to a new § 147.132, in which paragraph (a) discussed objecting entities, paragraph (b) discussed objecting individuals, paragraph (c) set forth a definition, and paragraph (d) discussed severability. The prefatory language to § 147.132(a)(1) stated that HRSA's Guidelines ''must not provide for or support the requirement of coverage or payments for contraceptive services'' for the health plan or coverage of an ''objecting organization,'' and thus that HRSA ''will exempt'' such an organization from the contraceptive coverage requirments of the Guidelines. The remainder of paragraph (a)(1), which is discussed in greater detail below, describes what entities are included as objecting organizations.

This language not only specifies that certain entities are ''exempt,'' but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only ''as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.'' To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are ''exempt'' by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as ''exempt,'' and in referring to the ''exemption'' encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When sections § 147.132(a)(1) and (a)(1)(i) specify that ''[a] group health plan,'' ''health insurance coverage provided in connection with a group health plan,'' and ''health insurance coverage offered or arranged by an objecting organization'' are exempt ''to the extent'' of the objections ''as specified in paragraph (a)(2),'' that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv)), the plan

sponsor, issuer, and plan covered in the exemption of § 147.132(a)(1) and (a)(1)(i) would face no penalty as a result of omitting certain contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while the objection of a plan sponsor (or entity that arranges coverage under the plan, as applicable) removes penalties from that plan's issuer, it only does so for that plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.132(a)(1)(iii) is included below.

The exemptions in § 147.132(a)(1) apply ''to the extent'' of the objecting entities' sincerely held religious convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters said it was unclear whether the plans of entities or individuals that religiously object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite religious objection against some but not all contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects, and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules, the Departments finalize the prefatory language of § 147.132(a) with the following change, so that the final rules state that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, ''to the extent of the objections specified below.''

The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying ''to the extent'' of the objection(s).

C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)

In 45 CFR 147.132(a)(1)(i) through (iii) and (b), the Religious IFC expands the exemption to plans of additional entities and individuals not encompassed by the exemption set forth in the regulations prior to the Religious IFC. Specific entities to which the expanded exemptions apply are discussed below.

The exemptions contained in previous regulations, at § 147.131(a), did not require exempt entities to submit any particular self-certification or notice, either to the government or to their issuer or third party administrator, in order to obtain or qualify for the exemption. Similarly, under the expanded exemptions in § 147.132, the Religious IFC did not require exempt entities to comply with a self-certification process. We finalize that approach in this respect without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[55] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosure documents must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported the expanded exemption's approach which maintained the policy of the previous exemption in not requiring exempt entities to comply with a self-certification process. They suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to religious objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters, however, favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process. Some commenters asked that the government publish a list of entities that claim the exemption.

The Departments believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption. The Departments believe the approach under the previous exemption is appropriate for the expanded exemption. Adding a self-certification or notice to the exemption process would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries in plans that reduce or eliminate contraceptive benefits as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these rules to continue to not require notices or self-certifications for using the exemption.

[55] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 102–3, & 104b–3(d), and 29 CFR 2590.715–2715. *See also* 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group and individual issuers).

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these rules. The expanded exemptions in these rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. The rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (Below, these rules discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that, where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed below, the Departments are including, in these final rules, language from the previous regulations protecting issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in and derived from the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators.

Regarding the Religious IFC's expansion of the exemption to other kinds of entities and individuals in general, commenters disagreed about the likely effects of the exemptions on the health coverage market. Some commenters said that expanding the exemptions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or offer only some contraceptives—to houses of worship and integrated auxiliaries; some commenters and litigants said that issuers were doing so. These cases where plans did not need to comply with the Mandate, and the Departments' previous accommodation process allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[56]

Concerning the prospect raised by commenters of different risk pools between men and women, PHS Act section 2713(a) itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage would be required. These rules do not require issuers to offer products that satisfy religiously objecting entities or individuals; they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to religious entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) Prefatory Text)

With respect to employers and others that sponsor group health plans, in § 147.132(a)(1)(i), the Religious IFC provided exemptions for non-governmental plan sponsors that object to coverage of all, or a subset of, contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs. The Departments finalize the prefatory text of § 147.132(a)(1)(i) without change.

The expanded exemptions covered any kind of non-governmental employer plan sponsor with the requisite objections, stating the exemption encompassed ''[a] group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section.'' For the sake of clarity, the expanded exemptions also stated that ''[s]uch non-governmental plan sponsors include, but are not limited to, the following entities,'' followed by an illustrative, non-exhaustive list of non-governmental organizations whose objections qualify the plans they sponsor for an exemption. Each type of such entities, and comments specifically concerning them, are discussed below.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.132(a)(1)(i). Some commenters suggested that the expanded religious exemptions should include government entities. Others disagreed. The Departments are not aware of reasons why it would be appropriate or necessary to offer a religious exemption to governmental employer plan sponsors with respect to the contraceptive Mandate. We are unaware of government entities that would attempt to assert a religious exemption to the Mandate, and it is not clear to us that a governmental entity could do so. Accordingly, we conclude that it is appropriate for us to not further expand the religious exemption to include governmental entities in the religious plan-sponsor exemption.

Nevertheless, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and, thus, to provide

[56] *See also Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.,* 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

health coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union, or a sponsor of a multiemployer plan) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization. Some commenters objected to extending the exemption to such entities, arguing that they could not have the same kind of religious objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite religious objection. The Departments conclude that it is appropriate, where the plan sponsor of a union, multiemployer, or similar plan adopts a religious objection using the same procedures that such a plan sponsor might use to make other decisions, that the expanded exemptions should respect that decision by providing an exemption from the Mandate.

E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only ''an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.'' Section 6033(a)(3)(A)(i) or (iii) of the Code encompasses ''churches, their integrated auxiliaries, and conventions or associations of churches,'' and ''the exclusively religious activities of any religious order.''

The Religious IFC expanded the exemption to include, in § 147.132(a)(1)(i)(A), plans sponsored by ''[a] church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.'' Most commenters did not oppose the exemptions continuing to include these entities, although some contended that the Departments have no authority to exempt any entity or plan from the Mandate, an objection to which the Departments respond above. Notably, this exemption exempts ''a religious order,'' and not merely ''the exclusively religious activities of any religious order.'' In addition, section 6033(a)(3)(A)(i) specifies that it covers churches, not merely ''the exclusively religious activities'' of a church. Some religious people might express their beliefs through a church, others might do so through a religious order, and still others might do so through religious bodies that take a different form, structure, or nomenclature based on a different cultural or historical tradition. *Cf. Hosanna-Tabor Evangelical Lutheran Church and School* v. *E.E.O.C.,* 565 U.S. 171, 198 (2012) (Alito and Kagan, JJ., concurring) (''The term 'minister' is commonly used by many Protestant denominations to refer to members of their clergy, but the term is rarely if ever used in this way by Catholics, Jews, Muslims, Hindus, or Buddhists.''). For the purposes of respecting the exercise of religious beliefs, which the expanded exemptions in these rules concern, the Departments find it appropriate that this part of the exemption encompasses religious orders and churches similarly, without limiting the scope of the protection to the exclusively religious activities of either kind of entity. Based on all these considerations, the Departments finalize § 147.132(a)(1)(i)(A) without change.

Moreover, the Departments also finalize the regulatory text to exempt plans ''established or maintained by'' a house of worship or integrated auxiliary on a plan, not employer, basis. Under previous regulations, the Departments stated that ''the availability of the exemption or accommodation [was to] be determined on *an employer by employer basis,* which the Departments . . . believe[d] best balance[d] the interests of religious employers and eligible organizations and those of employees and their dependents.'' (78 FR 39886 (emphasis added)). Therefore, under the prior exemption, if an employer participated in a house of worship's plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not covered by the exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a ''plan established or maintained by a [house of worship].'' Upon further consideration, in the Religious IFC, the Departments changed their view on this issue and expanded the exemption for houses of worship and integrated auxiliaries. Under these rules, the Departments intend that, when this regulation text exempts a plan ''established or maintained by'' a house of worship or integrated auxiliary, such exemption will no longer ''be determined on an employer by employer basis,'' but will be determined on a plan basis—that is, by whether the plan is a ''plan established or maintained by'' a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices, but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the requirement of being integrated auxiliaries. Under this interpretation, houses of worship would not be faced with the potential of having to include, in the plans that they have established and maintained, coverage for services to which they have a religious objection for employees of an affiliated employer participating in the plans.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted to participate in its health plan but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior regulation where with respect to self-insured church plans, hundreds of nonprofit religious entities participating in those plans were provided a mechanism by which their plan participants would not receive contraceptive coverage through the plan or third party administrator.[57]

Therefore, the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))

The exemption under previous regulations did not encompass nonprofit religious organizations beyond one that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code. The Religious IFC expanded the exemption to include plans sponsored by any other

[57] See supra at II.A.3.

''nonprofit organization,'' § 147.132(a)(1)(i)(B), if it has the requisite religious objection under § 147.132(a)(2) (see § 147.132(a)(1)(i) introductory text). The Religious IFC also specified in § 147.132(a)(1)(i)(A), as under the prior exemption, that the exemption covers ''a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.'' (Hereinafter ''houses of worship and integrated auxiliaries.'') These rules finalize, without change, the text of § 147.132(a)(1)(i)(A) and (B).

The Departments received comments in support of, and in opposition to, this expansion. Some commenters supported the expansion of the exemptions beyond houses of worship and integrated auxiliaries to other nonprofit organizations with religious objections (referred to herein as ''religious nonprofit'' organizations, groups or employers). They said that religious belief and exercise in American law has not been limited to worship, that religious people engage in service and social engagement as part of their religious exercise, and, therefore, that the Departments should respect the religiosity of nonprofit groups even when they are not houses of worship and integrated auxiliaries. Some public commenters and litigants have indicated that various religious nonprofit groups possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Other commenters did not support the expansion of exemptions to nonprofit organizations. Some of them described churches as having a special status that should not be extended to religious nonprofit groups. Some others contended that women at nonprofit religious organizations may support or wish to use contraceptives and that if the exemptions are expanded, it would deprive all or most of the employees of various religious nonprofit organizations of contraceptive coverage.

After evaluating the comments, the Departments continue to believe that an expanded exemption is the appropriate administrative response to the substantial burdens on sincere religious beliefs imposed by the contraceptive Mandate, as well as to the litigation objecting to the same. We agree with the comments that religious exercise in this country has long been understood to encompass actions outside of houses of worship and their integrated auxiliaries. The Departments' previous assertion that the exemptions were intended to respect a certain sphere of church autonomy (80 FR 41325) is not, in itself, grounds to refuse to extend the exemptions to other nonprofit entities with religious objections. Respect for churches does not preclude respect for other religious entities. Among religious nonprofit organizations, the Departments no longer adhere to our previous assertion that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.'' (78 FR 39874.) It is not clear to the Departments that the percentage of women who work at churches that oppose contraception, but who support contraception, is lower than the percentage of woman who work at nonprofit religious organizations that oppose contraception on religious grounds, but who support contraception. In addition, public comments and litigation reflect that many nonprofit religious organizations publicly describe their religiosity. Government records and those groups' websites also often reflect those groups' religious character. If a person who desires contraceptive coverage works at a nonprofit religious organization, the Departments believe it is sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit religious organization that opposes contraceptive coverage to hire a person who the organization knows disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[58]

In addition, it is not at all clear to the Departments that expanding the exemptions would, as some commenters asserted, remove contraceptive coverage from employees of many large religious nonprofit organizations. Many large religious nonprofit employers, including but not limited to some Catholic hospitals, notified the Department under the last Administration that they had opted into the accommodation and expressed no objections to doing so. We also received public comments from organizations of similar nonprofit employers indicating that the accommodation satisfied their religious objections. These final rules leave the accommodation in place as an optional process. Thus, it is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation. If they continue to use the accommodation, their insurers or third party administrators would continue to be required to provide contraceptive coverage to the plan sponsors' employees through such accommodation.

Given the sincerely held religious beliefs of many nonprofit religious organizations, some commenters also contended that continuing to impose the contraceptive Mandate on certain nonprofit religious objectors might also undermine the Government's broader interests in ensuring health coverage by causing some entities to stop providing health coverage entirely.[59] Although the Departments do not know the extent to which that effect would result from not extending exemptions, we wish to avoid that potential obstacle to the general expansion of health coverage.

G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))

The previous regulations did not exempt plans sponsored by closely held for-profit entities; however, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(C), ''[a] closely held for-profit entity.'' These rules finalize § 147.132(a)(1)(i)(C) without change.

Some commenters supported including these entities in the exemption, saying owners of such entities exercise their religious beliefs through their businesses and should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise religion or should not have their religious opposition to contraceptive coverage protected by the exemption. Some said the entities should not be able to impose their beliefs about contraceptive coverage on their employees, and that doing so constitutes discrimination.

As set forth in the Religious IFC, the Departments believe it is appropriate to expand the exemptions to include closely held for-profit employers in

[58] Notably, ''the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.' '' *Boy Scouts of America* v. *Dale,* 530 U.S. 640, 655 (2000).

[59] See, *e.g.,* Manya Brachear Pashman, ''Wheaton College ends coverage amid fight against birth control mandate,'' Chicago Tribune, July 29, 2015; Laura Bassett, ''Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,'' HuffPost, May 15, 2012.

order to protect the religious exercise of those entities and their owners. The ACA did not apply the preventive services mandate to the many grandfathered health plans among closely held as well as publicly traded for-profit entities, encompassing tens of millions of women. As explained below, we are not aware of evidence showing that the expanded exemptions finalized here will impact such a large number of women. And, in the Departments' view, the decision by Congress to not apply the preventive services mandate to grandfathered plans did not constitute improper discrimination or an imposition of beliefs. We also do not believe RFRA or the large number of other statutory exemptions Congress has provided for religious beliefs (including those exercised for profit) in certain health contexts such as sterilization, contraception, or abortion have been improper.

Including closely held for-profit entities in the exemption is also consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization, and rejected the previous Administration's argument to the contrary. 134 S. Ct. at 2768–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.[60]

H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))

The previous regulations did not exempt for-profit entities that are not closely held. However, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(D), ''[a] for-profit entity that is not closely held.'' These rules finalize § 147.132(a)(1)(i)(D) without change.

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. Some commenters supported including such entities, including publicly traded businesses, in the scope of the exemption. Some of them said that publicly traded entities have historically taken various positions on important public concerns beyond merely (and exclusively) seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to exercise religious views against contraceptive coverage. They also said that other protections for religious beliefs in federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines ''persons,'' protected under RFRA, to include corporations at 1 U.S.C. 1. Other commenters opposed including publicly traded companies in the expanded exemptions. Some of these commenters stated that such companies could not exercise religious beliefs, and opposed the effects on women if they could. These commenters also objected that including such employers, along with closely held businesses, would extend the exemptions to all or virtually all employers.

The Departments conclude it is appropriate to include entities that are not closely held within the expanded exemptions for entities with religious objection. RFRA prohibits the federal government from ''substantially burden[ing] a person's exercise of religion . . . .'' unless it demonstrates that the application of the burden to the person'' is the least restrictive means to achieve a compelling governmental interest. 42 U.S.C. 2000bb–1(a) & (b). As commenters noted, the definition of ''person'' applicable in RFRA is found at 1 U.S.C. 1, which defines ''person'' as including ''corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.'' Accordingly, the Departments' decision to extend the religious exemption to publicly traded for profit corporations is supported by the text of RFRA. The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making,[61] and the Departments expect that application of such laws would cabin the scope of this exemption.

As to the impact of so extending the religious exemption, the Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief. As noted above, before the ACA, a substantial majority of employers covered contraceptives. Some commenters opposed to including publicly traded entities in these exemptions noted that there did not appear to be any known religiously motivated objections to the Mandate from publicly traded for-profit corporations. These comments support our estimates that including publicly traded entities in the exemptions will have little, if any effect, on contraceptive coverage for women. We likewise agree with the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage. *See* 134 S. Ct. at 2774. Some commenters contended that, because many closely held for-profit businesses expressed religious objections to the Mandate, or took advantage of the accommodation, it is likely that many publicly traded businesses will do so. The Departments agree it is possible that publicly traded businesses may use the expanded exemption. But while scores of closely held for-profit businesses filed suit against the Mandate, no publicly traded entities did so, even though they were not authorized to seek the accommodation. Based on these data points, we believe the impact of the extension of the exemption to publicly traded for-profit organizations will not be significant. Below, based on limited data, but on years of receiving public comments and defending litigation brought by organizations challenging the Mandate on the basis of their religious objections, our best estimate of the anticipated effects of these rules is that no publicly traded employers will invoke the religious exemption.

In the Departments' view, such estimate does not lead to the conclusion that the religious exemption should not be extended to publicly traded corporations. The Departments are generally aware that, in a country as large as the U.S., comprised of a supermajority of religious persons,[62] some publicly traded entities might claim a religious character for their company, or the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.[63] Thus we consider

[60] *See* Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627.*

[61] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which the organization is incorporated or organized.

[62] For example, in 2017, 74 percent of Americans said that religion is fairly important or very important in their lives, and 87 percent of Americans said they believe in God. Gallup, ''Religion,'' available at *https://news.gallup.com/poll/1690/religion.aspx.*

[63] *See, for example,* Kapitall, ''4 Publicly Traded Religious Companies if You're Looking to Invest in

it possible that a publicly traded company might have religious objections to contraceptive coverage. Moreover, as noted, there are many closely held for-profit corporations that do have religious objections to covering some or all contraceptives. The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became a publicly traded entity. The Departments also find it relevant that other federal conscience statutes, such as those applying to hospitals or insurance companies, do not exclude publicly traded businesses from protection.[64] As a result, the Departments continue to consider it appropriate not to exclude such entities from these expanded exemptions.

I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. The Religious IFC included, in its list of exempt plan sponsors at § 147.132(a)(1)(i)(E), ''[a]ny other non-governmental employer.'' These rules finalize § 147.132(a)(1)(i)(E) without change.

Some commenters objected to extending the exemption to other nongovernmental employers, asserting that it is not clear such employers should be protected, nor that they can assert religious objections. The Departments, however, agree with other commenters that supported that provision of the Religious IFC. The Departments believe it is appropriate that any nongovernmental employer asserting the requisite religious objections should be protected from the Mandate in the same way as other plan sponsors. Such other employers could include, for example, association health plans.[65] The reasons discussed above for providing the exemption to various specific kinds of employers, and for their ability to assert sincerely held religious beliefs using ordinary mechanisms of corporate decision-making, generally apply to other nongovernmental employers as well, if they have sincerely held religious beliefs opposed to contraceptive coverage and otherwise meet the requirements of these rules. We agree with commenters who contend there is not a sufficient basis to exclude other nongovernmental employers from the exemption.

J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))

Based on the expressed intent in the Religious IFC, as discussed above, to expand the exemption to encompass plans established or maintained by nonprofit organizations with religious objections, and on public comments received concerning those exemptions, these rules finalize new language in § 147.132(a)(1)(ii) to better clarify the scope and application of the exemptions.

The preamble to the Religious IFC contained several discussions about the Departments' intent to exempt plans established or maintained by certain religious organizations that have the requisite objection to contraceptive coverage, including instances in which the plans encompass multiple employers. For example, as noted above, the Departments intended that the exemption for houses of worship and integrated auxiliaries be interpreted to apply on a plan basis, instead of on an employer-by-employer basis. In addition, the Departments discussed at length the fact that, under the prior regulations, where an entity was enrolled in a self-insured church plan exempt from ERISA under ERISA section 3(33) and the accommodation in the previous regulations was used, that accommodation process provided no mechanism to impose, or enforce, the accommodation requirement of contraceptive coverage against a third party administrator of such a plan. As a result, the prior accommodation served, in effect, as an exemption from requirements of contraceptive coverage for all organizations and employers covered under a self-insured church plan.

In response to these discussions in the Religious IFC, some commenters, including some church plans, supported the apparent intent to exempt such plans on a plan basis, but suggested that additional clarification is needed in the text of the rule to effect this intent. They observed that some plans are established or maintained by religious nonprofit entities that might not be houses of worship or integrated auxiliaries, and that some employers that adopt or participate in such plans may not be the ''plan sponsors.'' They recommended, therefore, that the final rules specify that the exemption applies on a plan basis when plans are established or maintained by houses of worship, integrated auxiliaries, or religious nonprofits, so as to shield employers that adopt such plans from penalties for noncompliance with the Mandate.

The text of the prefatory language of § 147.132(a)(1), as set forth in the Religious IFC, declared that the Guidelines would not apply ''with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization.'' We intended this language to exempt a plan and/or coverage where the entity that established or maintained a plan was an objecting organization, and not just to look at the views or status of individual employers (or other entities) participating in such plan. The Departments agree with commenters who stated that additional clarity is needed and appropriate in these final rules, in order to ensure that such plans are exempt on a plan basis, and that employers joining or adopting those plans are exempt by virtue of the plan itself being exempt. Doing so will make the application of the expanded exemption clearer, and protect employers (and other entities) participating in such plans from penalties for noncompliance with the Mandate. Clearer language will better realize the intent to exempt plans and coverage ''established or maintained by an objecting organization,'' and make the operation of that exemption simpler by specifying that the exemption applies based on the objection of the entity that established or maintains the plan. Such language would also resolve the anomaly that, under the previous rules, only self-insured church plans (not insured church plans) under ERISA section 3(33) were, in effect, exempt—but only indirectly through the Departments' inability to impose, or enforce, the accommodation process against the third party administrators of such plans, instead of being specifically exempt in the rules.

We believe entities participating in plans established or maintained by an objecting organization usually share the views of those organizations. Multiple lawsuits were filed against the Departments by churches that established or maintained plans, or the church plans themselves, and they generally declared that the entities or individuals participating in their plans

Faith'' (Feb. 7, 2014), *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665.*

[64] *See, for example,* 42 U.S.C. 300a–7, 42 U.S.C. 238n, Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d), Public Law 115–141, and *id.* at Div. E, Sec. 808.

[65] See 29 CFR 2510.3–5.

are usually required to share their religious affiliation or beliefs. In addition, because, as we have stated before, ''providing payments for contraceptive services is cost neutral for issuers'' (78 FR 39877), we do not believe this clarification would produce any financial incentive for entities that do not have religious objections to contraceptive coverage to enter into plans established or maintained by an organization that does have such objections.

Therefore, the Departments finalize the text of § 147.132(a)(1) of the Religious IFC with the following change: adding a provision that makes explicit this understanding, in a new paragraph at § 147.132(a)(1)(ii). This language now specifies that the exemptions encompassed by § 147.132(a)(1) include: ''[a] group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan[.]''

K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))

The previous regulations did not exempt student health plans arranged by institutions of higher education, although it did, for purposes of the accommodation, treat plans arranged by institutions of higher education similar to the way in which the regulations treated plans of nonprofit religious employers. *See* 80 FR at 41347. The Religious IFC included in its list of exemptions, at § 147.132(a)(1)(ii), ''[a]n institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to 'plan participants and beneficiaries' will be interpreted as references to student enrollees and their covered dependents.'' These rules finalize this language with a change to clarify their application, as discussed below, and by redesignating the paragraph as § 147.132(a)(1)(iii).

These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.132(a)(1)(iii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held religious beliefs, to their arrangement of student health insurance coverage in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.

Some commenters supported including, in the expanded exemptions, institutions of higher education that provide health coverage for students through student health plans but have religious objections to providing certain contraceptive coverage. They said that religious exemptions allow freedom for certain religious institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemptions would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result among those women.

In the Departments' view, the reasons for extending the exemptions to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. Only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities.[66] It is necessarily true that an even smaller number receive such coverage from religious schools, and from religious or other private schools that object to arranging contraceptive coverage. Religious institutions of higher education are private entities with religious missions. Various commenters asserted the importance, to many of those institutions, of being able to adhere to their religious tenets. Indeed, many students who attend such institutions do so because of the institutions' religious tenets. No student is required to attend such an institution. At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange. Some students wish to receive contraceptive coverage from a health plan arranged by an institution of higher education. But other students wish to attend an institution of higher education that adheres to its religious mission about contraceptives in health insurance. And still other students favor contraception, but are willing to attend a religious university without forcing it to violate its beliefs about contraceptive coverage. Exempting religious institutions that object to contraceptive coverage still allows contraceptive coverage to be provided by institutions of higher education more broadly. The exemption simply makes it legal under federal law for institutions to adhere to religious beliefs that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, and makes it more possible for students to attend institutions of higher education that hold those views.

In addition, under the previous exemption and accommodation, it was possible for self-insured church plans exempt from ERISA that have religious objection to certain contraceptives to avoid any requirement that either they or their third party administrators provide contraceptive coverage. As seen

[66] The American College Health Association estimates that, in 2014, student health insurance plans at colleges and universities covered ''more than two million college students nationwide.'' ''Do You Know Why Student Health Insurance Matters?'' available at *https://www.acha.org/documents/Networks/Coalitions/Why_SHIPs_Matter.pdf.* We assume for the purposes of this estimate that those plans covered 2,100,000 million students. Data from the Department of Education shows that in 2014, there were 20,207,000 students enrolled in degree-granting postsecondary institutions. National Center for Education Statistics, Table 105.20, ''Enrollment in elementary, secondary, and degree-granting postsecondary institutions, by level and control of institution, enrollment level, and attendance status and sex of student: Selected years, fall 1990 through fall 2026,'' available at *https://nces.ed.gov/programs/digest/d16/tables/dt16_105.20.asp?current=yes.*

in some public comments and litigation statements, some such self-insured church plans provide health coverage for students at institutions of higher education covered by those church plans. In order to avoid the situation where some student health plans sponsored by institutions with religious objections are effectively exempt from the contraceptive Mandate, and other student health plans sponsored by other institutions with similar religious objections are required to comply with the Mandate, the Departments consider it appropriate to extend the exemption, so that religious colleges and universities with objections to the Mandate would not be treated differently in this regard.

The Departments also note that the ACA does not require institutions of higher education to provide student health insurance coverage. As a result, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student health insurance plans, rather than comply with the Mandate or be subject to the accommodation.[67] Extending the exemption in these rules removes an obstacle to such entities deciding to offer student health insurance plans, thereby giving students another health insurance option.

As noted above, it is not clear that studies discussing various effects of birth control access clearly and specifically demonstrate a negative impact to students in higher education because of the expanded exemption in these final rules. The Departments consider these expanded exemptions to be an appropriate and permissible policy choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these expanded exemptions.

Finally, the Religious IFC specified that the plan sponsor exemption applied to ''non-governmental'' plan sponsors (§ 147.132(a)(1)(i)), including ''[a]ny other non-governmental employer'' (§ 147.132(a)(1)(i)(E)). Then, in § 147.132(a)(1)(ii), the rule specified that the institution of higher education exemption applicable to the arrangement of student health insurance coverage applied ''in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.'' Consequently, the Religious IFC's expanded exemptions only applied to non-governmental institutions of higher education, including for student health insurance coverage, not to governmental institutions of higher education. Nevertheless, the term ''non-governmental,'' while appearing twice in § 147.132(a)(1)(i) concerning plan sponsors, was not repeated in in § 147.132(a)(1)(ii). To more clearly specify that this limitation was intended to apply to § 147.132(a)(1)(ii), we finalize this paragraph with a change by adding the phrase ''which is non-governmental'' after the phrase ''An institution of higher education as defined in 20 U.S.C. 1002''.

L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))

The previous regulations did not exempt health insurance issuers. However, the Religious IFC included in its list of exemptions at § 147.132(a)(1)(iii), ''[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]'' These rules finalize this exemption with technical changes to clarify the language based on public comments, and redesignate the paragraph as § 147.132(a)(1)(iv).

The Religious IFC extends the exemption to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services. Under this exemption, the only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on their objection. An exempt issuer can then offer an exempt health insurance product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless it is also exempt from that requirement.

Under these rules, issuers that hold their own objections, based on sincerely held religious beliefs, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their religious beliefs, or on their moral convictions under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held moral convictions, that are exempt under those companion final rules, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments provided a similar exemption for issuers in the context of moral objections, but we used slightly different operative language. There, in the second sentence, instead of saying ''the plan remains subject to any requirement to provide coverage for contraceptive services,'' the exemption stated, ''the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services.'' Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. Consequently, these rules finalize the issuer exemption paragraph from the Religious IFC with minor technical changes so that the final language will mirror language from the Moral IFC, stating that the exemption encompasses: ''[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iv) of this section, the group health plan established or maintained by the plan sponsor with

[67] See, *e.g.,* Manya Brachear Pashman, ''Wheaton College ends coverage amid fight against birth control mandate,'' Chicago Tribune, July 29, 2015; Laura Bassett, ''Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,'' HuffPost, May 15, 2012.

which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]''

Some commenters supported including this exemption for issuers in these rules, both to protect the religious exercise of issuers, and so that in the future religious issuers that may wish to specifically serve religious plan sponsors would be free to organize. Other commenters objected to including an exemption for issuers. Some objected that issuers cannot exercise religious beliefs, while others objected that exempting issuers would threaten contraceptive coverage for women. Some commenters said that it was arbitrary and capricious for the Departments to provide an exemption for issuers if we do not know that issuers with qualifying religious objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage. The issuer exemption therefore serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors and plans that independently qualify for an exemption, will remove a possible obstacle to religious issuers being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers from being required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise religious beliefs. First, since RFRA protects the religious exercise of corporations as persons, the religious exercise of health insurance issuers—which are generally organized as corporations—is protected by RFRA. In addition, many federal health care conscience laws and regulations specifically protect issuers or plans. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment specifically protects, among other entities, provider-sponsored organizations, health maintenance organizations (HMOs), health insurance plans, and ''any other kind of health care facilit[ies], organization[s], or plan[s]'' as a ''health care entity'' from being required to pay for, or provide coverage of, abortions. *See for example,* Consolidated Appropriations Act of 2018, Public Law 115–141, Div. H, Sec. 507(d), 132 Stat. 348, 764 (Mar. 23, 2018).[68] Congress also declared this year that ''it is the intent of Congress'' to include a ''conscience clause'' which provides exceptions for religious beliefs if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans.'' *See id.* at Div. E, Sec. 808, 132 Stat. at 603. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators, and, therefore, would not normally act as plan administrators, under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or decline to continue, contracts as third party administrators of such plans.

M. Description of the Religious Objection (45 CFR 147.132(a)(2))

The previous regulations did not specify what, if any, religious objection applied to its exemption; however, the Religious IFC set forth the scope of the religious objection of objecting entities in § 147.132(a)(2), as follows: ''The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.'' These rules finalize this description with technical changes to clarify the scope of the objection as intended in the Religious IFC, and based on public comments.

Throughout the exemptions for objecting entities, the rules specify that they apply where the entities object as specified in § 147.132(a)(2) of the Religious IFC. That paragraph describes the religious objection by specifying that exemptions for objecting entities will apply to the extent that an entity described in paragraph (a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(a)(2), provided a similar description of the scope of the objection based on moral convictions rather than religious beliefs, but we used slightly different operative language. There, instead of saying the entity ''objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services,'' the paragraph stated the entity ''objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.'' Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. The Religious IFC explained that the intent of the expanded exemptions was to encompass entities that objected to providing or arranging for contraceptive coverage in their plans, and to encompass entities that objected to the previous accommodation process, by which their issuers or third party administrators were required to provide contraceptive coverage or payments in connection with their plans. In other words, an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation. The language in the Religious IFC encompassed both circumstances by encompassing an objection to providing ''coverage [or] payments'' for contraceptive services, and by encompassing an objection to ''a plan that provides'' coverage or payments for contraceptive services. But the language describing the objection set forth in the Moral IFC does so more clearly, and restructuring the sentence could make it clearer still. Questions by commenters about the scope of the description suggests that we should restructure the description, in a non-substantive way, to provide more clarity. The Departments do this by breaking some of the text out into subparagraphs, and rearranging clauses so that it is clearer which words they modify. The new structure specifies that it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for contraceptive services, and it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) a plan, issuer, or third party administrator that provides contraceptive coverage. This more clearly encompasses objections to complying with either the Mandate or the accommodation. Consequently, these rules finalize the paragraph describing the religious objection in the Religious IFC with minor technical changes so that the final language will essentially mirror language from the Moral IFC. The introductory phrase of the religious objection set forth in paragraph (a)(2) is finalized to state the exemption ''will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable)''. The remainder of the paragraph is broken into two sub-paragraphs, regarding either ''coverage or payments for some or all contraceptive services,'' or ''a plan, issuer, or third party administrator that provides or arranges such coverage or payments.''

Some commenters observed that by allowing exempt groups to object to ''some or all'' contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators. The Departments have concluded, however, that, just as the exemption under the previous regulations allowed entities to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. Notably, even where an entity or individual qualifies for an exemption under these rules, these rules do not require the issuer or third party administrator to contract with that entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual variation of a plan. These rules simply remove the federal Mandate that, in some cases, could have led to penalties for an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying religious objection. Similarly, under the previous exemption, the plans of houses of worship and integrated auxiliaries were exempt from offering some or all contraceptives, but the previous regulations did not require issuers and third party administrators to contract with those exempt entities if they chose not to do so.

N. Individuals (45 CFR 147.132(b))

The previous regulations did not provide an exemption for objecting individuals. However, the Religious IFC expanded the exemptions to encompass objecting individuals (referred to here as the ''individual exemption''), at § 147.132(b). These rules finalize the individual exemption from the Religious IFC with changes, which reflect both non-substantial technical revisions, and changes based on public comments to more clearly express the intent of the Religious IFC.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Religious IFC described what may be offered to objecting individuals as ''a separate benefit package option, or a separate policy, certificate or contract of insurance,'' the Moral IFC said a willing issuer and plan sponsor may offer ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects'' under the individual exemption. Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of ''a separate group health plan,'' as set forth in the version found in § 147.133(b), because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual

exemption by making a technical change to the language to adopt the formulation, ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects'' under the individual exemption.

Some commenters supported the individual exemption as providing appropriate protections for the religious beliefs of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to contraceptive coverage but is willing (and, as applicable, the issuer is also willing) to provide coverage that is consistent with an individual's religious objections. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage. Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. As discussed in the Religious IFC, the individual exemption only operates in the case where the group health plan sponsor or group or individual market health insurance issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases.

In addition, Congress has provided several protections for individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. *See for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–141, 132 Stat. 348, 593–94 (Mar. 23, 2018). While some commenters proposed to construe this provision narrowly, Congress likewise provided that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions''. *Id.* at Div. E, Sec. 808, 132 Stat. at 603. A religious exemption for individuals would not be effective if the government simultaneously made it illegal for issuers and group health plans to provide individuals with policies that comply with the individual's religious beliefs.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers.

By its terms, the individual exemption would also apply with respect to individuals in plans arranged by institutions of higher education, if the issuers offering those plans were willing to provide plans complying with the individuals' objections. Because federal law does not require institutions of higher education to arrange such plans, the institutions would not be required by these rules to arrange a plan compliant with an individual's objection if the institution did not wish to do so.

As an example, in one lawsuit brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these final rules do not affect such other laws or terms.

Some individuals commented that they welcomed the individual exemption so that their religious beliefs were not forced to be in tension with their desire for health coverage. The Departments believe the individual exemption may help to meet the ACA's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.[69] At the same time, this individual exemption ''does not undermine the governmental interests furthered by the contraceptive

[69] See also, for example, *Wieland,* 196 F. Supp. 3d at 1017, and *March for Life,* 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to ''forgo health insurance altogether.''

coverage requirement,'' [70] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives. Other commenters expressed concern that there might be multiple variations in the kinds of contraceptive coverage to which individuals object, and this might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the religious beliefs of an exempt individual. As discussed above, where the individual exemption applies, it only affects the coverage of an individual. If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons they can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Religious IFC implied this conclusion, by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, this was different than the language applicable to the exemptions under § 147.132(a), which specifies that the exemptions apply ''to the extent'' of the religious objections, so that, as discussed above, the exemptions include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b) with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the individual with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held religious beliefs objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to this employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under a policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with clarifying changes to reflect the Departments' intent.

O. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations set forth an accommodation process at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, as an alternative method of compliance with the Mandate. Under the accommodation, if a religious nonprofit entity, or a religious closely held for-profit business, objected to coverage of some or all contraceptive services in its health plan, it could file a notice or fill out a form expressing this objection and describing its objection to its plan and issuer or third party administrator. Upon doing so, the plan would not cover some or all contraceptive services, and the issuer or third party administrator would be responsible for providing or arranging for persons covered by the plan to receive coverage or payments of those services (except in the case of self-insured church plans exempt from ERISA, in which case no such obligation was imposed on the third party administrator). The accommodation was set forth in regulations of each of the Departments. Based on each Department's regulatory authority, HHS regulations applied to insured group health plans, and DOL and Treasury regulations applied to both insured group health plans and self-insured group health plans.

The Religious IFC maintained the accommodation process. Nevertheless, by virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process and its location in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, but the Departments do so with several changes based on public comments.

Many commenters supported keeping the accommodation as an optional process, including some commenters who otherwise supported creating the expanded exemptions. Some commenters opposed making the accommodation optional, but asked the Departments to return to the previous regulations in which entities that did not meet the narrower exemption could only choose between the accommodation process or direct compliance with the Mandate. Some commenters believed there should be no exemptions and no accommodation process.

The Departments continue to consider it appropriate to make the accommodation process optional for entities that are otherwise also eligible for the expanded exemptions—that is, to keep it in place as an option that exempt entities can choose. The accommodation provides contraceptive access, which is a result many opponents of the expanded exemptions said they desire. The accommodation involves some regulation of issuers and third party administrators, but the previous

[70] 78 FR 39874.

regulations had already put that regulatory structure in place. These rules for the most part merely keep it in place and maintain the way it operates. The Religious IFC adds some additional paperwork burdens as a result of the new interaction between the accommodation and the expanded exemptions; those are discussed below.

Above, the Departments discussed public comments concerning whether we should have merely expanded the accommodation rather than expanding the exemptions. The Religious IFC and these final rules expand the kinds of entities that may use the optional accommodation, by expanding the exemptions and allowing any exempt entities to opt to make use of the accommodation. Consequently, under these rules, objecting employers may make use of the exemption or may choose to utilize the optional accommodation process. If an eligible organization uses the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

Some commenters asked that these final rules create an alternative payment mechanism to cover contraceptive services for third party administrators obligated to provide or arrange such coverage under the accommodation. These rules do not concern the payment mechanism, which is set forth in separate rules at 45 CFR 156.50. The Departments do not view an alternative payment mechanism as necessary. As discussed below, although the Departments do not know how many entities will use the accommodation, it is reasonably likely that some entities previously using it will continue to do so, while others will choose the expanded exemption, leading to an overall reduction in the use of the accommodation. The Departments have reason to believe that these final rules will not lead to a significant expansion of entities using the accommodation, since nearly all of the entities of which the Departments are aware that may be interested in doing so were already able to do so prior to the Religious IFC. Moreover, it is still the case under these rules that if an entity serving as a third party administrator does not wish to satisfy the obligations it would need to satisfy under an accommodation, it could choose not to contract with an entity that opts into the accommodation. This conflict is even less likely now that entities eligible for the accommodation are also eligible for the exemption. For these reasons, the Departments do not find it necessary to add an additional payment mechanism for the accommodation process.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these rules, and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation. Some commenters suggested HHS has not yet issued guidance on the revocation process, but CCIIO provided guidance concerning this process on November 30, 2017.[71] These rules supersede that guidance, and adopt or modify its specific guidelines as explained below. As a result, these rules delete references, set forth in the Religious IFC's accommodation regulations, to ''guidance issued by the Secretary of the Department of Health and Human Services.''

The guidance stated that an entity that was using the accommodation under the previous rules, or an entity that adopts the accommodation maintained by the IFCs, could revoke its use of the accommodation and use the exemption. This guideline applies under the final rules. This revocation process applies both prospectively to eligible organizations that decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that invoked the accommodation prior to the effective date of the Religious IFC either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies.

The guidance stated that, when the accommodation is revoked by an entity using the exemption, the issuer of the eligible organization must provide participants and beneficiaries written notice of such revocation. These rules adopt that guideline. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. The guidance further stated that the notice may be provided by the organization itself, its group health plan, or its third party administrator, as applicable. The guidance stated that, under the regulation at 45 CFR 147.200(b), ''[t]he notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section,'' and (a)(4) has detailed rules on when electronic notice is permitted. These guidelines still apply under the final rules. These rules adopt those guidelines.

The guidance further specified that the revocation of the accommodation would be effective notice on the first day of the first plan year that begins on or after 30 days after the date of the revocation, or alternatively, whether or not the objecting entity's group health plan or issuer listed the contraceptive benefit in its Summary of Benefits of Coverage (SBC), the group health plan or issuer could revoke the accommodation by giving at least 60-days prior notice pursuant to section 2715(d)(4) of the PHS Act (incorporated into ERISA and the Code)[72] and applicable regulations thereunder to revoke the accommodation. The guidance noted that, unlike the SBC notification process, which can effectuate a modification of benefits in the middle of a plan year, provided it is allowed by State law and the contract of the policy, the 30 day notification process under the guidance can only effectuate a benefit modification at the beginning of a plan year. This part of the guidance is adopted in part and changed in part by these final rules, as follows, based on public comments on the issue.

Some commenters asked that revocations only be permitted to occur on the first day of the next plan year, or no sooner than January 2019, to avoid burdens on plans and because some states do not allow for mid-year plan changes. The Departments believe that providing 60-days notice pursuant to section 2715(d)(4) of the PHS Act, where applicable, is a mechanism that already exists for making changes in health benefits covered by a group health plan during a plan year; that process already takes into consideration any applicable state laws. However, in response to public comments, these rules change the accommodation provisions from the Religious IFC to indicate that, as a transitional rule, providing 60-days notice for revoking an accommodation is only available, if applicable, to plans that are using the accommodation at the time of the

[71] *See* Randy Pate, ''Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services,'' CMS (Nov. 30, 2017), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf.*

[72] *See also* 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

publication of these final rules. As a general rule, for plans that use the accommodation in future plan years, the Departments believe it is appropriate to allow revocation of an accommodation only on the first day of the next plan year. Based on the objections of various litigants and public commenters, we believe that some entities already using the accommodation may have been doing so only because previous regulations denied them an exemption. For them, access to the transitional 60-days notice procedure (if applicable) is appropriate in the period immediately following the finalization of these rules. In future plan years, however—plan years that begin after the effective date of these final rules—plans and entities that qualify as exempt under these rules will have been on notice that they qualify for an exemption or the accommodation. If they have opted to enter or remain in the accommodation in those future plan years, when they could have chosen the exemption, the Departments believe it is appropriate for them to wait until the first day of the following plan year to change to exempt status.[73]

This change is implemented in the following manner. In the Religious IFC, the accommodation provisions addressing revocation were found at 45 CFR 147.131(c)(4), 26 CFR 54.9815–2713AT(a)(5),[74] and 29 CFR 2590.715–2713A(a)(5).

The provisions in the Religious IFC (with technical variations among the HHS, Labor, and Treasury rules) state that a written notice of revocation must be provided ''as specified in guidance issued by the Secretary of the Department of Health and Human Services.'' On November 30, 2017, HHS issued the guidance regarding revocation. These final rules incorporate this guidance, with certain clarifications, and state that the revocation notice must be provided ''as specified herein.'' The final rule incorporates the two sets of directions for revoking the accommodation initially set forth in the interim guidance in the following manner. The first, designated as subparagprah (1) as a ''[t]ransitional rule,'' explains that if contraceptive coverage is being offered through the accommodation process on the date on which these final rules go into effect, 60-days notice may be provided to revoke the accommodation process, or they revocation may occur ''on the first day of the first plan year that begins on or after 30 days after the date of the revocation'' consistent with PHS Act section 2715(d)(4), 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), or 29 CFR 2590.715–2715(b). The second direction, set forth in subparagraph (ii), explains the ''[g]eneral rule'' that, in plan years beginning after the date on which these final rules go into effect, revocation of the accommodation will be effective on ''the first day of the first plan year that begins on or after 30 days after the date of the revocation.''

The Religious IFC states that if an accommodated entity objects to some, but not all, contraceptives, an issuer for an insured group health plan that covers contraceptives under the accommodation may, at the issuer's option, choose to provide coverage or payments for all contraceptive services, instead of just for the narrower set of contraceptive services to which the entities object. Some commenters supported this provision, saying that it allows flexibility for issuers that might otherwise face unintended burdens from providing coverage under the accommodation for entities that object to only some contraceptive items. The Departments have maintained this provision in these final rules. Note that this provision is consistent with the other assertions in the rules saying that an entity's objection applies ''to the extent'' of the entity's religious beliefs, because in this instance, under the accommodation, the plan participant or beneficiary still receives coverage or payments for all contraceptives, and this provision simply allows issuers more flexibility in choosing how to help provide that coverage.

Some commenters asked that the Departments retain the ''reliance'' provision, contained in the previous accommodation regulations, under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. The Departments omitted this provision from the Religious IFC, on the grounds that this provision was less necessary where any organization eligible for the optional accommodation is also exempt. Nevertheless, in order to respond to concerns in public comments, and to prevent any risk to issuers of a mistake or misrepresentation by an organization seeking the accommodation process, the Departments have finalized the Religious IFC with an additional change that restores this clause. The clause uses the same language that was in the regulations prior to the Religious IFC, and it is inserted at 45 CFR 147.131(f), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e). As a result, these rules renumber the subsequent paragraphs in each of those sections.

P. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under ''Contraceptive methods and counseling,'' ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' The previous regulations concerning the exemption and the accommodation used the terms contraceptive services and contraceptive coverage as catch-all terms to encompass all of those Guidelines' requirements. The 2016 update to the Guidelines are similarly worded. Under ''Contraception,'' they include the ''full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,'' ''instruction in fertility awareness-based methods,'' and ''[c]ontraceptive care'' to ''include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).'' [75]

To more explicitly state that the exemption encompasses any of the contraceptive or sterilization services, items, or information that have been required under the Guidelines, the Religious IFC included a definition at 45

[73] These final rules go into effect 60 days after they are published in the **Federal Register**. Some entities currently using the accommodation may have a plan year that begins less than 30 days after the effective date of these final rules. In such cases, they may be unable, after the effective date of these final rules, to provide a revocation notice 30 days prior to the start of their next plan year. However, these final rules will be published at least 60 days prior to the start of that plan year. Therefore, entities exempt under these final rules that have been subject to the accommodation on the date these final rules are published, that wish to revoke the accommodation, and whose next plan years start after these final rules go into effect, but less than 30 days thereafter, may submit their 30 day revocation notices after these final rules are published, before these final rules are in effect, so that they will have submitted the revocation at least 30 days before their next plan year starts. In such cases, even though the revocation notice will be submitted before these final rules are in effect, the actual revocation will not occur until after these final rules are in effect, and plan participants will have been provided with 30 days' notice of the revocation.

[74] The Department of the Treasury's rule addressing the accommodation is being finalized at 26 CFR 54.9815–2713A, superseding its temporary regulation at 26 CFR 54.9815–2713AT.

[75] *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713AT(e), and 29 CFR 2590.715–2713A(e). These rules finalize those definitions without change, but renumber them as 45 CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e), respectively.

Q. Severability

The Departments finalize without change (except for certain paragraph redesignations), the severability clauses in the interim final rules, namely, at paragraph (g) of 26 CFR 54.9815–2713A, the redesignated paragraph (g) of 29 CFR 2590.715–2713A, and 45 CFR 147.132(d).

R. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to ''preventive'' care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to ''preventive'' services or care.[76] The requirement in the Guidelines concerning ''contraception'' specifies several times that it encompasses ''contraceptives,'' that is, medical products, methods, and services applied for ''contraceptive'' uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage, without cost-sharing, of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[77] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use, or for another use. Section 2713(a)(4), however, draws a distinction between preventive care and screenings and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of contraceptive methods or care unless such methods or care is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules also do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply to the extent the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that under section 2713(a)(4), exempt organizations must provide coverage for drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the expanded exemptions could take contraceptive coverage away from many or most women. Still others opposed expanding the exemptions and contended that accurately determining the number of women affected by the expanded exemptions is not possible.

After reviewing the public comments, the Departments agree with commenters who said that estimating the impact of these final rules is difficult based on the limited data available to us, and with commenters who agreed with the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women. The Departments do not find the estimates of large impacts submitted by some commenters more reliable than the estimates set forth in the Religious and Moral IFCs. Even certain commenters that ''strongly oppos[ed]'' the Religious IFC commented that merely ''thousands'' would be impacted, a number consistent with the Departments' estimate of the number of women who may be affected by the rule. The Departments' estimates of the impact of these final rules are discussed in more detail in the following section. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious IFC are still the best estimates available. Our estimates are discussed in more detail in the following section.

3. Interaction With State Laws

Some commenters asked the Departments to discuss the interaction between these final rules and state laws that either require contraceptive

[76] *Id.*

[77] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that ''there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act 2713(a)(4) or the Guidelines require coverage of ''contraceptive'' methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead, it was an observation that such drugs—generally referred to as ''contraceptives''—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the reference prior to the Religious IFC to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage for contraceptive use. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

coverage or provide religious exemptions from those and other requirements. Some commenters argued that providing expanded exemptions in these rules would negate state contraceptive requirements or narrower state religious exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage. The Department agrees that these rules concern only the applicability of the Federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state religious exemptions. If a plan is exempt under the Religious IFC and these rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the religious exemptions to declare that the Federal contraceptive Mandate will still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[78]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1). These rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with religious objections to cover contraceptives.

IV. Economic Impact and Paperwork Burden

The Departments have examined the impacts of the Religious IFC and the final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an ''economically significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding their anticipated effects, the Religious IFC and these rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These final rules adopt as final and further change the amendments made by the Religious IFC, which amended the Departments' July 2015 final regulations. The Religious IFC and these final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held religious beliefs, and they revise the accommodation process to make it optional for eligible organizations. The expanded exemption applies to certain individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action has been taken, among other reasons discussed above, to provide for participation in the health insurance market by certain entities or individuals, by freeing them from penalties they could incur if they follow their sincerely held religious beliefs against contraceptive coverage.

2. Anticipated Effects

a. Removal of Burdens on Religious Exercise

Regarding entities and individuals that are extended an exemption by the Religious IFC and these final rules, without that exemption the Guidelines would require many of them to either pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which

[78] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the Federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. Elsewhere in this preamble, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

some entities also believe entangles them in the provision of such objectionable coverage; or pay tax penalties, or be subject to other adverse consequences, for non-compliance with these requirements. These final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections to, and exempting them on the basis of such objections from, the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

b. Notices When Revoking Accommodated Status

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption, a notice will need to be sent to enrollees (either by the objecting entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during the current plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of the entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be $302,036.

c. Impacts on Third Party Administrators and Issuers

The Departments estimate that these final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their new exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation to which they were not previously provided access. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations for serving the fewer number of entities that will now opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation. While these rules make it legal for issuers to offer insurance coverage that omits contraceptives to exempt entities and individuals, these final rules do not require issuers to do so.

The Departments anticipate that the effect of these rules on adjustments made to the federally facilitated Exchange user fees under 45 CFR 156.50 will be that fewer overall adjustments will be made using the accommodation process, because there will be more entities who previously were reluctant users of the accommodation that will choose to operate under the newly expanded exemption than there will be entities not previously eligible to use the accommodation that will opt into it. The Departments' estimates of each number of those entities is set forth in more detail below.

d. Impacts on Persons Covered by Newly Exempt Plans

These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.

i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans

As referenced above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- How many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- Which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby,* several objecting entities have still provided coverage for 14 of the 18 FDA-approved women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- How many women will be covered by plans of entities using their newly exempt status.
- Which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- Whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- The degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- The degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- The degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- The extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

ii. Public Comments Concerning Estimates in Religious IFC

In the public comments, some commenters agreed with the Departments' estimate that, at most, the economic impact would lead to a potential transfer cost, from employers (or other plan sponsors) to affected women, of $63.8 million. Some commenters said the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women.

These general comments do not, however, substantially assist us in

estimating how many women would be affected by these expanded exemptions specifically, or among them, how many unintended pregnancies would result, or how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the transfer costs the Departments estimate, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives. The Departments conclude, therefore, that our estimates of the anticipated effect in the Religious IFC are still the best estimates we have based on the limited data available to make those estimates. We do not believe that the higher estimates submitted by various public commenters sufficiently took into consideration, or analyzed, the various factors that suggest the small percentage of entities that will now use the expanded exemptions out of the large number of entities subject to the Mandate overall. Instead, the Departments agree with various public commenters providing comment and analysis that, for a variety of reasons, the best estimate of the impact of the expanded exemptions finalized in these rules is that most women receiving contraceptive coverage under the Mandate will not be affected. We agree with such commenters that the number of women covered by entities likely to make use of the expanded exemptions in these rules is likely to be very small in comparison to the overall number of women receiving contraceptive coverage as a result of the Mandate.

iii. Possible Sources of Information for Estimating Impact

The Departments have access to the following general sources of information that are relevant to this issue, but these sources do not provide a full picture of the impact of these final rules. First, the regulations prior to the Religious IFC already exempted certain houses of worship and their integrated auxiliaries and, as explained elsewhere, effectively did not apply contraceptive coverage requirements to various entities in self-insured church plans. The effect of those previous exemptions or limitations are not included as effects of these rules, which leave those impacts in place. Second, in the Departments' previous regulations creating or expanding exemptions and the accommodation process we concluded that no significant burden or costs would result. 76 FR 46625; 78 FR 39889. Third, some entities, including some for-profit entities, object to only some but not all contraceptives, and in some cases will cover 14 of 18 FDA-approved women's contraceptive and sterilization methods.[79] *See Hobby Lobby,* 134 S. Ct. at 2766. The effects of the expanded exemptions will be mitigated to that extent. No publicly traded for-profit entities sued challenging the Mandate, and the public comments did not reveal any that specifically would seek to use the expanded exemptions. Consequently, the Departments agree with the estimate from the Religious IFC that publicly traded companies would not likely make use of these expanded exemptions.

Fourth, HHS previously estimated that 209 entities would make use of the accommodation process. To arrive at this number, the Departments used, as a placeholder, the approximately 122 nonprofit entities that brought litigation challenging the accommodation process, and the approximately 87 closely held for-profit entities that filed suit challenging the Mandate in general. The Departments' records indicate, as noted in the Religious IFC, that approximately 63 entities affirmatively submitted notices to HHS to use the accommodation,[80] and approximately 60 plans took advantage of the contraceptive user fees adjustments, in the 2015 plan year, to obtain reimbursement for contraceptive service payments made for coverage of such services for women covered by self-insured plans that were accommodated. Overall, while recognizing the limited data available, the Departments assumed that, under an expanded exemption and accommodation, approximately 109 previously accommodated entities would use an expanded exemption, and about 100 would continue their accommodated status. We also estimated that another 9 entities would use the accommodation where the entities were not previously eligible to do so.

These sources of information were outlined in the Religious IFC. Some commenters agreed with the Departments' estimates based on those sources, and while others disagreed, the Departments conclude that commenters did not provide information that allows us to make better estimates.

iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions

Based on these and other factors, the Departments considered two approaches in the Religious IFC to estimate the number of women affected among entities using the expanded exemptions. First, following the use in previous regulations of litigating entities to estimate the effect of the exemption and accommodation, the Departments attempted to estimate the number of women covered by plans of litigating entities that could be affected by expanded exemptions. Based on papers filed in litigation, and public sources, the Departments estimated in the Religious IFC that approximately 8,700 women of childbearing age could have their contraception costs affected by plans of litigating entities using these expanded exemptions. The Departments believe that number is lower based upon the receipt, by many of those litigating entities, of permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate, which have been entered by federal district courts since the issuance of the Religious IFC.[81] As a result, these final rules will not affect whether such entities will be subject to the contraceptive Mandate. Subtracting those entities from the total, the Departments estimate that the remaining litigating entities employ

[79] By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, *https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf,* Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). *See* 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives (''the Pill''—combined pill); oral contraceptives (''the Pill''—extended/continuous use/combined pill); oral contraceptives (''the Mini Pill''—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and ''[t]he pill and female sterilization have been the two most commonly used methods since 1982.'' *See* Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[80] This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. In addition, the Departments have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or the Departments were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage.

[81] *See, for example, Catholic Benefits Ass'n LCA* v. *Hargan,* No. 5:14–cv–00240–R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll.* v. *Burwell,* No. 5:13–cv–04100 (N.D. Iowa order filed June 12, 2018).

approximately 49,000 persons, male and female. The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent.[82] This amounts to approximately 29,000 employees covered under those plans. EBSA estimates that for each employee policyholder, there is approximately one dependent.[83] This amounts to approximately 58,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15 to 44—compose 20.2 percent of the general population.[84] Furthermore, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[85] Therefore, the Departments estimate that approximately 5,200 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that might be affected by these final rules. The Departments also estimate that, for the educational institutions that brought litigation challenges objecting to the Mandate as applied to student coverage that they arranged—where (1) the institutions were not exempt under the prior rule, (2) their student plans were not self-insured, and (3) they have not received permanent injunctions preventing the application of the previous regulations—such student plans likely covered approximately 2,600 students. Thus, the Departments estimate the female members of those plans is 2,600 women.[86] Assuming, as referenced above, that 43.6 percent of such women use contraception covered by the Guidelines, the Departments estimate that 1,150 of those women would be affected by these final rules.

Together, this leads the Departments to estimate that approximately 6,400 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted previously, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do the Departments know how many would have alternative contraceptive access from a parent's or spouse's plan, or from federal, state, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

v. Estimates of Accommodated Entities That May Use Expanded Exemptions

In the Religious IFC, the Departments also examined data concerning user-fee reductions to estimate how many women might be affected by entities that are using the accommodation and would use the expanded exemptions under these final rules. Under the accommodation, HHS has received information from issuers that seek user fees adjustments under 45 CFR 156.50(d)(3)(ii), for providing contraceptive payments for self-insured plans that make use of the accommodation. HHS receives requests for fees adjustments both where Third Party Administrators (TPAs) for those self-insured accommodated plans are themselves issuers, and where the TPAs use separate issuers to provide the payments and those issuers seek fees adjustments. Where the issuers seeking adjustments are separate from the TPAs, the TPAs are asked to report the number of persons covered by those plans. Some users do not enter all the requested data, and not all the data for the 2017 plan year is complete. Nevertheless, HHS has reviewed the user fees adjustment data received for the 2017 plan year. HHS's best estimate from the data is that there were $38.4 million in contraception claims sought as the basis for user fees adjustments for plans, and that these claims were for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female.

This number fluctuates from year to year. It is larger than the estimate used in the Religious IFC because, on closer examination of the data, this number better accounts for plans where TPAs were also issuers seeking user fees adjustments, in addition to plans where the TPA is separate from the issuer seeking user fees adjustments. The number of employers using the accommodation where user fees adjustments were sought cannot be determined from HHS data, because not all users are required to submit that information, and HHS does not necessarily receive information about fully insured plans using the accommodation. Therefore, the Departments still consider our previous estimate of 209 entities using the accommodation as the best estimate available.

As noted in the Religious IFC, HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly tens of thousands of persons each and are proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

The Departments continue to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[87]

[82] See Kaiser Family Foundation and Health Research and Educational Trust, ''Employer Health Benefits: 2018 Annual Survey'' at 62, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[83] Employee Benefits Security Administration, ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[84] United States Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/;* also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/*contraceptive-use-united-states.

[85] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 61,491,766 women aged 15–44, 26,809,5550 use women's contraceptive methods covered by the Guidelines).

[86] On average, the Departments expect that approximately half of those students (1,300) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. The Departments expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, the Departments assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 2,6,00. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, the Departments assume they are. Therefore, for the purposes of this estimate, the Departments assume that the effect of these expanded exemptions on student plans of litigating entities includes 2,600 women.

[87] See, *e.g., https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule* (''HHS has now established an accommodation that will allow our ministries to continue offering health

Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[88] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[89] (The Departments take no view on the status of these particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.) Nevertheless, considering all these factors, it generally seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations, the Religious IFC and these final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.''). In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it ''is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia.'' Comments on CMS–9968–ANPRM (dated June 15, 2012).

[88] See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, Advocate Health Care Network, Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) (''CHA members have relied for decades that the 'church plan' exemption contained in'' ERISA.).

[89] See *https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf;* see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

vi. Combined Estimates of Litigating and Accommodated Entities

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these final rules. In addition to the estimate of 6,400 women of childbearing age that use contraception covered by the Guidelines, who will be affected by use of the expanded exemption among litigating entities, the Departments calculate the following number of women who we estimate to be affected by accommodated entities using the expanded exemption. As noted above, approximately 1,823,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2017. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, the Departments do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, the Departments assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans.[90] Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation under the previous regulations.

Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans. The data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems and other entities likely to continue using the accommodation constitute over 60 percent of plans using the accommodation, and encompass more than 90 percent of the persons covered in accommodated plans.[91] In other words, plans sponsored by such entities appear to be a majority of plans using the accommodation, and also have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. Moreover, as cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these final rules would not impact the contraceptive coverage their employees receive.

The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons

[90] ''Health Insurance Coverage Bulletin'' Table 3A, page 14. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[91] The data also reflects a religious university using the accommodation that has publicly affirmed the accommodation is consistent with its religious views, and two houses of worship that are using the accommodation despite already qualifying for the previous exemption. We assume for the purposes of this estimate these three entities will also continue using the accommodation instead of the expanded exemption.

previously covered in accommodated plans.

Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, women of childbearing age comprise 20.2 percent of the population, which means that approximately 147,000 women of childbearing age are covered in previously accommodated plans that the Departments estimate will use the expanded exemption. As noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that the Departments expect approximately 64,000 women that use contraception covered by the Guidelines will be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 6,400 women in plans of litigating entities that may be affected by these rules. In order to more broadly estimate the possible effects of these rules, the Departments assume there is no overlap between the two numbers, and therefore that these final rules would affect the contraceptive costs of approximately 70,500 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these final rules is approximately 0.1 percent of the 55.6 million women in private plans that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated in 2015 received preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the previous accommodation process, the total amount of contraceptive claims sought for self-insured plans for the 2017 benefit year was $38.5 million.[92] These adjustments covered the cost of contraceptive coverage provided to women. As also discussed above, the Departments estimate that amount corresponded to plans covering 1,823,000 persons. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age, and of those, approximately 43.6 percent use women's contraceptive methods covered by the Guidelines. This amounts to approximately 161,000 women. Therefore, entities using contraceptive user fees adjustments received approximately $239 per year per woman of childbearing age that used contraception covered by the Guidelines and covered in their plans. But in the Religious IFC, we estimated that the average annual cost of contraception per woman per year is $584. As noted above, public commenters cited similar estimates of the annual cost of various contraceptive methods, if calculated for the life of the method's effectiveness. Therefore, to estimate the annual transfer effects of these final rules, the Departments will continue to use the estimate of $584 per woman per year. With an estimated impact of these final rules of 70,500 women per year, the financial transfer effects attributable to these final rules on those women would be approximately $41.2 million.

Some commenters suggested that the Departments' estimate of women affected among litigating entities was too low, but they did not support their proposed higher numbers with citations or specific data that could be verified as more reliable than the estimates in the Religious IFC. Their estimates appeared to be overinclusive, for example, by counting all litigating entities and not just those that may be affected by these rules because they are not in church plans, or by counting all plan participants and not just women of childbearing age that use contraception. Moreover, since the Religious IFC was issued, additional entities have received permanent injunctions against enforcement of any regulations implementing the contraceptive Mandate and so will not be affected by these final rules. Taking all of these factors into account, the Departments are not aware of a better method of estimating the number of women affected by these expanded exemptions.

vii. Alternate Estimates Based on Consideration of Pre-ACA Plans

To account for uncertainty in the estimates above, the Departments conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these final rules.

In 2015, ASPE estimated that 55.6 million women aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[93] The Religious IFC used this estimate in this second analysis of the possible impact of the expanded exemptions in the interim final rules. ASPE has not issued an update to its report. Some commenters noted that a private organization published a fact sheet in 2017 claiming to make similar estimates based on more recent data, in which it estimated that 62.4 million aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[94] The primary difference between these numbers appears to be a change in the number of persons covered by grandfathered plans.

The methodology of both reports do not fully correspond to the number the Departments seek to estimate here for the purposes of *Executive Orders 12866 and 13563.* These final rules will not affect all women aged 15 to 64 who are covered by private insurance and have coverage of preventive services under the Affordable Care Act. This is partly because the Departments do not have evidence to suggest that most employers will have sincerely held religious objections to contraceptive coverage and will use the expanded exemptions. In addition, both reports include women covered by plans that are not likely affected by the expanded exemptions for other reasons. For example, even though the estimates in those reports do not include enrollees in public plans such as Medicare or Medicaid, they do include enrollees in plans obtained on the health insurance marketplaces, purchased in the individual market, obtained by self-employed persons, or offered by government employers. Women who purchase plans in the marketplaces, the individual market, or as self-employed persons are not required to use the exemptions in these rules. Government employers are also not affected by the exemptions in these rules.

In response to public comments citing the more recent report, the Departments offer the following estimates based on more recent data than used in the Religious IFC. Data from the U.S. Census Bureau indicates that 167.6 million individuals, male and female, under 65 years of age, were covered by

[92] The amount of user fees adjustments provided was higher than this, since an additional administrative amount was added to the amount of contraceptive costs claimed.

[93] Available at *https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf.*

[94] The commenters cited the National Women's Law Center's Fact Sheet from September 2017, available at *https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf.*

employment-based insurance in 2017.[95] Of those, 50.1 percent were female, that is, 84 million.[96] The most recent Health Insurance Coverage Bulletin from EBSA states that, within employer-sponsored insurance, 76.5% are covered by private sector employers.[97] As noted above, these expanded exemptions do not apply to public sector employers. Assuming the same percentage applies to the Census data for 2017, 64.2 million women under 65 years of age were covered by private sector employment based insurance. EBSA's bulletin also states that, among those covered by private sector employer sponsored insurance, 5% receive health insurance coverage from a different primary source.[98] We assume for the purposes of this estimate that an exemption claimed by an employer under these rules need not affect contraceptive coverage of a person who receives health insurance coverage from a different primary source. Again assuming this percentage applies to the 2017 coverage year, we estimate that 61 million women under 65 years of age received primary health coverage from private sector, employment-based insurance. In conducting this analysis, the Departments also observed that for 3.8 percent of those covered by private sector employment sponsored insurance, the plan was purchased by a self-employed person, not by a third party employer. Self-employed persons who direct firms are not required to use the exemptions in these final rules, but if they do, they would not be losing contraceptive coverage that they want to have, since they would be using the exemption based on their sincerely held religious beliefs. If those persons have employees, the employees would be included in this estimate in the number of people who receive employer sponsored insurance from a third party. Assuming this percentage applies to the 2017 coverage year, we estimate that 58.7 million women under 65 years of age received primary health coverage from private sector insurance from a third party employer plan sponsor.

The Kaiser Family Foundation's Employer Health Benefits Annual Survey 2018 states that 16% of covered workers at all firms are enrolled in a plan grandfathered under the ACA (and thus not subject to the preventive services coverage requirements), but that only 14% of workers receiving coverage from state and local government employer plans are in grandfathered plans.[99] Using the data cited above in EBSA's bulletin concerning the number of persons covered in public and private sector employer sponsored insurance, this suggests 16.6% of persons covered by private sector employer sponsored plans are in grandfathered plans, and 83.4% in non-grandfathered plans.[100] Applying this percentage to the Census data, 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans. Census data indicates that among women under age 65, 46.7% are of childbearing age (aged 15 to 44).[101] Therefore, we estimate that 22.9 million women aged 15–44 received primary health insurance coverage from private sector, third party employment based, non-grandfathered insurance plans.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.[102] The 6 percent may have included approximately 1.37 million of the women aged 15 to 44 primarily covered by employer-sponsored insurance plans in the private sector. And as noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore, the Departments estimate that 599,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[103]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for religious or other reasons. Despite the lack of information about their motives, the Departments attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, the Departments estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby,* where the Court observed that ''HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable.'' 134 S. Ct. at 2774. The Departments are aware of several federal health care conscience

[95] See U.S. Census Bureau Current Population Survey Table HI–01, ''Health Insurance Coverage in 2017: All Races,'' available at *https://www2.census.gov/programs-surveys/cps/tables/hi-01/2018/hi01_1.xls.*

[96] *Id.*

[97] Table 1A, page 5 (stating that in coverage year 2015, 177.5 million persons of all ages were covered by employer sponsored insurance, with 135.7 million of those being covered by private sector employers), available at *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[98] *Id.* at Table 1C, page 8 (168.7 million persons received health insurance coverage from employer sponsored insurance as their primary source, compared to 177.5 million persons covered by employer sponsored insurance overall).

[99] ''Employer Health Benefits: 2018 Annual Survey'' at 211, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[100] EBSA's bulletin shows 168.7 million persons with primary coverage from employer sponsored insurance, with 131.6 million in the private sector and 37.1 million in the public sector. 16% of 168.7 million is 26.9 million. 14% of 37.1 million is 5.2 million. 26.9 million − 5.2 million is 21.8 million, which is 16.6% of the 131.6 million persons with primary coverage from private sector employer sponsored insurance.

[101] U.S. Census Bureau, Table S0101 ''Age and Sex'' (available at *https://data.census.gov/cedsci/results/tables?q=S0101:%20AGE%20AND%20SEX&ps=table*currentPage@1*).

[102] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2010 Annual Survey'' at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf.*

[103] Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these final rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these final rules.

laws [104] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but the Departments are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while the Departments consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those reasons used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions, the Departments agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.[105] That means that only approximately 411,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, because these final rules build on previous regulations that already exempted houses of worship and integrated auxiliaries and, as explained above, effectively eliminated obligations to provide contraceptive coverage within objecting self-insured church plans, the Departments attempt to estimate the number of such employers whose employees would not be affected by these rules. In attempting to estimate the number of such employers, the Departments consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the United States,[106] 197 Catholic dioceses,[107] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[108] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention covering 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[109] Christian Brothers is a plan that covers Catholic organizations including Catholic churches and integrated auxiliaries, which are estimated above, but has also said in litigation that it covers about 500 additional entities that are not exempt as churches.[110] In total, therefore, without having certain data on the number of entities exempt under the previous rules, the Departments estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous regulations. The Departments do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include ''churches, mission-sending agencies, hospitals, educational institutions and other related ministries.'' Using that ratio, the Departments estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 women would be of childbearing age, and 32,100 may use contraceptives covered by the Guidelines.

Taking all of these factors into account, the Departments estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines. But to estimate the likely actual transfer impact of these final rules, the Departments must estimate not just the number of such women covered by those entities, but how many of those entities would actually qualify for, and use, the expanded exemptions.

The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. Consequently, as explained below, the Departments believe that the potential impact of these final rules falls substantially below the $100 million threshold for an economically significant major rule.

First, as mentioned, the Departments are not aware of information, or of data from public comments, that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons. It would seem reasonable to assume that many of those entities did not do so based on sincerely held religious beliefs. According to a 2016 poll, only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective).[111] In addition,

[104] For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

[105] John Asker, et al., ''Corporate Investment and Stock Market Listing: A Puzzle?'' 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at *https://doi.org/10.1093/rfs/hhu077*. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, ''The number of publicly-traded US companies is down 46% in the past two decades,'' *Yahoo! Finance* (Aug. 8, 2016), available at *https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html*.

[106] Roman Catholic Diocese of Reno, ''Diocese of Reno Directory: 2016–2017,'' available at *http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf*.

[107] Wikipedia, ''List of Catholic dioceses in the United States,'' available at *https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States*.

[108] National Catholic Educational Association, ''Catholic School Data,'' available at *http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx*.

[109] Guidestone Financial Resources, ''Who We Serve,'' available at *https://www.guidestone.org/AboutUs/WhoWeServe*.

[110] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[111] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination''

various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage, such as avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.[112] Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees and, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

It may not be the case that all entities that objected on religious grounds to contraceptive coverage before the ACA brought suit against the Mandate. However, it is worth noting that, while less than 100 for-profit entities challenged the Mandate in court (and an unknown number joined two newly formed associational organizations bringing suit on their behalf), there are more than 3 million for-profit private sector establishments in the United States that offer health insurance.[113] Six percent of those would be 185,000, and one third of that number would be 62,000. The Departments consider it unlikely that tens or hundreds of thousands of for-profit private sector establishments omitted contraceptive coverage pre-ACA specifically because of sincerely held religious beliefs, when, after six years of litigation and multiple public comment periods, the Departments are aware of less than 100 such entities. The Departments do not know how many additional nonprofit entities would use the expanded exemptions, but as noted above, under the rules predating the Religious IFC, tens of thousands were already exempt as churches or integrated auxiliaries, or were covered by self-insured church plans that are not penalized if no contraceptive coverage is offered.

Finally, among entities that omitted contraceptive coverage based on sincerely held conscientious objections as opposed to other reasons, it is likely that some, albeit a minority, did so based on moral objections that are non-religious, and therefore would not be compassed by the expanded exemptions in these final rules.[114] Among the general public, polls vary about religious beliefs, but one prominent poll shows that 13 percent of Americans say they do not believe in God or have no opinion on the question.[115] Therefore, the Departments estimate that, of the entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, a small fraction did so based on sincerely held non-religious moral convictions, and therefore would not be affected by the expanded exemption provided by these final rules for religious beliefs.

For the reasons stated above, the Departments believe it would be incorrect to assume that all or even most of the plans that did not cover contraceptives before the ACA did so on the basis of religious objections. Instead, without data available on the reasons those plans omitted contraceptive coverage before the ACA, we assume that no more than one third of those plans omitted contraceptive coverage based on sincerely held religious beliefs. Thus, of the estimated 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines, who received primary coverage from plans of private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations, we estimate that no more than 126,400 women would be in plans that will use these expanded exemptions.

viii. Final Estimates of Persons Affected by Expanded Exemptions

Based on the estimate of an average annual expenditure on contraceptive products and services of $584 per user, the effect of the expanded exemptions on 126,400 women would give rise to approximately $73.8 million in potential transfer impact. It is possible, however, that premiums would adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As referenced elsewhere in this analysis, such women may make up approximately 8.8 percent of the covered population,[116] in which case the offset would also be approximately 8.8 percent, yielding a potential transfer of $67.3 million.

Thus, in their most expansive estimate, the Departments conclude that no more than approximately 126,400 women would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. The Departments estimate this financial transfer to be approximately $67.3 million. This falls substantially below the $100 million threshold for an economically significant and major rule.

As noted above, the Departments view this alternative estimate as being the highest possible bound of the transfer effects of these rules, but believe the number of establishments that will actually exempt their plans as the result of these rules will be far fewer than contemplated by this estimate. The Departments make these estimates only for the purposes of determining whether the rules are economically significant under Executive Orders 12866 and 13563.

After reviewing public comments, both those supporting and those disagreeing with these estimates and similar estimates from the Religious IFC, and because the Departments do not have sufficient data to precisely

at page 26 (Sept. 28, 2016), available at *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[112] On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered ''yes'' or ''don't know'' to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule's effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

[113] Tables I.A.1 and I.A.2, Medical Expenditure Panel Survey, ''Private-Sector Data by Firm Size, Industry Group, Ownership, Age of Firm, and Other Characteristics: 2017,'' HHS Agency for Healthcare Research and Quality (indicating total number of for-profit incorporated, for-profit unincorporated, and non-profit establishments in the United States, and the percentage of each that offer health insurance), available at *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia1.htm* and *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia2.htm.* 2523.

[114] Such objections may be encompassed by companion final rules published elsewhere in today's **Federal Register**. Those final rules, however, are narrower in scope than these final rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[115] Gallup, ''Religion,'' available at *https://news.gallup.com/poll/1690/religion.aspx.*

[116] As cited above, women of childbearing age are 20.2 percent of woman aged 15–65, and 43.6 percent of women of childbearing age use contraceptives covered by the Guidelines.

estimate the amount by which these factors render our estimate too high, or too low, the Departments simply conclude that the financial transfer falls substantially below the $100 million threshold for an economically significant rule based on the calculations set forth above.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. The Religious IFC was an interim final rule with comment period, and in these final rules, the Departments adopt the Religious IFC as final with certain changes. These final rules are, thus, being issued after a notice and comment period.

The Departments also carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866 and do not expect that these final rules will have a significant economic effect on a substantial number of small entities. These final rules will not result in any additional costs to affected entities, and, in many cases, may relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization—businesses and organizations that would otherwise be faced with the dilemma of complying with the Mandate (and violating their religious beliefs) or following their beliefs (and incurring potentially significant financial penalties for noncompliance)—the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In the October 13, 2017 (82 FR 47792) interim final rules, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). A description of the information collection provisions implicated in these final rules is given in the following section with an estimate of the annual burden. The burden related to these ICRs received emergency review and approval under OMB control number 0938–1344. They have been resubmitted to OMB in conjunction with these final rules and are pending re-approval. The Departments sought public comments on PRA estimates set forth in the Religious IFC, and are not aware of significant comments submitted that suggest there is a better way to estimate these burdens.

1. Wage Data

Average labor costs (including 100 percent fringe benefits and overhead) used to estimate the costs are calculated using data available derived from the Bureau of Labor Statistics.[117]

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupational code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Executive Secretaries and Executive Administrative Assistants	43–6011	$27.84	$27.84	$55.68
Compensation and Benefits Manager	11–3111	61.01	61.01	122.02
Legal Counsel	23–1011	67.25	67.25	134.50
Senior Executive	11–1011	93.44	93.44	186.88
General and Operations Managers	11–1021	58.70	58.70	117.40

2. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under these final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations (80 FR 41318).

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party

[117] May 2016 National Occupational Employment and Wage Estimates United States found at *https://www.bls.gov/oes/current/oes_nat.htm.*

administrator). As explained above, HHS assumes that, among the 209 entities the Departments estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.[118] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour, 5 minutes for legal counsel at a cost of $134.50 per hour, and 5 minutes by a senior executive at a cost of $186.88 per hour) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost of approximately $74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

HHS estimates that each self-certification or notice to HHS will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be $0.55. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for $1.38 of the cost burden.

[118] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations (80 FR 41318), a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language previously provided by HHS or substantially similar language.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $55.68 per hour) and 15 minutes of management review (at $117.40 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an associated cost of approximately $85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately $9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of $4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. We reach this estimate using calculations set forth above, in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As noted above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data.

Based on these assumptions and without better data available, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000

persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.[119] For 109 entities, the total number of notices will be 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[120] Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.55. The total cost for sending approximately 551,254 notices by mail will be approximately $303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $151,595 of the cost burden.

4. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization that now wishes to take advantage of the expanded exemption may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke their use of the accommodation fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour, 30 minutes for legal counsel at a cost of $134.50 per hour, 1 hour for clerical staff at a cost of $55.68 per hour). The burden per respondent will be 2 hours with an associated cost of approximately $182; for 109 entities, the total hour burden will be 218 hours with an associated cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an associated cost of approximately $9,899.

As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[121] As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.55. The total cost for sending approximately 168,579 notices by mail is approximately $93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately $46,772.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB Control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Self-Certification or Notices to HHS	0938–1344	*5	5	0.83	3.75	$89.95	$337	$339
Notice of Availability of Separate Payments for Contraceptive Services	0938–1344	*55	595,307	1.25	68.13	68.02	4,634	156,229
Notice of Revocation of Accommodation	0938–1344	*55	182,051	2.00	109	90.82	9,899	56,671
Total		*115	777,363		180.88		14,870	213,239

*The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

[119] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[120] According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

[121] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the number of women in accommodated plans affected by these final rules overlap with the number of women in plans offered by litigating entities that will be affected by these final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

5. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

The Religious final rules amended the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer revokes their accommodation; these final rules confirm as final the Religious IFC provisions on the accommodation process. DOL submitted the ICRs to OMB in order to obtain OMB approval under the PRA for the regulatory revision. In an effort to consolidate the number of information collection requests, DOL is combining the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150 and discontinuing OMB control number 1210–0152. Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 1,190,613 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke their use of the accommodation (in favor of the expanded exemption) and will therefore be required to cause the Notice of Revocation of Accommodation to be sent, with the issuer or third party administrator able to send the notice on behalf of the entity. These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 364,102 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 [122] (combined with HHS total is 227).

Total Responses: 777,362 (combined with HHS total is 1,554,724).

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: $197,955 (combined with HHS total is $395,911).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the states more flexibility and control to create a freer and open healthcare market.'' These final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these final rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[123] However, in order to avoid double-counting with the Religious IFC, which has already been tallied as an Executive Order 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

[122] Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

[123] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (Dominic J. Mancini, ''Guidance Implementing Executive Order 13771, Titled ''Reducing Regulation and Controlling Regulatory Costs,'' Office of Mgmt. & Budget (Apr. 5, 2017), *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' In 2018, that threshold after adjustment for inflation is $150 million. For purposes of the Unfunded Mandates Reform Act, the Religious IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of $150 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These final rules do not have any federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code, and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Pub. L. 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4); Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701); and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 3. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the

Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(b) *Optional accommodation—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services) will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not

apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): ''Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].''

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be

incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2713T [Removed]

■ 4. Section 54.9815–2713T is removed.

§ 54.9815–2713AT [Removed]

■ 5. Section 54.9815–2713AT is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim final rules amending 29 CFR part 2590 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read, as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713A is amended by:
■ a. Revising paragraph (a)(5);
■ b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g); and
■ c. Adding new paragraph (e).

The revision and addition read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * *

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 8. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 9. Section 147.131 is amended by:
■ a. Revising paragraph (c)(4);
■ b. Redesignating paragraphs (f) and (g) as (g) and (h); and
■ c. Adding new paragraph (f).

The revision and addition read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

* * * * *

(c) * * *

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if

contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

■ 10. Section 147.132 is amended by:
■ a. Revising paragraph (a)(1) introductory text;
■ b. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (iii) and (iv);
■ c. Adding new paragraph (a)(1)(ii);
■ d. Revising newly designated paragraph (a)(1)(iii);
■ e. Revising newly designated paragraph (a)(1)(iv); and
■ f. Revising paragraphs (a)(2) and (b).

The revisions and addition read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24512 Filed 11–7–18; 4:15 pm]

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FEDERAL REGISTER

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Part III

Department of the Treasury

Internal Revenue Service

Department of Labor

Employee Benefits Security Administration

Department of Health and Human Services

26 CFR Part 54
29 CFR Part 2590
45 CFR Part 147
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9841]

RIN 1545–BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9925–F]

RIN 0938–AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, the interim final rules issued in the **Federal Register** on October 13, 2017 concerning moral exemptions and accommodations regarding coverage of certain preventive services. These rules finalize expanded exemptions to protect moral beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an optional ''accommodation'' process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT:
Jeff Wu at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
Amber Rivers or Matthew Litton at (202) 693–8335 for Employee Benefits Security Administration (EBSA), Department of Labor (DOL).
William Fischer at (202) 317–5500 for Internal Revenue Service, Department of the Treasury.
Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit DOL's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of these final rules is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47838), ''Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (the Moral IFC). The rules are necessary to protect sincerely held moral objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their moral beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, which was created by HHS through guidance promulgated by the Health Resources and Services

Administration (HRSA), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules finalize references to these moral exemptions in the previously created accommodation process that permit entities with certain objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's guidelines. The changes to the rules being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Moral Exemptions

These rules finalize exemptions provided in the Moral IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held moral convictions opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's guidelines. As in the Moral IFC, the exemptions include plan sponsors that are nonprofit organization plan sponsors or for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The exemptions also continue to include institutions of higher education in their arrangement of student health insurance coverage; health insurance issuers (but only with respect to plans that are otherwise also exempt under the rules); and objecting individuals with respect to their own coverage, where their health insurance issuer and plan sponsor, as applicable, are willing to provide coverage complying with the individual's moral objection. After considering public comments, the Departments have decided not to extend the moral exemptions to non-federal governmental entities at this time, although individuals receiving employer-sponsored insurance from a governmental entity may use the individual exemption if the other terms of the individual exemption apply, including that their employer is willing to offer them a plan consistent with their moral objection.

In response to public comments, various changes are made to clarify the intended scope of the language in the Moral IFC's exemptions. The prefatory exemption language is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to specify that the exemption for institutions of higher education applies to non-governmental entities. The Departments also modified language describing the moral objection applicable to the exemptions, to specify that the entity objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable) either: Coverage or payments for some or all contraceptive services; or a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The clarification is made to ensure that the HRSA guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. References to Moral Exemptions in Accommodation Regulations and in Regulatory Restatement of Statutory Language

These rules finalize without change the references to the moral exemptions that were inserted by the Moral IFC into the rules that regulatorily restate the statutory language from section 2713(a) and (a)(4) of the Public Health Service Act. Similarly, these rules finalize without change from the Moral IFC references to the moral exemptions that were inserted into the regulations governing the optional accommodation process. These references operationalize the effect of the moral exemptions rule, and they allow contraceptive services to be made available to women if any employers with non-religious moral objections to contraceptive coverage choose to use the optional accommodation process.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and Benefits	Costs
Finalizing insertion of references to moral exemptions into restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	These provisions, finalized without change, are for the purpose of inserting references to the moral exemptions into the regulatory restatement of section 2713(a) and (a)(4) of the Public Health Service Act, which already references the religious exemptions. This operationalizes the moral exemptions in each of the tri-agencies' rules. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.

Provision	Savings and Benefits	Costs
Finalized moral exemptions	The moral exemptions to the contraceptive coverage requirement are finalized with technical changes. Their purpose is to relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their moral beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage in violation of their sincerely held moral beliefs.	We estimate there will be only a small amount of costs for these exemptions, because they will primarily be used by organizations and individuals that do not want contraceptive coverage. To the extent some other employers will use the exemption where there will be transfer costs for women previously receiving contraceptive coverage who will no longer receive that coverage, we expect those costs to be minimal due to the small number of entities expected to use the exemptions with non-religious moral objections. We estimate the transfer costs will amount to $8,760.
Finalizing insertion of references to moral exemptions into optional accommodation regulations.	These provisions, finalized without change, will allow organizations with moral objections to contraceptive coverage on the basis of sincerely held moral convictions to use the accommodation as an optional process. These provisions will allow contraceptive coverage to be made available to women covered by plans of employers that object to contraceptive coverage but do not object to their issuers or third party administrators arranging for such coverage to be provided to persons covered by their plans.	We do not estimate any entities with non-religious moral objections to use the accommodation process at this time.

B. Background

Over many decades, Congress has protected conscientious objections including based on moral convictions in the context of health care and human services, and including health coverage, even as it has sought to promote access to health services.[1] In 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended PPACA. As amended by HCERA, PPACA is known as the Affordable Care Act (ACA).

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter ''section 2713(a)(4)''), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, ''with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported'' by HRSA (the ''Guidelines'').

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *Id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *Id.* at Div. E, Sec. 808 (regarding any requirement of ''the provision of contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *Id.* at Div. K, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice, now Medicare Advantage, managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] The references in this document to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to ''Contraceptive Methods and Counseling'' as ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header ''Contraception,'' to: ''the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family

time period, the administering agencies—HHS, the Department of Labor, and the Department of the Treasury (collectively, ''the Departments'' [3])—exercised discretion to allow exemptions to those requirements by issuing rulemaking various times, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments crafted exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Public comments were submitted on various iterations of the regulations issued before 2017, and some of those comments supported expanding the exemptions to include those who oppose the contraceptive coverage mandate for either religious ''or moral'' reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[5]

During the period when the Departments were publishing and modifying the regulations, organizations and individuals filed dozens of lawsuits challenging the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate''). Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. For-profit entities with religious objections won various court decisions leading to the Supreme Court's ruling in *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[6] Later, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On May 16, 2016, the Supreme Court issued a per curiam decision, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases ''in light of the substantial clarification and refinement in the positions of the parties'' that had been filed in supplemental briefs. *Zubik* v. *Burwell,* 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would ''allow the parties sufficient time to resolve any outstanding issues between them.'' *Id.*

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations stated that they believe some methods classified by the Food and Drug Administration (FDA) as contraceptives may have an abortifacient effect and, therefore, in their view, are morally equivalent to abortion to which they have a moral objection. Under regulations preceding October 2017, these organizations neither received an exemption from the Mandate nor qualified for the accommodation. For example, March for Life filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, 77 FR 8727, March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who ''want'' the coverage so as to prevent ''unintended'' pregnancy. March for Life contended that, because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and, therefore, was arbitrary and capricious in violation of the APA. March for Life further contended that, because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on the assumption that such entities are relatively more likely than other nonprofits with religious objections to have employees that share their views against certain contraceptives), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and, therefore, violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violated their rights under RFRA by making it impossible for them to obtain health coverage consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real*

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planning practices, and sterilization procedures,'' ''contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),'' and ''instruction in fertility awareness-based methods, including the lactation amenorrhea method.'' *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

[5] *See, for example,* Denise M. Burke, Re: file code CMS–9968–P, *Regulations.gov* (posted May 5, 2013), *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54142;* David Sater, Re: CMS–9931–NC: Request for Information, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54218;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

[6] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. *See* 134 S. Ct. at 2774.

Alternatives, Inc. v. *Burwell,* 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims, while not specifically ruling on the APA claim, and issued a permanent injunction against the Departments that is still in place. *March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, federal district and appellate courts in Pennsylvania disagreed with the reasoning in *March for Life,* and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* v. *Sec'y of HHS* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. 867 F.3d 338, 367 (3d Cir. 2017) (Jordan, J., dissenting).

The Departments most recently solicited public comments on these issues again in two interim final regulations with request for comments published in the **Federal Register** on October 13, 2017: The regulations (82 FR 47838) (the Moral IFC) that are being finalized with changes here, and the regulations (82 FR 47792) (the Religious IFC) published on the same day as the Moral IFC, which are being finalized with changes in the companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Moral IFC, the Departments explained several reasons why, after exercising our discretion to reevaluate the exemptions and accommodations for the contraceptive Mandate, we sought public comment on whether to protect moral convictions in the Moral IFC and these final rules. The Departments noted that we considered, among other things, Congress's history of providing protections for moral convictions regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); previously submitted public comments; and the extensive litigation over the contraceptive Mandate. The Departments concluded that it was appropriate that HRSA take into account the moral convictions of certain employers, individuals and health insurance issuers where the coverage of contraceptive services is concerned. Comments were requested on the interim final regulations.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Moral IFC, with changes based on comments as indicated herein.[7]

II. Overview of the Final Rules and Public Comments

During the 60-day comment period for the Moral IFC, which closed on December 5, 2017, the Departments received over 54,000 public comment submissions, which are posted to *www.regulations.gov*.[8] Below, the Departments provide an overview of the final rules and address the issues raised in the comments we received.

A. Moral Exemptions and Accommodation in General

These rules expand exemptions to protect certain entities and individuals with moral convictions that oppose contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also make available to exempt organizations the accommodation process, which was previously established in response to some objections of religious organizations, as an optional process for exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[9]

1. The Departments' Authority To Mandate Coverage or Provide Exemptions

The Departments received conflicting comments on their legal authority to provide exemptions and accommodations to the Mandate. Some commenters agreed that the Departments are legally authorized to provide expanded exemptions and an accommodation for moral convictions, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing moral exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the religious exemptions that existed prior to the 2017 IFCs, but not to protect moral convictions.

The Departments conclude that we are legally authorized to provide the exemption and accommodation for moral convictions set forth in the Moral IFC and these final rules. These rules concern section 2713 of the PHS Act, as incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Where it applies, section 2713(a)(4) requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' guidelines developed by HHS acting through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a

[7] The Department of the Treasury and Internal Revenue Service published proposed and temporary regulations as part of the joint rulemaking of the Moral IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules in these final rules. The Department of the Treasury and Internal Revenue Service are finalizing their regulations.

[8] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2017-0133* and *https://www.regulations.gov/docketBrowser?rpp=25&so=ASC&sb=postedDate&po=100&D=IRS-2017-0015.* Some of those submissions included form letters or attachments that, while not separately tabulated at regulations.gov, together included comments from, or were signed by, possibly over a hundred thousand separate persons. The Departments reviewed all of the public comments and attachments.

[9] *See, for example,* Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS to shape that development, as the administering agency of HRSA, and to all three agencies as the administering agencies of the statutes by which the Guidelines are enforced. *See* 26 U.S.C. 9833; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must ''provide for'' and ''support'' the application of Guidelines that it chooses to adopt. HRSA's authority to support ''comprehensive guidelines'' involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only ''as provided for in comprehensive guidelines supported by [HRSA].'' That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word ''as'' in the phrase ''as provided for,'' it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase ''as you like it.'' [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See for example,* 42 U.S.C. 1395x (''The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.'') (emphasis added). Thus, the inclusion of ''as'' in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has discretion whether to support how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word ''as'' is missing from the other three provisions in section 2713(a) of the PHS Act. Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require ''evidence-based'' or ''evidence-informed'' coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The moral objections at issue here, like the religious objections prompting exemptions dating back to the inception of the Mandate in 2011, may, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines ''exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,'' and ''it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.'' *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a mandate that contraceptives be covered or that they be covered without any exemptions or exceptions, lead the Departments to conclude that we are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The Departments' conclusions are consistent with our interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4) to grant broad discretion to decide the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments created an exemption to the contraceptive Mandate when that Mandate was announced in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to plan participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrator of self-insured church plans (see 80 FR 41323). Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. In doing so, the Departments have been acting contrary to commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or its incorporation into ERISA and the Code, and who contended instead that the Departments must enforce Guidelines on the broadest spectrum of group health plans as possible, even including churches (see, for example, 2012 final regulations at 77 FR 8726).

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (see for

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (''[u]sed to indicate by comparison the way something happens or is done'').

example, 76 FR 46623). On the contrary, Congress carved out an exemption from section 2713 of the PHS Act (and from several other provisions) for grandfathered plans. In contrast, the grandfathering exemption is not applicable to many of the other provisions in Title I of the ACA—provisions previously referred to by the Departments as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2764 n.10 (2014).

Some commenters argue that Executive Order 13535's reference to implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions in the Guidelines. The Departments, however, believe that they are acting consistent with Executive Order 13535 by creating exemptions using HRSA's authority under section 2713(a)(4), and the Departments' administrative authority over the implementation of section 2713(a) of the PHS Act. Executive Order 13535, issued upon the signing of the ACA, specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs or moral convictions from certain requirements in health care contexts. Although the text of Executive Order 13535 does not require the expanded exemptions confirmed in these final rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect conscience objections, based on religious beliefs or moral convictions regarding certain health matters, and are consistent with the intent that the ACA be implemented in accordance with the conscience protections set forth in those laws.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities instead of to individuals, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for sincerely held moral convictions in sensitive healthcare contexts.[12] Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held moral convictions to the extent the Departments otherwise impose a contraceptive Mandate. These exemptions do not prohibit any services, nor authorize employers to prohibit employees from obtaining any services. The exemptions in the Moral IFC and these final rules simply refrain from imposing a federal mandate that employers cover contraceptives in their health plans even if they have sincerely held moral convictions against doing so.

Some commenters stated that the Supreme Court ruled that the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but that exemptions beyond those are not. But the Supreme Court did not rule on the question whether the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate unless RFRA prohibits us from doing so.

The appropriateness of including exemptions to protect moral convictions is informed by Congress's long history of providing exemptions for moral convictions, especially in certain health care contexts.

2. Congress's History of Protecting Moral Convictions

The Department received numerous comments about its decision in the Moral IFC to exercise its discretion to provide moral exemptions to, and an accommodation under, the contraceptive Mandate. Some commenters agreed with the Departments' decision in the Moral IFC, arguing that it is appropriate to exercise the Departments' discretion to protect moral convictions in light of Congress's history of protecting moral convictions in various contexts, especially concerning health care. Other commenters disagreed, saying that existing conscience statutes protecting moral convictions do not require these exemptions and, therefore, the exemptions should not be offered. Some commenters stated that because Congress has provided conscience protections, but did not specifically provide them in section 2713(a)(4), conscience protections are inappropriate in the implementation of that section. Still other commenters went further, disagreeing with conscience protections regarding contraceptives, abortions, or health care in general.

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on the most recent statements of Congress, along with nearly 50 years of statutes and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health coverage. Most recently, Congress expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.'' Consolidated Appropriations Act, 2018, Div. E, section 808, Public Law 115–141, 132 Stat. 348, 603 (Mar. 23, 2018); *see also*

[11] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' Henry J Kaiser Family Foundation (Sept. 19, 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017*.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

Consolidated Appropriations Act, 2017, Div. C, section 808, Public Law 115–31 (May 5, 2017). The Departments consider it significant that Congress's most recent statements on the prospect of Government-mandated contraceptive coverage specifically intend that a conscience clause be included to protect moral convictions.

The Departments also consider significant the many statutes listed above, in section I—Background footnote 1, that show Congress's consistent protection of moral convictions alongside religious beliefs in the federal regulation of health care. These include laws such as the Church Amendments (dating back to 1973), which we discuss at length below, to the 2018 Consolidated Appropriations Act discussed above. Notably among those laws, and in addition to the Church Amendments, Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object ''on moral or religious grounds'' to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare + Choice (now Medicare Advantage) managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''). Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions.'' Consolidated Appropriations Act, 2018, Public Law 115–141, Division E, section 726(c); *see also* Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.[13]

The Departments disagree with commenters that suggested we should not consider Congress's history of protecting moral objections in certain health care contexts due to Congress's failure to explicitly include exemptions in section 2713(a)(4) itself. The argument by these commenters proves too much, since Congress also did not specifically require contraceptive coverage in section 2713 of the PHS Act. This argument would also negate not just these expanded exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting moral convictions in the context of certain federal health care requirements.

a. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations because they had received federal funds. These sections of the U.S. Code are known as the Church Amendments, named after their primary sponsor, Senator Frank Church (D-Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions, not just religious beliefs. Among other things, the amendments protect the recipients of certain federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object ''on the basis of religious beliefs or moral convictions,'' and they prohibit recipients of certain federal health funds from discriminating against any personnel ''because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions'' (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to ''any lawful health service,'' or to ''any part of a health service program.'' (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute ''any lawful health service'' or a ''part of a health service program.'' As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe* v. *Wade,* 410 U.S. 113 (1973). Although the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens facilitate its exercise. Indeed, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared, ''Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.'' 410 U.S. at 144 & n.38 (1973). Likewise, in *Roe*'s companion case, *Doe* v. *Bolton,* the Court observed that, under state law, ''a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.'' 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions ''obviously . . . afford appropriate protection.'' *Id.* at 198. As an Arizona court later put it, ''a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'' *Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe* v. *Wade,* but also an instance where a federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record records this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or

[13] The Departments also note that, in protecting those individual and institutional health care entities that object to certain abortion-related services and activities regardless of the basis for such objection, the Coats-Snowe Amendment, PHS Act section 245 (42 U.S.C. 238n), and the Weldon Amendment, Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141, protect those whose objection is based on moral conviction.

participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.

As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?

Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words ''or moral''?

Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words ''or moral conviction'' were added after ''religious belief.'' I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.

Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18

As the debate proceeded, Senator Church went on to quote *Doe* v. *Bolton'*s reliance on a Georgia statute that stated ''a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.'' 119 Congr. Rec. S5722 (quoting 410 U.S. at 197–98). Senator Church added, ''I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations.'' *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, ''if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?'' 119 Congr. Rec. S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic] [14] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words ''moral conviction,'' because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. S5723

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [15] likewise observed that ''the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious objector status in our selective service system has been protected'' and ''expanded by the Supreme Court to include moral conviction as well as formal religious belief.'' 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, ''We are concerned here only with the right of moral conscience, which has always been a part of our national tradition.'' *Id.* at 4149.

These first sections of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions, as well as those who object to such services on the basis of religious beliefs. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion. *See* 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141.
- Protections for entities and individuals that object to providing or covering contraceptives. *See id.* at Div. E, Sec. 808; *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act); *id.* at Div. K, Title III.
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives. *See* 42 U.S.C. 290bb–36; 42 U.S.C. 1396a(w)(3); 42 U.S.C. 14406; 42 U.S.C. 18113 (adopted as part of the ACA).

The Departments believe that the intent behind Congress's protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports the Departments' decision in the Moral IFC and these final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

b. Court Precedents Relevant to These Expanded Exemptions

As reflected in the legislative history of the first Church Amendments, the Supreme Court has long afforded protection to moral convictions alongside religious beliefs. Indeed, Senator Church cited *Doe* v. *Bolton,* 410 U.S. 179, as a parallel instance of conscience protection and spoke of the Supreme Court generally giving ''comparable treatment to deeply held moral convictions.'' Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh* v. *United States,* 398 U.S. 333 (1970), which the Supreme Court had decided just three years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on ''religious training and belief,'' that protection would also extend to avowedly non-religious objections to war held with the same moral strength.

[14] The Senator might have meant ''[forced] . . . against his will.''

[15] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

Id. at 343. The Court declared, ''[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by . . . God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a 'religious' conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions.''

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby,* Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in *Welsh,* 398 U.S. at 357–58, in support of her statement that ''[s]eparating moral convictions from religious beliefs would be of questionable legitimacy.'' 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious beliefs constitute an illegitimate ''separat[ion]'' of moral convictions, nor do the Departments assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress's intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

c. Conscience Protections in Other Federal and State Contexts

The tradition of protecting moral convictions in certain health contexts is not limited to laws passed by Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[16] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs in particular circumstances. The Equal Employment Opportunity Commission has consistently protected ''moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views'' alongside religious views under the ''standard [ ] developed in *United States* v. *Seeger,* 380 U.S. 163 (1965) and [*Welsh*].'' 29 CFR 1605.1. The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so ''is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics.'' 28 CFR 26.5.[17]

Forty-five states have health care conscience protections covering objections to abortion; several of these also cover sterilization or contraception.[18] Most of those state laws protect objections based on ''moral,'' ''ethical,'' or ''conscientious'' grounds in addition to ''religious'' grounds. Particularly in the case of abortion, some federal and state conscience laws do not require any specified motive for the objection. 42 U.S.C. 238n; Consolidated Appropriations, 2018, Public Law 115–141, Div. H, section 507(d).

These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts. The contraceptive Mandate implicates that governmental interest. Many persons and entities object to the Mandate in part because they consider some forms of FDA-approved contraceptives to be morally equivalent to abortion due to the possibility that such items may prevent the implantation of a human embryo after fertilization.[19] The Supreme Court, in describing family business owners with religious objections, explained that ''[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions.'' *Hobby Lobby,* 134 S. Ct. at 2751. Based on pleadings in the litigation, all of the litigants challenging the Mandate and asserting purely non-religious objections share this view. And as Congress has implicitly recognized in providing health care conscience protections pertaining to sterilization, contraception, and other health care services and practices, individuals or entities may have additional moral objections to contraception.[20]

d. Founding Principles

The Departments also look to guidance from, and draw support for the Moral IFC and these final rules from, the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. In supporting the protection of conscience based on non-religious moral convictions, Senator Buckley declared ''[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.'' Representative Heckler similarly stated that ''the right of moral conscience . . . has always been a part of our national tradition.'' This tradition is reflected, for example, in a letter President George Washington wrote saying that ''[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of

[16] *See, for example,* 42 CFR 422.206 (declaring that the general Medicare Advantage rule ''does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds.''); 42 CFR 438.102 (declaring that information requirements do not apply ''if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds''); 48 CFR 1609.7001 (''health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs.''); 48 CFR 352.270–9 (''Non-Discrimination for Conscience'' clause for organizations receiving HIV or Malaria relief funds).

[17] *See also* 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on ''[c]ultural, religious, or moral objections to the request'').

[18] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). ''Refusing to Provide Health Services,'' The Guttmacher Institute (June 1, 2017), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

[19] FDA, ''Birth Control,'' U.S. Food and Drug Administration (Mar. 6, 2018), *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm* (various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization, but ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization).

[20] *See supra* note 1.

citizenship.'' [21] Thomas Jefferson similarly declared that ''[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority.'' [22] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience ''the most sacred of all property,'' and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that ''the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed.'' [23]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context, and the Departments do not suggest that the specific protections offered in the Moral IFC and these final rules would be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These final rules do not address in any way how the Government would balance its interests with respect to other health services not encompassed by the contraceptive Mandate.[24] Instead, the Departments highlight this tradition of respect for conscience from the Nation's Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4), while protecting conscience in the exercise of moral convictions. The Departments believe that these final rules are consistent both with the American tradition of respect for conscience and with Congress's history of providing conscience protections in the kinds of health care matters involved in this Mandate.

e. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in these expanded exemptions and accommodation in these final rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for ''religious'' beliefs, but for ''conscience.'' We interpret that term to include both religious beliefs and moral convictions. Moreover, President Trump's first Executive Order, E.O. 13765, declared that ''the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' The exemption and accommodation adopted in these final rules relieves a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage and is therefore consistent with both Executive Orders.

f. Litigation Concerning the Mandate

The Departments have further taken into consideration the litigation surrounding the Mandate in exercising their discretion to adopt the exemption in these final rules. Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court affirmed a district court ruling that allows the previous regulations to be imposed in a way that affects the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.,* 867 F.3d 338 (3d Cir. 2017). The Departments' litigation of these cases has thus led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have adopted longstanding moral tenets opposed to certain FDA-approved contraceptives, and hire only employees who share this view. As a result, it is reasonable to conclude that employees of these organizations would not benefit from the Mandate. Thus, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, as well as the legal requirement to comply with permanent injunctive relief currently imposed in *March for Life,* provide substantial reasons for the Departments to protect moral convictions through these final rules. Although, as discussed below, the Departments assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, the Departments know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, the Departments consider it appropriate to issue the protections set forth in these final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so the Departments, too, believe that ''our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government'' in this situation. *See* 119 Congr. Rec. S5717–18.

The litigation concerning the Mandate has also underscored how important it is for the Government to tread carefully when engaging in regulation concerning sensitive health care areas. As demonstrated by the litigation, as well as the public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that certain contraceptive items may cause early abortions. Providing conscience protections advances the ACA's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to

[21] Letter from George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790) (available at *https://founders.archives.gov/documents/Washington/05-06-02-0135*).

[22] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809) (available at *https://founders.archives.gov/documents/Jefferson/99-01-02-9714*).

[23] James Madison, ''Essay on Property'' (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

[24] As the Supreme Court stated in *Hobby Lobby,* the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

cover procedures that the owners ''could not in good conscience'' cover, such as abortion, ''HHS would effectively exclude these people from full participation in the economic life of the Nation.'' 134 S. Ct. at 2783. That sort of outcome is one the Departments wish to avoid. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) in a way that respects the moral convictions of Americans so that they are freer to engage in ''full participation in the economic life of the Nation.'' The exemptions in these final rules do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

3. Whether Moral Exemptions Should Exist, and Whom They Should Cover

As noted above, the Department received comments expressing diverse views as to whether exemptions based on moral convictions should exist and, if so, whom they should cover.

Some commenters supported the expanded exemptions and accommodation in the Moral IFC, and the choice of entities and individuals to which they applied. They stated the expanded exemptions and accommodation would be an appropriate exercise of discretion and would be consistent with moral exemptions Congress has provided in many similar contexts. Similarly, commenters stated that the accommodation would be an inadequate means to resolve moral objections and that the expanded exemptions are needed. They contended that the accommodation process was objectionable because it was another method of complying with the Mandate, its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and the coverage for contraceptive services ''hijacked'' or flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to moral objections that organizations would not have with an expanded exemption. Commenters also stated that, with respect to non-profit organizations that have moral objections and only hire persons who agree with those objections, the Mandate serves no legitimate government interest because the mandated coverage is neither wanted nor used and, therefore, would yield no benefits—it would only suppress the existence of non-profit organizations holding those views.

Several other commenters stated that the exemptions were still too narrow. They asked that the exemptions set forth in these final rules be as broad as the exemptions set forth in the Religious IFC concerning sincerely held religious beliefs. Some of these commenters also asked that HHS withdraw its Mandate of contraceptive coverage from the Guidelines entirely. They contended that fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of a preventive health service; that contraceptives can pose medical risks for women; and that studies do not show that contraceptive programs reduce abortion rates or unintended pregnancies. Some commented that many women report that they sought an abortion because their contraception failed. Some other commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacient and, therefore, violate federal conscience protections such as the Weldon Amendment, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, § 507(d).

Other commenters contended that the exemptions in the Moral IFC were too broad. Some of these commenters expressed concern about the prospect of publicly traded for-profit entities also being afforded a moral exemption. One such commenter commented that allowing publicly traded for-profit entities a moral exemption could cause instability and confusion, as leadership changes at such a corporation may effectively change the corporation's eligibility for a moral exemption. Still others stated that the Departments should not exempt various kinds of entities such as businesses, issuers, or nonprofit entities, arguing that only individuals, not entities, can possess moral convictions. Some commenters were concerned that providing moral exemptions would contribute to population growth and related societal woes. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318), which did not encompass moral convictions. Other commenters stated that the Departments should not provide exemptions, but merely an accommodation process, to resolve moral objections to the Mandate.

Some commenters objected to providing any exemption or accommodation for moral objections at all. Some of these commenters contended that even the previous regulations allowing an exemption and accommodation were too broad and that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible. Other commenters did not go that far, but rejected the idea of exemptions or an accommodation based on moral convictions, contending that such exemptions or accommodation would contribute to population growth and related social woes. Some of these commenters also contended that the exemption in the Moral IFC would constitute an exemption covering every business and non-profit organization.

After considering these comments, and although the previous Administration declined to afford any exemption based on moral convictions, the Departments have concluded that it is appropriate to provide moral exemptions and access to the accommodation, as set forth in these final rules. Congress did not mandate contraceptive coverage, nor provide any explicit guidance about incorporating conscience exemptions into the Guidelines. But as noted above, it is a long-standing Congressional practice to provide consistent exemptions for both religious beliefs and moral convictions in many federal statutes in the health care context, and specifically concerning issues such as abortion, sterilization, and contraception. It is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases. The exemptions finalized in these final rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. As noted above, the Departments consider the exemptions in these final rules consistent with the intent of Executive Order 13535. The Departments also wish to avoid the stark disparity that may result from respecting religious objections to providing contraceptive coverage among certain entities and individuals, but not respecting parallel objections for moral convictions possessed by any entities and

individuals at all because those objections are not specifically religious.

In addition, the Departments note that a significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[25] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the ACA, nor a statement about what the Federal Government may do consistent with other limitations in federal law, such state practices can inform the Departments' view that it is appropriate to provide conscience protections when exercising agency discretion.

The Departments decline to use these final rules to remove the contraceptive Mandate altogether, such as by declaring that HHS acting through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). HRSA's Guidelines were not issued, ratified, or updated through the regulations that preceded the Moral IFC and these final rules. Those Guidelines were issued in separate processes in 2011 and 2016, directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The regulations preceding these final rules attempted only to restate the statutory language of section 2713 in regulatory form, and delineate what exemptions and accommodations would apply if HRSA listed contraceptives in its Guidelines. We decline to use these final rules to direct the separate process that HRSA uses to determine what specific services are listed in the Guidelines generally. Some commenters stated that if contraceptives are not removed from the Guidelines entirely, entities or individuals with moral objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in these rules include a broad range of entities and individuals of whom we have notice may object based on moral convictions. The Departments are not aware of specific employers or individuals whose moral convictions would still be violated by compliance with the Mandate after the issuance of the Moral IFC and these final rules.

Some commenters stated that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions. Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These final rules focus on what moral exemptions and accommodation shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacient.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content and process of developing and updating the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov.*

The Departments also conclude that it would be inadequate to merely attempt to amend or expand the accommodation process to account for moral objectors, instead of providing the exemptions. In the past, the Departments stated in our regulations and court briefs that the previous accommodation required contraceptive coverage in a way that is ''seamless'' with the coverage provided by the objecting employer. As a result, in significant respects, the accommodation process did not actually accommodate the objections of many entities, as indicated by many entities with religious objections. The Departments have attempted to identify an accommodation that would eliminate the religious plaintiffs' objections, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but stated in January 2017 that we were unable to develop such an approach at that time.[26] Just as the Departments continue to believe merely amending the accommodation process would not adequately address religious objections to compliance with the Mandate, we do not believe doing so would adequately address similar moral objections. Furthermore, the few litigants raising non-religious moral objections have been non-profit organizations that assert they only hire persons who share the employers' objection to contraceptive coverage. Consequently, the Departments conclude that the most appropriate approach to resolve these concerns is to provide the exemptions set forth in the Moral IFC and these final rules. These final rules also finalize the modifications to the accommodation process to make it available to entities with moral objections, without forcing such entities to choose between compliance with either the Mandate or the accommodation.

Some commenters expressed concern over the lack of a definition of ''moral convictions'' in the Moral IFC, arguing that, without a definition, any objection could be encompassed by the exemptions even if it is not based on moral convictions. The Departments did not adopt a regulatory definition of ''moral convictions'' in the Moral IFC, and have decided not to adopt such a definition in response to public comments at this time. Nevertheless, the Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in the Moral IFC and these final rules. Neither these final rules or the Moral IFC, nor the Church Amendments or other Federal health care conscience statutes, define ''moral convictions'' (nor do they define ''religious beliefs''). But in issuing these final rules, we adopt the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions in parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the ''individual deeply and sincerely holds''; (2) ''that are purely ethical or moral in source and content''; (3) ''but that nevertheless impose upon him a duty''; (4) and that ''certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons,'' such

[25] *See* ''Insurance Coverage of Contraceptives,'' The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[26] *See* Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation Part 36, (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

that one could say ''his beliefs function as a religion in his life.'' 398 U.S. at 339–40. As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises ''capriciously.'' Instead, along with the requirement that protected moral convictions must be ''sincerely held,'' this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

While moral convictions are the sort of principles that, in the life of an individual, occupy a place parallel to religion, sincerely held moral convictions can also be adopted by corporate bodies, not merely by individuals. Senators Church and Nelson, while discussing the fact that opposition to abortion or sterilization on the basis of ''moral questions'' does not include capricious opposition to abortion for no reason at all, were specifically talking about opposition to abortion by corporate entities: A ''hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise.'' [27] Corporate bodies operate by the decision-making actions of individuals. Thus, if individuals act in the governance of a corporate body so as to adopt a position for that body of adopting moral convictions against coverage of contraceptives, such an entity can be considered to have an objection to contraceptive coverage on the basis of sincerely held moral convictions.

4. The Departments' Rebalancing of Government Interests

The Departments also received comments on their rebalancing of interests as expressed and referenced in the Moral IFC. Some public commenters agreed with the Departments' conclusion that our interest in ensuring contraceptive coverage does not preclude the Departments from offering exemptions and an accommodation for entities, plans, and individuals with a qualifying objection to contraceptive coverage based on moral convictions. Some public commenters pointed out that protecting moral convictions serves to respect not only the interests of certain persons to access contraceptives, but also the interests of other persons to participate in a health coverage market consistent with their moral convictions. Other commenters disagreed with this rebalancing, and contended that the interest of women in receiving contraceptive coverage without cost-sharing is so great that it overrides private interests to the contrary, such that the government should or must force private entities to provide this coverage to other private citizens.

The Departments agree with the commenters who stated that the governmental interest in requiring contraceptive coverage does not override the interest in protecting moral convictions and does not make these expanded exemptions inappropriate. For additional discussion of the Government's balance of interests as applicable to religious beliefs, see section II.C.2.b. of the companion final rules concerning religious exemptions published by the Departments contemporaneously with these final rules elsewhere in today's **Federal Register**. There, and in the Religious and Moral IFCs, the Departments acknowledged the reasons why the Departments have changed the policies and interpretations previously adopted with respect to the Mandate and the governmental interests underlying it. For parallel reasons, the Departments believe the Government's legitimate interests in providing for contraceptive coverage do not require the Departments to violate sincerely held moral convictions while implementing the Guidelines. The Departments likewise believe Congress did not set forth interests that require us to violate sincerely held moral convictions if we otherwise require contraceptive coverage in our discretionary implementation of the women's preventive services Guidelines under section 2713(a)(4).

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4), added to the PHS Act in 2010. The Departments' expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after considering public comments on various sides of the issue, and reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant federal law, the Departments have determined that affording the exemptions to protect moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to invoke these exemptions and accommodation may be small, the Departments believe that it is important to provide such protection, given the long-standing recognition of such protections in law and regulation in the health care and health insurance contexts. The Moral IFC and these final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, including through such programs as Medicaid and Title X. The Departments also note that the exemptions created here, like the exemptions created by the previous Administration, do not burden third parties to a degree that counsels against providing the exemptions, as discussed below.

5. Burdens on Third Parties

The Department received a variety of comments about the effect that the exemptions and accommodation based on moral convictions would have on third parties. Some commenters stated that the exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might otherwise receive contraceptive coverage with no cost sharing. Other commenters disagreed, asserting that the exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more

[27] Nor was this recognition of the need to protect organizations that object to performance of certain health care procedures on the basis of moral conviction limited to the Church Amendments' legislative history. The first of the Church Amendments provides, in part, that the receipt of certain federal funds ''by any individual or entity does not authorize any court or any public official or other public authority to require— . . . (2) such entity to—(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.'' 42 U.S.C. 300a–7(b).

unintended pregnancies,[28] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as prioritizing conscientious objection of exempted entities over the conscience, choices, or religious liberty of women who would not receive contraceptive coverage where an exemption is used. Some commenters disagreed and said the exemptions do not violate laws and constitutional protections, nor do they inappropriately prioritize the conscience of exempted entities over those of third parties.

The Departments note that the exemptions in the Moral IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. Agency discretion was exercised to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties whom the government chooses not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: That the government has an obligation to force private parties to benefit those third parties, and that the third parties have a right to those benefits. Congress did not create a right to receive contraceptive coverage from other private citizens through section 2713 of the PHS Act, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to which they morally object, to benefit other private parties, does not prevent the government from relieving some or all of the burden of that Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Moral IFC and these final rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through the grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae,* 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the government refrain from requiring private citizens, in violation of their moral convictions, to cover contraception for other citizens. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.''). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting moral objections to such governmental mandates, especially where, as here, the Mandate is not an explicit statutory requirement.[29] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these rules.

Some commenters objected that the exemptions would violate the Establishment Clause of the First Amendment. The Moral IFC and these final rules create exemptions for moral convictions, not religious beliefs, and they do so for the same neutral purposes for which Congress has created similar exemptions for over four decades. Not only do these final rules not violate the Establishment Clause, but the Departments' decision to provide the exemptions and accommodation for moral convictions, instead of limiting the exemptions to identical objections based on religious beliefs, further demonstrates that neither the purpose nor the effect of these exemptions is to establish religion. The Establishment Clause does not force the Department to impose a contraceptive Mandate in violation of the moral convictions of entities and individuals protected by these rules.

American governmental bodies have, in many instances, refrained from requiring certain private parties to cover contraceptive services for other private parties. From 1789 through 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under section 2713 of the PHS Act to be covered by grandfathered plans. Many states do not impose contraceptive coverage mandates, or they offer religious, and in some cases moral, exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or state courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. The Departments are not aware of federal courts declaring that the exemptions, safe harbor, or accommodations gave rise to third party burdens that required the government to mandate contraceptive coverage by entities eligible for an exemption or accommodation. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including

[28] Some commenters attempted to quantify the costs of unintended pregnancy, but were unable to provide estimates with regard to the number of women that this exemption may affect.

[29] *See, for example, Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (''[A] woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'').

under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters stated that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others commenters stated that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. Until 2012, there was no federal mandate of contraceptive coverage across health insurance and health plans nationwide. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to state or local governments. The various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage, have not been deemed to cause a cognizable injury to state or local governments. The Departments find no legal prohibition on finalizing these final rules based on the allegation of an impact on state or local governments, and disagree with the suggestion that once having exercised our discretion to deny exemptions—no matter how recently or incompletely—the Departments cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, the exemptions at issue here are available only to a tiny fraction of entities to which the Mandate would otherwise apply—those with qualifying moral objections. Public comments did not provide reliable data on how many entities would use these expanded moral exemptions, in which states women in those plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would potentially have to cover. As noted below, at least one study [30] has concluded the Mandate caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates. In addition, the only entities that have brought suit based on their moral objections to the Mandate are non-profit entities that have said they only hire persons who share their objections and do not use the contraceptives to which their employers object, so it is unlikely that exemptions for those entities would have any impact on safety net programs. Below, we predict that a small number of additional nonprofit and closely held for-profit entities will use the exemptions based on moral convictions. In light of the limited evidence of third party or state and local government impact of these final rules, the Departments consider it an appropriate policy option to provide the exemptions.

Some commenters contended that the exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead, they allow entities that have sincerely held moral objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

Those commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these final rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not in its capacity as an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.,* 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII ''does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women''). Second, these rules create no disparate impact. The women's preventive service mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inure to the specific benefit of women—men are denied any benefit from section 2713(a)(4). Both before and after these rules are in effect, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions encompass moral objections. The previous rules, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship and integrated auxiliaries, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby's* holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women

[30] M.L. Kavanaugh et al., ''Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,'', 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters stated that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some commenters objected that the Moral IFC's estimate of a $584 yearly cost of contraceptives for women was too low. But some of those same commenters provided similar estimates, citing sources claiming that birth control pills can cost up to $600 per year, and stated that IUDs, which can last 3 to 6 years or more,[31] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters stated that, for lower income women, contraceptives and related education and counseling can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately covered individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member, and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, emphasizing that income and eligibility thresholds could prevent some women from receiving contraceptives through certain government programs if they were no longer covered in their group health plans or health insurance plans.

The Departments do not believe that such differences make it inappropriate to issue the expanded exemptions set forth in these rules. As explained more fully below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. Moreover, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed rule to amend the regulations governing its Title X family planning program. The proposed rule would amend the definition of ''low income family''—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions. (83 FR 25502). If that rule is finalized as proposed, it would further reduce any potential effect of these final rules on women's access to contraceptives.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS ''shall not promulgate any regulation'' that ''creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,'' ''impedes timely access to health care services,'' ''interferes with communications regarding a full range of treatment options between the patient and the provider,'' ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,'' ''violates the principles of informed consent and the ethical standards of health care professionals,'' or ''limits the availability of health care treatment for the full duration of a patient's medical needs.'' 42 U.S.C. 18114. Such commenters urged, for example, that the Moral IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554 of the ACA. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections; multiple courts considered those regulations; and while many ruled that entities did not need to provide contraceptive coverage, none ruled that the exemptions or accommodations in the regulations violated section 1554 of the ACA. Moreover, the decision not to impose a governmental mandate is not the creation of a ''barrier,'' especially when that mandate requires private citizens to provide services to other private citizens. This would turn the assumptions of the United States' system of government on its head. *See, for example,* U.S. Constitution, Ninth Amendment. Section 1554 of the ACA likewise does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 of the ACA prohibit the Departments from providing exemptions to relieve burdens on moral convictions, or as is the case here, from refraining to impose the Mandate in cases where moral convictions would be burdened by the Mandate. Moral exemptions from federal mandates in certain health contexts, including sterilization, contraception, or items believed to be abortifacient, have existed in federal laws for decades. Some of those laws were referenced by President Obama in signing Executive Order 13535. In light of that Executive Order and Congress's long history of providing exemptions for moral convictions in the health context, providing moral exemptions is a reasonable administrative response to this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts.

In short, we do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered, or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

In summary, members of the public have widely divergent views on whether the exemptions in the Moral IFC and these final rules are good public policy. Some commenters stated that the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind the exemption, and arguing that the exemption would not interfere with the physician-patient relationship. The Departments have determined that these final rules are an appropriate exercise of public policy discretion. Because of the importance of the moral convictions being accommodated, the limited impact of these final rules, and uncertainty about

[31] *See, for example,* ''IUD,'' Planned Parenthood, *https://www.plannedparenthood.org/learn/birth-control/iud.*

the impact of the Mandate overall according to some studies, the Departments do not believe these final rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

6. Interim Final Rulemaking

The Departments received several comments about the decision to issue the Moral IFC as interim final rules with request for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Moral IFC in that way, agreeing with the Departments that there was explicit statutory authority to do so, good cause under the APA, or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe authority existed to issue the Moral IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of that Act, and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Moral IFC, the Departments issued three interim final regulations implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Moral IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Moral IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules were issued after receiving and thoroughly considering public comments as requested in the Moral IFC. These final rules therefore comply with the APA's notice and comment requirements.

7. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause, or are associated with, an increased risk of depression,[32] venous thromboembolic disease,[33] fatal pulmonary embolism,[34] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[35] hypertension,[36] HIV–1 acquisition and transmission,[37] and breast, cervical, and liver cancers.[38] Some commenters also stated that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that it is not the case that contraceptive access reduces unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated

[32] Commenters cited Charlotte Wessel Skovlund, et al., ''Association of Hormonal Contraception with Depression,'' *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) (''Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.'').

[33] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception: Recent Advances and Controversies,'' 82 *Fertility and Sterility* S26, S30 (2004); V.A. Van Hylckama et al., ''The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,'' 339 *Brit. Med. J.* b2921 (2009); Y. Vinogradova et al., ''Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,'' 350 *Brit. Med. J.* h2135 (2015) (''Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.''); Ø. Lidegaard et al., ''Hormonal contraception and risk of venous thromboembolism: national follow-up study,'' 339 *Brit. Med. J.* b2890 (2009): M. de Bastos et al., ''Combined oral contraceptives: venous thrombosis,'' Cochrane Database Syst. Rev., Mar. 3, 2014. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J. Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* and Robert A. Hatcher et al., *Contraceptive Technology,* 405–07 (Ardent Media 18th rev. ed. 2004).

[34] Commenters cited N.R. Poulter, ''Risk of Fatal Pulmonary Embolism with Oral Contraceptives,'' 355 *Lancet* 2088 (2000).

[35] Commenters cited Ø. Lidegaard et al., ''Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception, 366 *N. Engl. J. Med.* 2257, 2257 (2012) (risks ''increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg''); Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception''; M. Vessey et al., ''Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,'' 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, ''Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,'' 349 *Lancet* 1202, 1202–09 (1997); K.M. Curtis et al., ''Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review,'' 73 Contraception 179, 179–188 (2006); L.A. Gillum et al., ''Ischemic stroke risk with oral contraceptives: A meta analysis,'' 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology,* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[36] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology,* 407, 445 (Ardent Media 18th rev. ed. 2004).

[37] Commenters cited Renee Heffron et al., ''Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study,'' 12 *Lancet Infectious Diseases* 19, 24 (2012) (''Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men.''); and ''Hormonal Contraception Doubles HIV Risk, Study Suggests,'' *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[38] Commenters cited ''Oral Contraceptives and Cancer Risk,'' National Cancer Institute (Mar. 21, 2012), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* S. N. Bhupathiraju et al., ''Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study,'' 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, ''Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment,'' (Sept. 2005), available at *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, ''Known and Probably Human Carcinogens,'' American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 Report of the Institute of Medicine (IOM), ''Clinical Preventive Services for Women: Closing the Gaps,'' in its discussion of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality. Commenters also stated that studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer, and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[39] Some commenters stated that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters stated that, in the Moral IFC, the Departments relied on incorrect statements concerning scientific studies. For example, some commenters stated that there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Departments for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR 47804, the 2013 Agency for Healthcare Research and Quality study, and other sources, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to consider these studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[40] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some commenters agreed with the quotation, in the Moral IFC, of FDA materials [41] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Moral IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Moral IFC that some persons believe those possible effects are ''abortifacient.''

This objection on this issue appears to be partially one of semantics. People disagree about whether to define ''conception'' or ''pregnancy'' to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items ''abortifacient''—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 (''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.'').

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere moral objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of an objection based on sincerely held religious belief under RFRA.[42] Several litigants have separately raised non-religious moral objections to contraceptive coverage based on the same basic rationale. Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer moral exemptions with respect to this Mandate.

The Departments also received comments about their discussion, located in the Religious IFC but partly relied upon in the Moral IFC, concerning uncertainty about the effects the Mandate's expanded exemptions might have on teen sexual activity. In this respect, the Departments stated, ''With respect to teens, the Santelli and Melnikas study cited by IOM 2011

[39] To the extent that contraceptives are prescribed to treat health conditions, and not for preventive purposes, the Mandate would not be applicable.

[40] 82 FR at 47803–04.

[41] FDA's guide ''Birth Control'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

[42] ''Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.'' *Hobby Lobby,* 134 S. Ct. at 2762–63. ''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.'' *Id.* at 2765–66.

observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that '[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.' '' [43] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that limiting the exemptions to the Mandate to those that existed prior to the Religious and Moral IFCs is not tailored towards advancing the Government's interests in reducing teen pregnancy. Instead they suggested there are means of reducing teen pregnancy that are less burdensome on conscientious objections.[44] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[45]

Many commenters opposing the moral exemptions misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, the Departments note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general make it difficult to establish causation between exemptions to the contraceptive Mandate, and an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including, but not limited to, reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline). It concluded that ''that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.'' [46] One study found that, during the teen pregnancy decline between 2007 through 2012, teen sexual activity was also decreasing.[47] One study concluded that falling unemployment rates in the 1990s accounted for 85 percent of the decrease in rates of first births among 18 to 19 year-old African Americans.[48] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[49] One study concluded that an ''increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.'' [50] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[51] Some commenters also cited studies—which are not limited to the issue of teen pregnancy—that have found that many women who have abortions report that they were using contraceptives when they became pregnant.[52]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of public comments has reinforced the Departments' view that the uncertainty surrounding these weighty and important issues makes it appropriate to provide the moral exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing moral exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments to implement the ACA.

8. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promoted the health and equality of women, especially low income women, and promoted female participation and

[43] Citing J.S. Santelli & A.J. Melnikas, ''Teen fertility in transition: recent and historic trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at *http://public.econ.duke.edu/~psarcidi/addicted13.pdf. See also* K. Buckles & D. Hungerman, ''The Incidental Fertility Effects of School Condom Distribution Programs,'' *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* (''access to condoms in schools increases teen fertility by about 10 percent'' and increased sexually transmitted infections).

[44] *See* Helen Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[45] *See, e.g.,* Lindberg L., Santelli J., ''Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,'' 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[46] Kearney MS and Levine PB, ''Investigating recent trends in the U.S. birth rate,'' 41 *J. Health Econ.* 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[47] *See, e.g.,* K. Ethier et al., ''Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,'' 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* (''Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall . . . .'').

[48] Colen CG, Geronimus AT, and Phipps MG, ''Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,'' 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[49] Atkins DN and Wilkins VM, ''Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,'' 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[50] E. Collins & B. Herchbein, ''The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,'' *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* (''[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women'').

[51] *See* D. Paton & L. Wright, ''The effect of spending cuts on teen pregnancy,'' 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* (''Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates'').

[52] Commenters cited, for example, Guttmacher Institute, ''Fact Sheet: Induced Abortion in the United States'' (Jan. 2018) (''Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant''), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

equality in the workforce. Other commenters contended there was insufficient evidence showing that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence to show that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed a study published and revised by the Guttmacher Institute in October 2017, concluding that ''[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy.'' [53] This timeframe includes the first two years of the contraceptive Mandate's implementation. Despite some changes in the use of various methods of contraceptives, the study concluded that, ''[f]or the most part, women are changing method type within the group of most or moderately effective methods and not shifting from less effective to more effective methods.'' Regarding the effect of this Mandate in particular, the authors concluded that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.'' The authors observed that other ''[s]tudies have produced mixed evidence regarding the relationship between the implementation of the ACA and contraceptive use patterns.'' In explaining some possible reasons or no clear effect on contraceptive use, the authors suggested that ''existence of these safety net programs [publicly funded family planning centers and Medicaid] may have dampened any impact that the ACA could have had on contraceptive use,'' ''cost is not the only barrier to accessing a full range of method options,'' and ''access to affordable and/or free contraception made possible through programs such as Title X'' may have led to income not being associated with the use of most contraceptive methods.[54] In addition, commenters noted that in the 29 states where contraceptive coverage mandates have been imposed statewide,[55] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[56]

Other commenters, however, disputed the significance of these state statistics, noting that, of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the exemption in these rules might have on the Mandate more broadly. The state mandates of contraceptive coverage still apply to a very large number of plans and plan participants notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups were already exempt from the federal Mandate prior to the 2017 Religious and Moral IFCs. The exemptions as set forth in the Moral IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might result from the contraceptive Mandate here.

Some commenters took a view that appears to disagree with the assertion in the 2017 Guttmacher study, that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.'' These commenters instead observed that, under the Mandate, more women have coverage of contraceptives and contraception counseling and that more contraceptives are provided without co-pays than before. Still others argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [57] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also stated that studies show that decreases in unintended pregnancies are due to broader access to contraceptives. Finally, some commenters also stated that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on that review, it is not clear that merely offering the exemption in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from contraceptive access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, the Departments

[53] M.L. Kavanaugh et al., ''Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,'' 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[54] Id.

[55] See Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (June 11, 2018); ''State Requirements for Insurance Coverage of Contraceptives,'' Henry J. Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[56] *See* Michael J. New, ''Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,'' 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

[57] Citing, for example, Adelle Simmons et al., ''The Affordable Care Act: Promoting Better Health for Women,'' Table 1, ASPE (June 14, 2016), *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

conclude that the Moral IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small number of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. The Departments also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, an appropriate exercise of the Departments' discretion.

Moreover, the Departments conclude that the best way to balance the various policy interests at stake in the Moral IFC and these final rules is to provide the exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules provide tangible conscience protections for moral convictions, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a burden on their moral convictions. The Departments view the provision of those protections to preserve conscience in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for moral convictions set forth in the Moral IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

9. Other General Comments

Some commenters expressed the view that the exemptions afforded in the Moral IFC and herein violate the RFRA rights of women who might not receive contraceptive coverage as the result of these final rules, by allowing their employers to impose their moral convictions on them by removing contraceptive coverage through use of the exemption. Still other commenters stated that employer payment of insurance premiums is part of any employee's compensation package, the benefits of which employers should not be able to limit. In the Departments' view, the expanded exemptions in these final rules do not prohibit employers from providing contraceptive coverage. Instead, they lift a government burden that was imposed on some employers to provide contraceptive coverage to their employees in violation of those employers' moral convictions. The Departments do not believe RFRA requires, or has ever required, the federal government to force employers to provide contraceptive coverage. The federal government's decision to exempt some entities from a requirement to provide no-cost-sharing services to private citizens does not constitute a federal government-imposed burden on the latter under RFRA.

Some commenters asked the Departments to discuss the interaction between these rules and state laws that either require contraceptive coverage or provide exemptions from those and other requirements. Some commenters argue that providing the exemptions in these rules would negate state contraceptive requirements or narrower state exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage.

The Departments agree that these rules only concern the applicability of the federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state exemptions. If a plan is exempt under the Moral IFC and these final rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the moral exemption rules to declare whether the federal contraceptive Mandate would still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[58]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1).

These final rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with moral objections to cover contraceptives.

Finally, some commenters expressed concern that providing moral exemptions to the mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, section 2713(a)(2) of the PHS Act requires coverage of ''immunizations,'' and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting moral convictions from certain health care mandates concerning issues such as sterilization, abortion and birth control.

B. Text of the Final Rules

In this section, the Departments describe the regulations from the Moral IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. We also note the regulatory text as it existed prior to the Religious and Moral IFCs, as appropriate. The Departments consider the exemptions finalized here to be an appropriate and permissible policy

[58] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. In the preamble to the companion final rules concerning religious exemptions published elsewhere in today's **Federal Register**, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these exemptions.

As noted above, various members of the public provided comments that were supportive, or critical, of the regulations overall, or of significant policies pertaining to the regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

1. Restatement of Statutory Requirements of Section 2713(a) and (a)(4) of the PHS Act (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) and (a)(4) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified those restatements to more closely align them with the text of section 2713(a) and (a)(4) of the PHS Act. Those sections cross-reference the other sections of the Departments' rules that provide exemptions to the contraceptive Mandate. After the Religious IFC changed those sections, the Moral IFC inserted, within those cross-references, references to the new § 147.133, which contains the text of the moral exemptions. The insertions correspond to the cross-references to the religious exemptions added by the Religious IFC. The Departments finalize these parts of the Moral IFC without change.

2. Exemption for Objecting Entities Based on Moral Convictions (45 CFR 147.133(a))

The previous regulations contained no exemption concerning moral convictions, as distinct from religious beliefs. Instead, at 45 CFR 147.131(a), they offered an exemption for houses of worship and integrated auxiliaries. In the remaining part of § 147.131, the previous regulations described the accommodation process for organizations with religious objections. The Religious IFC moved the religious exemption to a new section 45 CFR 147.132, and expanded its scope. The Moral IFC created a new section 45 CFR 147.133, providing exemptions for moral convictions similar to, but not exactly the same as, the exemptions for religious beliefs set forth in § 147.132.

The prefatory language of § 147.133(a) not only specifies that certain entities are ''exempt,'' but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only ''as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.'' To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are ''exempt'' by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as ''exempt,'' and in referring to the ''exemption'' encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.133(a) applies to several distinct entities involved in the provision of coverage to an objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When § 147.133(a)(1) and (a)(1)(i) specify that ''[a] group health plan,'' ''health insurance coverage provided in connection with a group health plan,'' and ''health insurance coverage offered or arranged by an objecting organization'' are exempt ''to the extent'' of the objections ''as specified in paragraph (a)(2),'' that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815 through 2713(a)(1)(iv) and 29 CFR 2590.715 through 2713(a)(1)(v)), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while a plan sponsor's or arranger's objection removes penalties from that group health plan's issuer, it only does so with respect to that group health plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.133(a)(1)(iii) is included below.

The exemptions in § 147.133(a)(1) apply ''to the extent'' of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters stated it was unclear whether the plans of entities or individuals that morally object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite moral objection to some, but not all, contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules the Departments finalize the prefatory language of § 147.133(a) so that the first sentence of that paragraph states that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, ''to the extent of the objections specified below.'' The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying ''to the extent'' of the objection(s).

The exemptions contained in previous regulations, at § 147.131(a), did not require an exempt entity to submit any particular self-certification or notice, either to the government or to the entity's issuer or third party administrator, in order to obtain or qualify for their exemption. Similarly, under the expanded exemptions in § 147.133, the Moral IFC did not require exempt entities to comply with a self-certification process. We finalize that approach without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan

document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[59] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported this approach, while others did not. Those in favor suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use their exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process.

After considering the comments, the Departments continue to believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption, although there may have been thousands of houses of worship and integrated auxiliaries covered by the previous exemption and the Departments think it likely that only a small number of entities will use the moral exemption. Adding a self-certification or notice to the exemption would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices are to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries will know whether their health plan claims a contraceptive Mandate exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these final rules to continue to not require notices or self-certifications for using the exemption.

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these final rules. The exemptions in these final rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. Final rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (In the companion rules concerning religious beliefs published elsewhere in today's **Federal Register**, the Departments discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed in the companion religious final rule published elsewhere in today's **Federal Register**, the Departments have added language from the previous regulations, in § 147.131(f), to protect issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in, and derived from, the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators. The Departments do not believe it necessary to do so in these final rules.

Commenters disagreed about the likely effects of the moral exemptions on the health coverage market. Some commenters stated that expanding the exemptions to encompass moral convictions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans, or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or only some contraceptives—to houses of worship and integrated auxiliaries, and some commenters and litigants said that issuers were doing so. These cases

[59] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b-3(d), and 29 CFR 2590.715–2715. See also 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group & individual issuers).

where plans did not need to comply with the Mandate, and the Departments' previous accommodation process which had the effect of allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[60]

Concerning the prospect raised by some commenters of different risk pools between men and women, section 2713(a) of the PHS Act itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage will be required. The Moral IFC and these final rules do not require issuers to offer health insurance products that satisfy morally objecting entities, they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to objecting entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

3. Exemption for Certain Plan Sponsors (45 CFR 147.133(a)(1)(i))

The exemption in § 147.133(a)(1)(i) of the Moral IFC covers a group health plan and health insurance coverage for non-governmental plan sponsors that object as specified in paragraph (a)(2), and that are either nonprofit organizations, or are for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The Departments finalize this paragraph without change, and discuss each part of the paragraph in turn.

a. Plan Sponsors in General (45 CFR 147.133(a)(1)(i) Prefatory Text)

Under the plan sponsor exemption in § 147.132(a)(1)(i), the prefatory text in that paragraph specifies that it encompasses group health plans, and health insurance coverage provided in connection with such group health plans, that are sponsored by certain kinds of entities, namely, nonprofit organizations or for-profit entities that have no publicly traded ownership interests.

Such plan sponsors, if they are otherwise nonprofit organizations or for-profit entities that have no publicly traded ownership interests, can include entities that are not employers (for example, a union, or a sponsor of a multiemployer plan), where the plan sponsor objects based on sincerely held moral convictions to coverage of contraceptives or sterilization. Plan sponsors encompassed by the exemption can also include employers, and consistent with the definition of ''employer'' in 29 CFR 2510.3–5, can include association health plans, where the plan sponsor is a nonprofit organization or a for-profit entity that has no publicly traded ownership interests.

Some commenters objected to extending the exemption to plan sponsors that are not single employers, arguing that they could not have the same kind of moral objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite moral objection. The Departments conclude that it is appropriate, where a plan sponsor of a multiemployer plan or multiple employer plan adopts a moral objection using the same procedures that such a plan sponsor might use to make other decisions, to respect that decision by providing an exemption from the Mandate.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.133(a)(1)(i), which instead limits the moral exemptions to ''non-governmental plan sponsors.'' As noted above, the Departments sought public comment on whether to extend the exemptions to non-federal governmental plan sponsors. Some commenters suggested that the moral exemptions should include government entities because other conscience laws can include government entities, such as when they oppose offering abortions. Others disagreed, contending that governmental entities should not or cannot object based on moral convictions, or that it would be unlawful for them to do so.

The Departments are sympathetic to the arguments of commenters that favor including government entities in the exemption for moral convictions. The protections outlined in the first paragraph of the Church Amendments for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Both the Weldon and Coats-Snowe Amendments also protect state and local government entities from providing, promoting, or paying for abortions in particular ways.[61] Congress has generally not limited protections for conscience based on the nature of an entity—even in the case of governmental entities.

At the same time, the Departments do not at this time have information suggesting that an exemption for governmental entities is needed or desired. The Departments have not been sued by any governmental entities raising objections to the Mandate based on non-religious moral convictions. Although the Departments sought public comment on the issue, the Departments received no public comments identifying governmental entities that need or desire such an exemption. Rather, the Departments are aware of governmental entities that, despite not possessing their own objections to contraceptive coverage, have acted to protect their employees who have conscientious objections to receiving contraceptive coverage in their employer-provided health insurance plans. *See Wieland* v. *U.S. Dep't of Health & Human Servs.,* 196 F. Supp. 1010, 1015–16 (E.D. Mo. 2016) (quoting Mo. Rev. Stat. 191.724). The individual exemption adopted in these rules will ensure the Mandate is not an obstacle to those efforts.

Thus, in light of the balance of public comments, the Departments decline to extend the moral convictions exemption to governmental entities. As is the case with the Departments' decision not to extend the moral exemption to publicly traded for-profit entities, this decision does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions

[60] *See also Real Alternatives,* 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

[61] Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), 132 Stat. at 764 (protecting any ''hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion); 42 U.S.C. 238n (protecting entities that object to abortion, including, but not limited to, any ''postgraduate physician training program'').

without categorically excluding governmental entities. The Departments remain open to the possibility of future rulemaking on this issue if the Departments become aware of a governmental entity seeking to be exempt from the contraceptive Mandate.

b. Nonprofit Organizations (45 CFR 147.133(a)(1)(i)(A))

As discussed above, some commenters opposed offering exemptions based on moral convictions to any plan sponsors, and/or objected to doing so for nonprofit organizations, on various grounds, including but not limited to arguments that the benefits of contraception access should override moral objections, entities cannot assert moral objections, and moral objections burden third parties. Other commenters supported the exemptions, generally defending the interest of nonprofit organizations not to be forced to violate their moral convictions, supporting the history of government protection of moral convictions in similar contexts, and disputing the claims of opponents of the exemptions.

The Departments are aware, through litigation, of only two non-religious nonprofit organizations with moral objections to the contraceptive Mandate. Many more nonprofit religious organizations have sued suggesting—as discussed below—that the effect of this exemption for non-religious nonprofit objections to the Mandate will be far less significant than commenters who oppose the exemption believe it will. The two non-religious nonprofit organizations that challenged the Mandate in court provide a good illustration of the reasons why the Department has decided to provide this exemption to nonprofit organizations. Both organizations have said in court they oppose certain contraceptives on non-religious moral grounds as being abortifacient and state that they only hire employees who share that view. Public comments and litigation reflect that many nonprofit organizations publicly describe their beliefs and convictions. Government records and many of those groups' websites also often reflect those groups' religious or moral character, as the case may be. If a person who desires contraceptive coverage works at a nonprofit organization, the Departments view it as sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit organization that opposes contraceptive coverage to hire a person who disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[62]

The Departments agree with commenters who support offering the exemption to nonprofit organizations and believe that doing so is an appropriate protection and is not likely to have a significant impact on women who want contraceptive coverage.

c. For-Profit Entities (45 CFR 147.133(a)(1)(i)(B))

With respect to for-profit organizations addressed in § 147.133(a)(1)(i)(B), in the Moral IFC, the Departments did not limit the exemption to nonprofit organizations, but also included some for-profit entities. Some commenters supported including for-profit entities in the exemption, saying owners of such entities exercise their moral convictions through their businesses, and that such owners should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise moral convictions or should not have their moral opposition to contraceptive coverage protected by the exemption. Some commenters stated that the entities should not be able to impose their beliefs about contraceptive coverage on their employees and that doing so constitutes discrimination.

The Departments agree with commenters who support including some for-profit entities in the exemption. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities, without regard to whether they operate as nonprofit organizations or for-profit entities. In addition, nearly half of the states either impose no contraceptive coverage requirement or offer ''an almost unlimited'' exemption encompassing both ''religious and secular organizations.'' [63] States also generally protect moral convictions in other health care conscience laws whether or not an entity operates as a nonprofit.[64]

Extending the exemption to certain for-profit entities is also consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization and rejected the Departments' argument to the contrary. 134 S. Ct. at 2768–75. The mechanisms by which a for-profit company makes decisions of conscience, or resolves disputes on those issues among their owners, are problems that ''state corporate law provides a ready means'' of solving. *Id.* at 2774–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby.*[65] Because all of those appear to be informed by religious beliefs, extending the exemption to entities with non-religious moral convictions would seem to have an even smaller impact on access to contraceptive coverage.

The Moral IFC only extended the exemption covering for-profit entities to those that are closely held, not to for-profit entities that are publicly traded, but asked for comment on whether publicly traded entities should be included in the moral exemption. In this way the Moral IFC differed from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in the Religious IFC, at § 147.132(a)(1), finalized in companion rules published elsewhere in today's **Federal Register**.

Some commenters supported including publicly traded entities in the moral exemption, contending that publicly traded entities have historically taken various positions on important public concerns beyond merely seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to establish and exercise moral convictions against contraceptive coverage. They observed that large publicly traded entities are exempt from the contraceptive Mandate by means of the grandfathering provision of the ACA, so

[62] Notably, ''the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.' '' *Boy Scouts of America* v. *Dale,* 530 U.S. 640, 655 (2000).

[63] ''Insurance Coverage of Contraceptives,'' The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[64] *See, e.g.,* ''Refusing to Provide Health Services,'' The Guttmacher Institute (June 1, 2018), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

[65] See Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627.*

that it is inappropriate to refuse to exempt publicly traded entities that actually have sincerely held moral convictions against compliance with the Mandate. They further argued that in some instances there are closely held companies that are as large as publicly traded companies of significant size. They also stated that other protections for moral convictions in certain federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines ''persons'' to include all forms of corporations, not just closely held corporations, at 1 U.S.C. 1. Additionally, some commenters were concerned that not providing a moral exemption for publicly traded for-profit entities but allowing a religious exemption for publicly traded for-profit entities (as was allowed in the Religious IFC, and as is allowed in the companion religious final rules published elsewhere in today's **Federal Register**), may raise Establishment Clause questions, may cause confusion to the public, and may make the exemptions more difficult for the Departments and enforcing agencies to administer. They stated that it is incongruous to include publicly traded entities in the exemption for religious beliefs, but exclude them from the exemption for moral convictions.

Other commenters opposed including publicly traded companies in these moral exemptions. Some stated that such companies could not exercise moral convictions and opposed the effects on women if they would. They also objected that including such companies, along with closely held businesses, would extend the exemptions to all or virtually all companies. Some commenters stated that many publicly traded companies would use a moral exemption if available to them, because many closely held for-profit businesses expressed religious objections to the Mandate, or availed themselves of the religious accommodation.

As is the case for non-federal governmental employers, the Departments are sympathetic to the arguments of commenters that favor including publicly traded entities in the exemption for moral convictions. In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without regard to their ownership status. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations; the protections of the Church Amendments do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. Other federal conscience protections in the health sector apply in the same manner:

- The Coats-Snowe Amendment (42 U.S.C. 238n) provides certain protections for health care entities and postgraduate physician training programs that, among other things, choose not to perform, refer for, or provide training for, abortions.
- The Weldon Amendment [66] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions.
- The ACA provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing. (42 U.S.C. 18113).[67]
- Social Security Act sections 1852(j)(3)(B) (Medicare) and 1932(b)(3)(B) (Medicaid), 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B), provide protections so that the statutes cannot be construed to require organizations that offer Medicare Advantage and Medicaid managed care plans in certain contexts to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds.
- Congress's most recent statement on contraceptive coverage specified that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.'' Consolidated Appropriations Act, 2018, Public Law 115–141, Div. E, Sec. 808.

In all of these instances, Congress did not limit the protection for conscience based on the nature of the entity—and did not exclude publicly traded entities from protection.

At the same time, as stated in the Moral IFC, the Departments continue to lack significant information about whether there is a need to extend the expanded exemption to publicly traded entities. The Departments have been sued by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, as well as by closely held for-profit entities expressing religious objections, but not by any publicly traded entities. In addition, the Departments sought public comments on whether publicly traded entities might benefit from extending the moral exemption to them. No such entities were brought to the attention of the Department through the comment process. The Supreme Court concluded it is improbable that publicly traded companies with numerous ''unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs.'' *Hobby Lobby,* 134 S. Ct. at 2774. It would appear to be even less probable that publicly traded entities would adopt that view based on non-religious moral convictions.

In light of the balance of public comments, the Departments decline to extend the moral convictions exemption to publicly traded entities. Because the Departments are aware of so many closely-held for-profit entities with religious objections to contraceptive coverage, and of some nonprofit entities with non-religious moral objections to contraceptive coverage, the Departments believe it is reasonably possible that closely held for-profit entities with non-religious moral objections to contraceptive coverage might exist or come into being. The Departments have also concluded that it is reasonably possible, even if improbable, that publicly traded entities with religious objections to contraceptive coverage might exist or come into being. But the Departments conclude there is not a similar probability that publicly traded for-profit entities with non-religious moral objections to contraceptive

[66] See Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d) (Mar. 2018).

[67] The lack of the limitation in this provision may be particularly relevant since it was enacted in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—were promulgated.

coverage may exist and need to be included in these expanded exemptions. The decision to not extend the moral exemption to publicly traded for-profit entities in these rules does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions without categorically excluding publicly traded entities. The Departments remain open to the possibility of future rulemaking on this issue, if we become aware of the need to expand the exemptions to publicly traded corporations with non-religious moral objections to all (or a subset of) contraceptives.

In contrast, the Departments finalize, without change, the Moral IFC's extension of the exemptions in these rules to closely held for-profit entities with moral convictions opposed to offering coverage of some or all contraceptives. The Departments conclude that it is sufficiently likely that closely held for-profit entities exist or may come into being and may maintain moral objections to certain contraceptives, so as to support including them in these expanded exemptions. The Departments seek to remove an obstacle that might prevent individuals with moral objections from forming or maintaining such small or closely held businesses and providing health coverage to their employees in accordance with their moral convictions.

In defining what constitutes a closely held for-profit entity to which these exemptions extend, the Moral IFC used language derived from the July 2015 final regulations. Those regulations, in offering the accommodation (not an exemption) to religious (not moral) closely held for-profit entities, did so by attempting to positively define what constitutes a closely held entity, formulating a multi-factor, and partially open-ended, definition for that purpose. (80 FR 41313). Any such positive definition runs up against the myriad state differences in defining such entities and potentially intrudes into a traditional area of state regulation of business organizations. Instead of attempting to positively define closely held businesses in the Moral IFC, however, the Departments considered it much clearer, effective, and preferable to define the category negatively, by reference to one element of the previous definition: that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

4. Institutions of Higher Education (45 CFR 147.133(a)(1)(ii))

The previous regulations did not exempt plans arranged by institutions of higher education, although they did include, in the accommodation, plans arranged by institutions of higher education similarly to the way in which the regulations provided the accommodation to plans of nonprofit religious employers. (See 80 FR 41347). The Moral IFC provided an exemption, in § 147.133(a)(1)(ii), encompassing institutions of higher education that arrange student health insurance coverage, and stating the exemption would operate in a manner comparable to the exemption for employers with respect to plans they sponsor. In these final rules, the Departments finalize § 147.133(a)(1)(ii) with one change.

These rules treat the health plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. The rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held moral convictions, to their arrangement of student health insurance coverage, in a manner comparable to the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

Some commenters supported including, in the exemptions, institutions of higher education that provide health coverage for students through student health plans but have moral objections to providing certain contraceptive coverage. They stated that moral exemptions allow freedom for certain institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemption would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result.

In the Departments' view, the reasons for extending the exemption to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. The Departments are not aware of any institutions of higher education that arrange student health insurance coverage and object to the Mandate based on non-religious moral convictions. But because the Departments have been sued by several institutions of higher education that arrange student health insurance coverage and object to the Mandate based on religious beliefs and by several nonprofit organizations with moral objections, the Departments believe the existence of institutions of higher education with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible to justify including protections for such entities in these final rules.

The Departments conclude that this aspect of the exemption is likely to have a minimal impact on contraceptive coverage for women at institutions of higher education. As noted above, the Departments are not aware of any institutions of higher education that would currently qualify for the objection. In addition, only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities, as opposed to from other sources, and an even smaller number receive such coverage from schools objecting to contraceptive coverage. Exempting institutions of higher education that object to contraceptive coverage based on moral convictions does not affect student health insurance contraceptive coverage at the vast majority of institutions of higher education. The exemption simply makes it legal under federal law for institutions to adhere to moral convictions that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, because it makes it easier for students to attend institutions of higher education that hold those views, if the institutions exist or come into being and students choose to attend them. Moreover, because institutions of higher education have no legal obligation to sponsor student health insurance coverage, providing this moral exemption removes an obstacle to such institutions sponsoring student health insurance coverage, thus possibly encouraging

more widespread health insurance coverage.

As noted above, after seeking public comment on whether the final moral exemptions rules should be extended to include non-federal governmental entities, the Departments have concluded they should only include non-governmental entities. For the same reasons, the Departments are inserting a reference into § 147.133(a)(1)(ii) specifying that it includes an institution of higher education ''which is non-governmental.'' This language is parallel to the same limiting phrase used in the religious exemptions rule governing institutions of higher education, at § 147.132(a)(1)(ii). Thus, the first sentence of § 147.133(a)(1)(ii) is finalized to read: ''An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section.'' The remaining text of § 147.133(a)(1)(ii) is finalized without change.

5. Health Insurance Issuers (45 CFR 147.133(a)(1)(iii))

The Moral IFC extended the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services. The issuer exemption only applied to the group health plan if the plan itself was also exempt under an exemption for the plan sponsor or individuals. In these final rules, the Departments finalize § 147.133(a)(1)(iii) without change.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing contraceptive coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on that objection. An exempt issuer can then offer an exempt product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer under this paragraph (a)(1)(iii) that does not include some or all contraceptive services, are plan sponsors or individuals who themselves object and are exempt.

Under these rules, issuers that hold their own objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their moral convictions, or if they are exempt based on their religious beliefs under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held religious beliefs, that are exempt under those companion final rules, could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Some commenters supported including this exemption for issuers in these rules, both to protect the moral convictions of issuers, and so that, in the future, issuers would be free to organize that may wish to specifically serve plan sponsors and individuals that object to contraception based on religious or moral reasons. Other commenters objected to including an exemption for issuers. Some commenters stated that issuers cannot exercise moral convictions, while others stated that exempting issuers would threaten contraceptive coverage for women. Some commenters stated that it was arbitrary and capricious for the Departments to provide an exemption for issuers if they do not know that issuers with qualifying moral objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage.

The issuer exemption serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors, plans, and individuals that independently qualify for an exemption, will remove a possible obstacle to issuers with moral convictions being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held moral convictions will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers both from being required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise moral convictions. Many federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicare Advantage or Medicaid. The Weldon Amendment specifically protects, among other entities, HMOs, health insurance plans, and ''any other kind of health care facility[ies], organization[s] or plan[s]'' as a ''health care entity'' from being required to provide coverage of, or pay for, abortions. See, for example, Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d).[68] The most recently enacted Consolidated Appropriations Act declares that Congress supports a

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

''conscience clause'' to protect moral convictions concerning ''the provision of contraceptive coverage by health insurance plans.'' *See id.* at Div. E, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion Religious IFC and final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**.[69]

6. Description of the Moral Objection (45 CFR 147.133(a)(2))

The Moral IFC set forth the scope of the moral objection of objecting entities in § 147.133(a)(2), so that it applies to the extent an entity described in paragraph (a)(1), based on sincerely held moral convictions, objects to ''establishing, maintaining, providing, offering, or arranging'' either ''coverage or payments'' for contraceptives, or ''for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.'' The Departments are finalizing this exemption with structural changes separating the second half of the sentence into separate subparagraphs, so as to more clearly specify, as set forth in the Moral IFC text, that the objection may pertain either to coverage or payments for contraceptives, or to a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

Some commenters observed that, by allowing exempt plan sponsors to object to ''some or all'' contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators.

The Departments have concluded, however, that just as the previous exemption rules allowed certain religious plan sponsors to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. These rules do not require any issuer or third party administrator to contract with an exempt entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual plan variation. These rules simply remove the federal Mandate, in some cases, where it could have led to penalties on an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying moral objection. That approach is consistent with the approach under the previous regulations, which did not require issuers and third party administrators to contract with exempt plans of houses of worship or integrated auxiliaries if they did not wish to do so.

The definition does not specify that the moral convictions that can support an exemption need to be non-religious moral convictions. We find it unnecessary to limit the definition in that way. Even though moral convictions need not be based on religious beliefs, religious beliefs can have a moral component. It is not always clear whether a moral conviction is based on religious tenets. As noted in *Welsh,* a moral conviction can be ''purely ethical or moral in source and content but that nevertheless . . . occupy in the life of that individual a place parallel to that filled by God [and] function as a religion in his life.'' 398 U.S at 340. One reason for providing exemptions for moral convictions is so that the government need not engage in the potentially difficult task of parsing which convictions are religious and which are not. If sincerely held moral convictions supporting an exemption are religious, they will be encompassed by the exemption for sincerely held religious beliefs. If the moral convictions are not also religious, or if their religious quality is unclear but they are ethical or moral, they can qualify as sincerely held moral convictions under these rules if the other requirements of these rules are met.

The Departments are not aware of any entities that qualify for an exemption under the religious exemptions finalized elsewhere in today's **Federal Register**, but not under the moral exemptions finalized here, such as publicly traded entities. If publicly traded entities object to the Mandate, it seems unlikely their objection is based on moral convictions and not religious beliefs, given that many more objections to the Mandate have been based on religious beliefs. Thus, the Departments find it unlikely that they would be faced with a situation where a publicly traded entity, for example, has an objection to the contraceptive Mandate, but it is not clear whether that objection is based on sincerely held religious beliefs or merely based on sincerely held moral convictions.

7. Individuals (45 CFR 147.133(b))

The previous regulations did not provide an exemption for objecting individuals. The Moral IFC provided such an exemption for objecting individuals (referred to here as the ''individual exemption''), using the following language at § 147.133(b): ''Objecting individuals''. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.''

The Departments finalize this language, with changes in response to public comments in some of the text and in a new sentence at the end of the paragraph that clarify how the exemption applies.

Section 147.133(b) sets forth a special rule pertaining to individuals (referred to here as the ''individual exemption''). This rule exempts plans of certain individuals with moral objections to contraceptive coverage where the plan sponsor and, as applicable, issuer is willing to provide a plan compliant with the individuals' objections to such plan sponsors or individuals, as applicable.

Some commenters supported this exemption as providing appropriate protections for the moral convictions of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to coverage of contraceptives but is willing (and, as applicable, the issuer is also willing) to provide coverage consistent with an individual's moral objections. They commented that this exemption

[69] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for employers. Because the issuer exemption operates more narrowly than the exemption for plan sponsors operates, in the ways described here (*i.e.,* the issuer exemption does not operate unless the plan sponsor or individual, as applicable, is also exempt), and exists in part to help preserve market options for objecting plan sponsors and individuals, the Departments consider it appropriate to not draw such a distinction among issuers.

would free individuals from having their moral convictions placed in tension with their desire for health coverage. They also contended that the individual exemption would not undermine any government interests behind the contraceptive Mandate, since the individuals would be choosing not to have the coverage. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage.

Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. The Departments note that this individual exemption only operates in the case where the issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases. But the Departments do not wish to pose an obstacle to the offering of such coverage.

The Departments note that their decision is consistent with the decision by Congress to provide protections in certain contexts for individuals who object to prescribing or providing contraceptives contrary to their moral convictions. *See, for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Mar. 23, 2018). While some commenters argued that such express protections are narrow, Congress likewise provided that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions''. *Id.* at Div. E, Sec. 808. A moral exemption for individuals would not be effective if the government did not, at the same time, permit issuers and group health plans to provide individuals with policies that comply with their moral convictions.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers. Thus, this individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations ''does not undermine the governmental interests furthered by the contraceptive coverage requirement.'' (78 FR 39874). For parallel reasons, as the Departments stated in the Moral IFC (83 FR at 47853 through 47854), this individual exemption does not undermine the governmental interests furthered by the contraceptive coverage requirement, because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the state is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees' religious beliefs ''or moral convictions,'' or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption in these rules, employers sponsoring governmental plans would be free to honor the moral objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

In the separate companion IFC to the Moral IFC—the Religious IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Moral IFC said a willing issuer and plan sponsor may offer ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects'' under the individual exemption, the Religious IFC described what may be offered to objecting individuals as ''a separate benefit package option, or a separate policy, certificate or contract of insurance.'' Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of ''a separate group health plan,'' because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual exemption by making a technical change to the language to adopt the formulation, ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects.''

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or

sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these rules do not affect such other laws or terms.

The Departments received numerous comments about the administrative burden from the potential variations in moral convictions held by individuals. Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives, while others expressed concern that the variations in the kinds of contraceptive coverage to which individuals object might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the moral convictions of an exempt individual.

If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Moral IFC implied this conclusion by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, that language differed from the language applicable to the exemptions under § 147.133(a), which specifies that those exemptions apply ''to the extent'' of the moral objections, so that, as discussed above, they include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b), with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held moral convictions objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to the employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under her policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to do so. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with changes, to read as follows: ''(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

8. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations did not offer the accommodation process to entities with moral non-religious objections. The Religious IFC amended the accommodation regulations to offer it to all entities that are exempt on the basis of religious beliefs under § 147.132, as an optional process in which such entities could participate voluntarily. The Moral IFC did not change that accommodation process, but inserted references in it to the new section § 147.133, alongside the references to section § 147.132. These changes made entities eligible for the voluntary accommodation process if they are exempt on the basis of moral convictions. The references were inserted in 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A.

In these rules, the Departments finalize, without change, the Moral IFC's revisions of 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. The operation of the accommodation process, changes made in the Religious IFC, and public comments concerning the accommodation, are more fully described in the Religious IFC, and in the companion final rules concerning the religious exemptions and accommodation, published elsewhere in today's **Federal Register**. Those descriptions are incorporated here by reference to the extent they apply to these rules.

Many commenters supported extending the accommodation process to entities with objections based on moral convictions. Others objected to doing so, raising arguments parallel to their objections to creating exemptions for group health plan sponsors with moral convictions. For much the same reasons discussed above concerning why the Departments find it appropriate to exempt entities with moral objections to contraceptive coverage, the Departments find it appropriate to extend the optional accommodation process to these entities. The Departments observe that, to the extent such entities wish to use the process, it will not be an obstacle to contraceptive coverage, but will instead help deliver contraceptive coverage to women who receive health coverage from such entities while respecting the moral convictions of the entities. The Departments are not aware of entities with non-religious moral convictions against contraceptive coverage that also consider the accommodation acceptable and would opt into it, but we are aware of a small number of entities with non-religious moral objections to the Mandate. The Departments, therefore, continue to consider it appropriate to extend the optional accommodation to such entities in case any wish to use it. Below, albeit based on very limited data, the Departments estimate that a small number of entities with non-religious moral objections may use the accommodation process.

9. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under ''Contraceptive methods and counseling,'' ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' The previous regulations concerning the exemption and the accommodation used the terms ''contraceptive services'' and ''contraceptive coverage'' as catch-all terms to encompass all of those Guidelines requirements. The 2016 update to the Guidelines are similarly worded. Under ''Contraception,'' they include the ''full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,'' ''instruction in fertility awareness-based methods,'' and ''[c]ontraceptive care'' to ''include contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).'' [70]

To more explicitly state that the expanded exemptions encompass any of the contraceptive or sterilization services, items, procedures, or related patient education or information that have been required under the Guidelines, the Moral IFC included a definition of contraceptive services, benefits or coverage, at 45 CFR 147.133(c). These rules finalize that definition without change.

10. Severability

The Departments finalize, without change, the severability clause set forth at § 147.133(d).

C. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that moral objections to the Mandate should not be permitted in cases where contraceptive methods are used to treat such existing medical conditions and not for preventive purposes, even if those contraceptive methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to ''preventive'' care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to ''preventive'' services or care.[71] The requirement in the Guidelines concerning ''contraception'' specifies several times that it encompasses ''contraceptives,'' that is, medical products, methods, and services applied for ''contraceptive'' uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[72] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so that plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use. Section 2713(a)(4), however, draws a distinction between preventive and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of care unless it is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

[70] ''Women's Preventive Services Guidelines,'' HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[71] *Id.*

[72] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that ''there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that section 2713(a)(4) or the Guidelines require coverage of ''contraceptive'' methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead, it was an observation that such drugs—generally referred to as ''contraceptives''—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply if the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that, under section 2713(a)(4), exempt organizations must provide coverage for drugs or items prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Moral IFC that the moral exemptions are likely to affect only a very small number of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the exemptions could take contraceptive coverage away from many or most women. Still others opposed establishing the exemptions, but contended that accurately determining the number of women affected by the exemptions is not possible. Public comments included various statements that these exemptions would impact coverage for a large number of women, while others stated they would affect only a very small number. But few, if any, public commenters provided data predicting a precise number of entities that would make use of the exemptions for moral convictions nor a precise number of employees that would potentially be affected.

After reviewing the public comments, the Departments do not find the suggestions of commenters who predicted a very large impact any more reliable than the estimates set forth in the Religious and Moral IFCs. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious and Moral IFCs are still the best estimates available. The Departments' estimates are discussed in more detail in the following section.

III. Economic Impact and Paperwork Burden

The Departments have examined the impacts of these final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and an ''economically significant'' regulatory action is subject to review by OMB. As discussed below regarding their anticipated effects, the these final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

The Religious IFC amended the Departments' July 2015 final regulations. The Moral IFC amended those regulations further, and added an additional rule at 45 CFR part 147.133. These final rules adopt as final, and further amend, the amendments made by the Moral IFC. The Departments do so in conjunction with the amendments made in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. These rules provide an exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4), section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, for certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process by making the accommodation applicable to organizations with such convictions as an option. The exemption applies to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action has been taken to provide for participation in the health insurance market by certain entities or individuals in a manner free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to ensure the preventive services coverage requirement is implemented in a way consistent with longstanding federal conscience statutes, to prevent lawsuits of the kind that were filed against the Departments when the expanded exemption in these final rules was not offered, and for the other reasons discussed above.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these final rules, we believe it to be small.

With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted

above, the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the nature of certain contraceptives subject to coverage under the Mandate.[73] One of them has obtained a permanent injunction against any regulations implementing the contraceptive Mandate, and so will not be affected by these final rules. Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists.[74] However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities.

The Departments also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with the conclusion in previous regulations that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). The Departments reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception and without requiring that such entities actually oppose contraception in order to be exempt (in contrast, the exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to contraceptive coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, the Departments relied on the assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is appropriate with respect to the expanded exemption for nonprofit organizations with objections based on moral convictions. To the knowledge of the Departments, the vast majority of organizations objecting to the Mandate assert objections based on religious beliefs. The only nonprofit organizations of which they are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under the Departments' previous regulations that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[75] Although the Departments are unable to find sufficient data on this issue, we believe that there are far fewer nonprofit organizations opposed to contraceptive coverage on the basis of moral convictions than there are houses of worship or integrated auxiliaries with religious objections to such coverage. Based on the limited data available, the Departments believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose certain contraceptive coverage. Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.

These rules extend the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and make exempt entities with moral objections eligible to avail themselves of the accommodation. The Departments are not aware of any institutions of higher education with this kind of non-religious moral convictions. Moreover, the Departments believe the overall number of entities that would object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education. Public comments did not reveal the existence of any institutions of higher education with such moral convictions. Therefore, for the purposes of estimating the anticipated effect of these final rules on contraceptive coverage of women who wish to receive such coverage, the Departments assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no other entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on reasons similar to those given above for why the exemptions and accommodations are extended to other entities.

The Departments believe that the exemption for issuers with objections based on moral convictions will not result in a distinct effect on contraceptive coverage for women who wish to receive it, because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein, or in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. The exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The moral exemption will also cover for-profit entities that do not have publicly traded ownership interests and that have non-religious moral objections to the Mandate, if such entities exist. Some commenters agreed that the impact of these final rules would be no more than the Departments estimated in the Moral IFC, and some commenters stated the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended

[73] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

[74] See, for example, Americans United for Life (''AUL'') Comment on CMA-9992-IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496*, and AUL Comment on CMS-9968-P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115*.

[75] *Cf., for example,* Frank Newport, ''Americans, Including Catholics, Say Birth Control Is Morally OK,'' Gallup, (May 22, 2012), *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx* (''Eighty-two percent of U.S. Catholics say birth control is morally acceptable'').

pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women. These general comments did not, however, substantially assist the Departments in estimating the number of women that would potentially be affected by these exemptions for moral convictions specifically, or among them, how many unintended pregnancies would result, how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the estimated transfer costs, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives.

Some of the comments opposing these exemptions assert that they will lead to a large number of entities dropping contraceptive coverage. The Departments disagree; they are aware of only two entities that hold non-religious moral convictions against contraceptive coverage. Both only hire employees that share their beliefs, and one will not be affected by these final rules because it is protected by an injunction from any regulations implementing the contraceptive Mandate. Commenters cited no other specific entities that might assert these moral convictions, and did not provide better data to estimate how many entities might exist. Likewise, the Departments find it unlikely that any of the vast majority of entities that covered contraceptives before this Mandate was announced in 2011 would terminate such coverage because of these exemptions based on moral convictions. The Departments also find it unlikely that a significant number of for-profit entities, whose plans include a significant number of women, omitted contraceptive coverage before the ACA on the basis of objections grounded in non-religious moral convictions, and would claim an exemption under these final rules. No such entities, or data concerning such entities, were identified by public commenters, nor are the Departments aware of any involved in litigation over the Mandate.

Numerous for-profit entities claiming religious objections have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—and both were nonprofit organizations. Among the general public, polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[76] Among non-religious persons, only a very small percentage of the population appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[77] Combined, this suggests that 0.2 percent of Americans at most[78] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. The Departments have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral convictions set forth in these final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, the Departments assume that some similar for-profit entities with non-religious moral objections exist. But the Departments expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities without publicly traded ownership interests and with sincere moral objections to the Mandate, the Departments expect that fewer than 10 entities, if any, will do so—so the Departments assume nine for-profit entities will use the exemption in these final rules.

The moral exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[79] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent.[80] This amounts to approximately 162 covered persons. Census data indicate that women of childbearing age, *i.e.,* women aged 15 to 44, comprise 20.2 percent of the general population.[81] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[82] Thus, the Departments estimate that approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules.[83] In the companion final

[76] Frank Newport, ''Most Americans Still Believe in God,'' Gallup (June 29, 2016), *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

[77] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination,'' Pew Research Center, 26 (Sept. 28, 2016), *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[78] The study defined religiously ''unaffiliated'' as agnostic, atheist or ''nothing in particular'', *id.* at 8, as distinct from several versions of Protestants, or Catholics. ''Nothing in particular'' might have included some theists.

[79] ''Health Insurance Coverage Bulletin,'' Dept. of Labor (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.* Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance.

[80] ''Health Insurance Coverage Bulletin'' Dept. of Labor'' (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[81] U.S. Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' Women's Preventive Services Guidelines, HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womensguidelines/; see also* 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. *See, e.g.,* ''Contraceptive Use in the United States,'' The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[82] *See* ''Contraceptive Use in the United States,'' The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[83] The Departments note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be

Continued

rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, in health plans that cover contraception, is $584. Consequently, the Departments estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded moral exemption in these final rules is approximately $8,760.

The Departments estimate that these final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will avail themselves of the accommodation, although the Departments wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. While these final rules make it legal for issuers to offer insurance coverage that omits contraceptives to/for exempt entities and individuals, these final rules do not require issuers to do so. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, the Departments do not anticipate that these final rules will result in any burden from such entities acting to revoke their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the exemptions finalized in these final rules. The Departments acknowledge uncertainty in the estimate and, therefore, conducted a second analysis using an alternative framework, which is set forth in the companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, with reference to the analysis conducted in the Religious IFC. Under either estimate, these final rules are not deemed to be economically significant.

The Departments reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) imposes certain requirements with respect to federal regulations that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The Moral IFC was a set of interim final rules with comment, and in these final rules, the Departments finalize the Moral IFC with certain changes based on public comments. The Moral IFC was exempt from the notice and comment requirements of the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA did not apply to the Moral IFC. These final rules are, however, issued after a notice and comment period.

The Departments carefully considered the likely impact of the rules on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization—businesses and organizations which would otherwise be faced with the dilemma of complying with the Mandate (and violating their moral convictions), or of following their moral convictions and incurring potentially significant financial penalties for noncompliance—the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

The Departments estimate that these final rules will not result in additional burdens not accounted for as set forth in companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**. As discussed there, rules covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(e)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burden related to these information collection requirements (ICRs) received emergency review and approval under OMB Control Number 0938–1344. They have been resubmitted to OMB in conjunction with this final rule and are pending re-approval.

covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion —and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

As discussed above, however, the Departments assume that no entities with non-religious moral objections to the Mandate will use the accommodation. The Departments know that no such entities were eligible for it until now, so that no entity possesses an accommodated status that would need to be revoked. Therefore, the Departments believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1344, as described in the final rules concerning religious beliefs issued contemporaneously with these final rules.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. In an effort to consolidate the number of information collections the Department is combining OMB control numbers 1210–0150 and 1210–0152 under OMB control number 1210–0150 and discontinuing OMB control number 1210–0152.

A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these final rules make entities with certain moral convictions eligible for the accommodation, the Department assumes (1) that no entities will use the accommodation rather than the exemption, and (2) entities using the moral exemption would not have to revoke an accommodation, because they previously were not eligible for it. Therefore, the Department believes these final rules do not involve additional burden not accounted for under OMB control number 1210–0150, which is published elsewhere in today's issue of the **Federal Register** in connection with the companion Religious Exemption and Accommodation Preventive Health Service final rule. The Department will publish a notice informing the public of OMB's action with respect to the Department's submission of the ICRs under OMB control number 1210–0150.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [Affordable Care] Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.'' The Moral IFC and these final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[84] However, in order to avoid double-counting with the Moral IFC, which has already been tallied as an E.O. 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) (Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year.'' In 2018, that threshold is approximately $150 million. For purposes of the Unfunded Mandates Reform Act, the Moral IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of $150 million or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

[84] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to these final rules' medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October, 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713 [Amended]

■ 2. Section 54.9815–2713, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraph (a)(1)(iv) by removing the reference ''147.131 and 147.132'' and adding in its place the reference ''147.131, 147.132, and 147.133''.

§ 54.9815–2713A [Amended]

■ 3. Section 54.9815–2713A, as amended elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (a)(1) by removing ''or (ii)'' and adding in its place ''or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)'';

■ b. In paragraph (a)(2) by removing the reference ''147.132(a)'' and adding in its place the reference ''147.132(a) or 147.133(a)'';

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ d. In paragraph (b)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ f. In paragraph (c)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''; and

■ g. In paragraph (c)(2) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ For the reasons set forth in the preamble, the Department of Labor adopts, as final, the interim final rules amending 29 CFR part 2590, published October 13, 2017 (82 FR 47838), without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47838) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147, as revised elsewhere in this issue of the **Federal Register**, continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 5. Section 147.133 is amended by revising paragraph (a)(1) introductory text, (a)(1)(ii), (a)(2), and (b) to read as follow:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health

insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

* * * * *

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24514 Filed 11–7–18; 4:15 pm]

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FEDERAL REGISTER

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Part IV

Environmental Protection Agency

40 CFR Part 721
Significant New Use Rules on Certain Chemical Substances; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2018–0650; FRL–9985–22]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 66 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 66 chemical substances for an activity that is proposed as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

DATES: Comments must be received on or before December 31, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0650, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@*epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to final SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after December 17, 2018 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances that were the subject of PMNs. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these proposed rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA

furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Proposed Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To preliminarily determine what would constitute a significant new use for the 66 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the conditions of use of the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 66 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) Order.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by the SNUR. This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.
- CFR citation assigned in the regulatory text section of the proposed rule.

The regulatory text section of each proposed rule specifies the activities that would be designated as significant new uses. Certain new uses, including exceedance of production volume limits (*i.e.,* limits on manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

These proposed rules include 66 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A) or section 5(f)(3)(A). Each Order is based on one or more of the findings in TSCA section 5(a)(3)(A) or section 5(a)(3)(B): There is insufficient information to permit a reasoned evaluation; in the absence of sufficient information to permit a reasoned evaluation, the activities associated with the PMN substances may present unreasonable risk to health or the environment; the substance is or will be produced in substantial quantities, and enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant (substantial) human exposure to the substance; presents an unreasonable risk of injury to health or environment. Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping.

However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELs approach for SNURs that are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

PMN Number: P–15–106

Chemical Name: Alkene reaction and distillation by-products and residues (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: May 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a mining and fuel additive. Based on test data for analogous chemicals, EPA identified concerns for developmental toxicity, irritation to the eyes, mucous membranes, and lungs, and dermal sensitization. EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 part per billion (ppb). The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing before manufacturing the confidential aggregate production volume specified in the Order;

2. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;

3. Use of a National Institute of Occupational Safety and Health (NIOSH) certified respirator with an assigned protection factor (APF) of 10 where there is a potential for inhalation exposure or compliance with a NCEL of 2 mg/m^3 as an 8-hour time-weighted average to prevent inhalation exposure;

4. Release of the PMN substance to water without resulting in surface water concentrations that exceed 1 ppb; and

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS).

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be that would be designated by this proposed SNUR. The submitter has agreed not to exceed a certain production volume limit without performing specific developmental toxicity testing. EPA has also determined that the results of acute aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11194.

PMN Number: P–15–726

Chemical name: Oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer.

CAS Number: 1644400–33–8.

Effective date of TSCA section 5(e) Order: March 7, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a co-polymer for use in adhesives and sealant formulations. Based on the reactivity of the triethoxysilyl group of the PMN substance, EPA identified concerns for respiratory irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. No manufacturing, processing, or use of the PMN substance in any manner that generates a vapor, dust, mist, or aerosol; and

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by this SNUR. EPA has also determined that the results of specific target organ toxicity or pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11195.

PMN Number: P–16–337

Chemical name: Aliphatic acrylate (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a monomer. Based on analogy to acrylates, EPA has identified concerns for mutagenicity, oncogenicity, developmental, liver, and kidney toxicity, sensitization, irritation/corrosion, and aquatic/terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;

2. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;

3. No use of the PMN substance other than as a chemical intermediate;

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and

5. No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific pulmonary effects and skin sensitization testing would help characterize the potential health effects of the PMN substance and results of chronic aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11196.

PMN Number: P–16–421

Chemical name: Flue dust, glass manufg. Desulfurization. Definition: The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na2S04, Na2CO3, and Na4(SO4)(CO3).

CAS Number: 1916486–36–6.

Effective date of TSCA section 5(e) Order: April 19, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the PMN substance will be as an additive to facilitate melting of sand during manufacture of glass. EPA identified concerns for reproductive, developmental, renal, neurological, hematological, gastrointestinal, and cardiovascular effects, and cancer, based on the substance containing toxic metal impurities. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure or when the PMN substance is in a mixture at a concentration below 1.0 percent by weight, an APF of 10;

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

3. Not modifying the processes or uses described in the PMN such that occupational exposure is increased;

4. Use of the PMN substance only as a site-limited intermediate;

5. Conducting and reporting to EPA an elemental analysis for the composition of the PMN substance six months after filing the notice of commencement and every six months, at each use site, for three years thereafter; and

6. Conducting and reporting to EPA an elemental analysis each time a change in the manufacturing process could result in the PMN substance possessing a different elemental composition.

The proposed SNUR would designate as a ''significant new use'' the absence of protective measures 1, 2, 3, 4, and manufacture of the substance with an elemental composition different from that described in the PMN.

Potentially useful information: EPA has determined that certain information about the composition of the PMN substance may be potentially useful to characterize the health effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to manufacture the PMN substance more than 6 months without performing an elemental analysis to characterize the elemental composition of the PMN substance.

CFR citation: 40 CFR 721.11197.

PMN Number: P–16–600

Chemical name: Organo-titanate (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 23, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an electrolyte. Based on submitted test data and the pH of the PMN substance, EPA identified concerns for mutagenicity, sensitization, irritation to skin, eyes and mucous membranes, and oncogenicity. EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 35 ppb based on analogy to phenols. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

3. Manufacturing, processing, or use of the PMN substance only for the confidential use specified in the Order;

4. No processing or use of the PMN substance in application methods that generate a vapor, mist, or aerosol; and

5. No release of the PMN substance to surface waters.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information. EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific aquatic toxicity and carcinogenicity tests would help characterize the potential environmental and health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information.

CFR citation: 40 CFR 721.11198.

PMN Number: P–17–7

Chemical name: Dialkyl 7,10-dioxa, dithiahexadeca diene (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 17, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a chemical intermediate. Based on physical chemical properties and that the epoxide may occur as an oxidation product, EPA has concerns for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive toxicity, liver toxicity, and kidney toxicity. Based on structure activity relationship (SAR) analysis on analogous neutral organic chemicals, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 67 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence

of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment where there is a potential for dermal exposure;

2. Refrain from manufacturing (including import) the PMN substance for use other than as a chemical intermediate;

3. No manufacturing, processing or use of the substance that would result in inhalation exposures by vapor, dust, mist, or aerosol;

4. No release of the PMN substance resulting in surface water concentrations that exceed 67 ppb; and

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about environmental effects and health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, carcinogenicity, and acute aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11199.

PMN Number: P–17–49

Chemical name: Haloalkyl substituted carbomonocycle (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 13, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a starting material for synthesis. EPA has identified concerns for dermal and respiratory sensitization, mutagenicity, oncogenicity, and developmental toxicity based on the potential for the chemical substance to be an alkylating agent. There are also concerns for possible effects on the liver and the chemical substance is expected to be a strong irritant and corrosive to all exposed tissues based on data on analogous chemicals. EPA predicts that the substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT). The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;

2. Use of a NIOSH certified respirator with an APF of at least 10 where there is potential for inhalation exposure;

3. Use of the confidential engineering controls specified in the Order;

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

5. Refraining from domestic manufacture in the United States (*i.e.,* import only);

6. Use of the PMN substance only for the confidential use specified in the Order;

7. No manufacture of the PMN substance beyond an annual production volume specified in the Order;

8. Disposal of the PMN substance only by incineration; and

9. No release of the PMN substance to surface waters.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the fate and health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific reproductive/developmental toxicity, genetic toxicity, and fate testing would help characterize the potential human and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11200.

PMN Numbers: P–17–249, P–17–380, and P–17–381

Chemical names: Amine- and hydroxy-functional acrylic polymer, neutralized (P–17–249), amine- and hydroxy-functional acrylic polymer (generic) (P–17–380), and hydroxy acrylic polymer, methanesulfonates (generic) (P–17–381).

CAS Numbers: Not available.

Effective date of TSCA section 5(e) Order: March 6, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the generic (non-confidential) use of the PMN substances will be open and non-dispersive. Based on analysis of test data on analogous polycationic polymers, EPA identified potential concerns for lung effects and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Use of the PMN substances only for the confidential uses specified in the Order;

2. Use of the confidential engineering controls specified in the Order;

3. No manufacturing or use of the PMN substances with methods that generate a dust, spray, mist, or aerosol;

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS; and

5. Disposal of the PMN substances only by incineration or with onsite pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information. EPA has determined that certain information about the physical-chemical properties, health effects and environmental effects of the PMN substances may be potentially useful to characterize the potential effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is

considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific particle size distribution, physical-chemical property, acute and chronic pulmonary toxicity, and acute and chronic aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11201 (P–17–249), 40 CFR 721.11202 (P–17–380) and 40 CFR 721.11203 (P–17–381).

PMN Number: P–17–270

Chemical name: Alkyl perfluorinated acryloyl ester (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a low refractive index coating. Based analysis of test data on an analogue, EPA identified concerns for liver toxicity, blood toxicity, and male reproductive toxicity for the potential degradant product. EPA predicts environmental toxicity from the effects of the potential degradation products based on analogue test data. EPA predicts that the substance will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT). The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (*i.e.,* import only);

2. No manufacture of the PMN substance beyond a confidential maximum annual manufacture (which includes import) volume; and

3. Use the PMN substance only for the confidential uses specified in the Order. The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information. EPA has determined that certain information about the environmental fate of the PMN substance may be potentially useful to characterize the potential effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific characterization, fate, and bioaccumulation testing would help characterize the potential health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions will remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11204.

PMN Number: P–17–271

Chemical name: Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy-.

CAS Number: 31497–33–3.

Effective date of TSCA section 5(e) Order: March 15, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a polymer intermediate. Based on the surfactant properties of the PMN substance, EPA has identified concerns for lung toxicity. There are concerns for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive toxicity, liver toxicity, and kidney toxicity based on the potential epoxide oxidation product. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance. To protect against these risks, the Order requires:

1. Refrain from manufacturing, processing or using the PMN substance in a manner that generates a vapor, mist, or aerosol, or that results in inhalation exposure;

2. Refraining from domestic manufacture in the United States (*i.e.,* import only);

3. No use of the PMN substance other than as a polymer intermediate; and

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific genetic toxicology, reproductive/developmental toxicity and pulmonary effect testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11205.

PMN Number: P–17–304

Chemical name: Alkylidene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 20, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a chemical intermediate for thermoset plastic material. Based on analogue data for low molecular weight moieties in the polymer, EPA has identified concern for sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (*i.e.,* import only);

2. Use of personal protective equipment to prevent dermal exposure where there is potential for dermal exposure;

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

4. Not manufacture (which under TSCA includes importing) the PMN substance to contain no more than 0.1% residual isocyanate by weight; and

5. No use of the PMN substance other than as a chemical intermediate for thermoset plastic material.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or

if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific skin sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11206.

PMN Numbers: P–17–337 and P–17–338

Chemical names: Aluminum boron cobalt lithium nickel oxide (P–17–337) and Aluminum boron cobalt lithium magnesium nickel oxide (P–17–338).

CAS Numbers: 207803–51–8 (P–17–337) and 2087499–33–8 (P–17–338).

Effective date of TSCA section 5(e) Order: March 5, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that use of the substances will be as cathode material for lithium ion batteries. Based on analysis of test data on the PMN substances and analysis of test data on analogous chemicals, EPA identified concerns for lung effects, oncogenicity, systemic effects, dermal corrosion and irritation. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the PMN substance P–17–337 is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Submit to EPA certain toxicity testing before exceeding the 24-month and 6-year time limit specified in the Order;

2. Use of personal protective equipment where there is a potential for dermal exposure;

3. Use of a NIOSH certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure;

4. As an alternative to using respirators maintain workplace airborne concentrations of the PMN substances at or below a specified NCEL of 0.000092 mg/m^3, verified by actual exposure monitoring data;

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

6. Manufacture and process the PMN substances only in a facility where all process air streams containing the PMN substances pass through control technology (such as a high-efficiency particulate air (HEPA) filter) with a rated removal efficiency of at least 99.99%.

7. Dispose of the PMN substances and manufacture, processing, and use waste streams containing the PMN substances by landfill or by metal reclamation by a person who agrees to follow the terms of the Order.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures. *Potentially useful information:* EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to exceed certain time limits without performing specific target organ toxicity or carcinogenic effects testing. The Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11207 (P–17–337) and 40 CFR 721.11208 (P–17–338).

PMN Number: P–17–343

Chemical name: Heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 3, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a corrosion inhibitor in aqueous systems. Based on test data on the PMN substance and SAR analysis of analogue data, EPA has identified hazards for eye irritation, developmental toxicity, systemic toxicity, and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order requires:

1. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure;

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

3. Use of the PMN substance only for the confidential use specified in the PMN; and

4. Refrain from manufacturing, processing, or using the PMN substance in a manner that results in inhalation exposure to vapors, dusts, mists or aerosols.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health and environmental effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific reproductive/developmental toxicity and chronic aquatic toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11209.

PMN Number: P–17–354

Chemical name: (Substituted-dialkyl(C=1~7)silyl)alkanenitrile (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: March 14, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as a solvent in electrolyte solution in batteries which will improve the performance of the batteries in consumer electronics and automotive applications. Based on test data on the PMN substance and SAR analysis of test data on analogous substances, EPA

identified hazard for mutagenicity, eye and skin irritation, sensitization, kidney toxicity, reproductive toxicity, developmental toxicity, and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure;

2. Use of a NIOSH-certified respirator with an APF of at least 50 to prevent inhalation exposure where there is potential for inhalation exposure;

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

4. Use of the PMN substance only for the confidential use specified in the Order; and

5. Dispose of the PMN substance only by incineration with an efficiency not less than 99.9%.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific reproductive toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11210.

PMN Number: P–17–361

Chemical name: Substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 26, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a dual-cure adhesion coating or barrier. EPA identified concerns for eye and skin irritation, and dermal and respiratory sensitization based on the isocyanate moiety. EPA also identified concerns for liver, kidney, and developmental toxicities, oncogenicity, and mutagenicity based on the presence of acrylates. The Order was issued under sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;

2. Use of a NIOSH-certified respirator with an APF of 50 or an APF of 1000 if spray applied where there is a potential for inhalation exposure;

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

4. Refraining from domestic manufacture in the United States (*i.e.,* import only);

5. Not manufacturing (which under TSCA includes import) the PMN substance with more than 0.25% residual isocyanate;

6. Manufacture (which under TSCA includes import) the PMN substance to have a number average molecular weight of greater than or equal to 2,280 Daltons (weight percent); and

7. Use the PMN substance only as a dual-cure adhesion coating or barrier.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of skin sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11211.

PMN Numbers: P–17–401 and P–17–402

Chemical names: Glycolipids, sophorose-contg., candida bombicola-fermented, from C16–18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts (P–17–401) and Glycolipids, sophorose-contg., candida bombicola-fermented, from C16–18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, potassium salts (P–17–402).

CAS Numbers: 2102535–74–8 (P–17–401) and 2102536–64–9 (P–17–402).

Effective date of TSCA section 5(e) Order: April 19, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances will be as a flow-back additive, surfactant for enhanced oil recovery, and foaming agent for well deliquification. Based on physical/chemical properties of the PMN substances, and analysis of test data on the PMN substances, EPA has identified concern for irritation to eyes, skin, mucous membranes and lungs. There is also concern for lung effects if respirable particulates or droplets are inhaled. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health and the environment. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

3. Refrain from manufacturing (excluding import) of the PMN substances in the United States;

4. Refrain from manufacturing (including import), processing, or using the PMN substances in a manner that would generate vapors, mists, aerosols or dusts; and

5. Refrain from manufacturing, processing, or using the PMN substances for consumer use or for commercial uses that could introduce the substance into a consumer setting.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the physical-chemical properties, environmental effects, and health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific physical-chemical property acute aquatic toxicity, and acute and chronic pulmonary effects testing would help characterize the potential health effects of the PMN substances. Although the Order does not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11212 (P–17–401) and 40 CFR 721.11213 (P–17–402).

PMN Number: P–17–404

Chemical name: 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile.

CAS number: 2058302–39–7.

Effective date of TSCA section 5(e) Order: March 27, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate completely used on site. Based on SAR analysis of test data on analogous high molecular weight polymers, EPA has identified concerns for lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against this risk, the Order requires: No manufacturing, processing, or use of the PMN substance in any manner that generate a spray, mist, aerosol, or respirable particles.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the physical-chemical properties and health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of particle size testing and acute and chronic pulmonary effects testing would help characterize the potential health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11214.

PMN Numbers: P–17–405, P–17–406, P–17–407, P–17–408, P–17–409, P–17–410, P–17–411, P–17–412, P–17–414, P–17–415, P–17–416, P–17–417, P–17–418, P–17–420, P–17–421, P–17–422, P–17–423, P–17–441, P–17–442, P–17–444, P–17–445, P–17–446, P–17–447, P–17–448, P–17–449, P–17–450

Chemical names and CAS Numbers:

Chemical names	CAS No.
Halogenated benzoic acid ethyl ester (P–17–405)	Not available.
Halogenated benzoic acid ethyl ester (P–17–406)	Not available.
Halogenated benzoic acid ethyl ester (P–17–407)	Not available.
Halogenated benzoic acid ethyl ester (P–17–408)	Not available.
Halogenated benzoic acid ethyl ester (P–17–409)	Not available.
Halogenated benzoic acid ethyl ester (P–17–410)	Not available.
Halogenated benzoic acid ethyl ester (P–17–411)	Not available.
Halogenated benzoic acid ethyl ester (P–17–412)	Not available.
Halogenated benzoic acid (P–17–414)	Not available.
Halogenated benzoic acid (P–17–415)	Not available.
Halogenated benzoic acid (P–17–416)	Not available.
Halogenated benzoic acid (P–17–417)	Not available.
Halogenated benzoic acid (P–17–418)	Not available.
Halogenated benzoic acid (P–17–420)	Not available.
Halogenated benzoic acid (P–17–421)	Not available.
Halogenated benzoic acid (P–17–422)	Not available.
Halogenated benzoic acid ethyl ester (P–17–423)	Not available.
Halogenated sodium benzoate (P–17–441)	Not available.
Halogenated sodium benzoate (P–17–442)	Not available.
Halogenated sodium benzoate (P–17–444)	Not available.
Halogenated sodium benzoate (P–17–445)	Not available.
Halogenated sodium benzoate (P–17–446)	Not available.
Halogenated sodium benzoate (P–17–447)	Not available.
Halogenated sodium benzoate (P–17–448)	Not available.
Halogenated sodium benzoate (P–17–449)	Not available.
Halogenated benzoic acid (P–17–450)	Not available.

Effective date of TSCA section 5(e) Order: May 17, 2018.

Basis for TSCA section 5(e) Order: The PMNs state that the use of the substances is for oil and gas well performance or monitoring well performance. Based on test data for a structurally analogous chemical and physical/chemical properties, EPA has identified concerns for reproductive toxicity, developmental toxicity, and neurotoxicity (ataxia), lung effects, and skin irritation. Based on SAR analysis for analogous chemicals, predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb for certain PMN substances and 460 ppb for certain other PMN substances. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence

of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to health and environment. To protect against these risks, the Order requires:

1. Refrain from using the PMN substances other than for oil and gas well performance or monitoring well performance;

2. Submit to EPA certain toxicity testing before exceeding the specified confidential production volume limits in the Order;

3. No manufacture of the PMN substances beyond an annual confidential production volume specified in the Order;

4. Use of personal protective equipment to prevent dermal exposure where there is a potential for dermal exposure;

5. Use of engineering controls as specified in the Order;

6. Use of a NIOSH certified respirator with an APF of 50 where there is a potential for inhalation exposure or compliance with a NCEL of 0.0184 mg/m^3 as an 8-hour time-weighted average to prevent inhalation exposure for P–17–414 to 418, P–17–420 to 422, and P–17–450;

7. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS;

8. Limit the amount of the PMN substances handled at processing and use sites as specified in the Order;

9. Limit manufacturing and use to liquid formulations for P–17–441 to 442 and P–17- 444 to 449;

10. No release of P–17–405 to 412 and P–17–0423 resulting in surface water concentrations that exceed 8 ppb; and

11. No release of P–17–414 to 418, P–17–420–422, P–17–441 to 442 and P–17–444 to 450 resulting in surface water concentrations that exceed 460 ppb.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the environmental and health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter has agreed not to exceed the specified production volume limits without performing specific reproductive/developmental toxicity testing, pulmonary effect testing and acute aquatic toxicity testing for certain PMN substances. EPA has also determined that the results of additional reproductive/developmental and pulmonary effects testing would help characterize the potential health effects of the PMN substance. The Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11215 (P–17–405, P–17–406, P–17–407, P–17–408, P–17–409, P–17–410, P–17–411, P–17–412, P–17–423) and 40 CFR 721.11216 (P–17–414, P–17–415, P–17–416, P–17–417, P–17–418, P–17–420, P–17–421, P–17–422, P–17–441, P–17–442, P–17–444, P–17–445, P–17–446, P–17–447, P–17–448, P–17–449, P–17–450).

PMN Numbers: P–17–424, P–17–425, P–17–426, P–17–427, P–17–428, P–17–429, P–17–430, P–17–431, P–17–432, P–17–433, P–17–435, P–17–436, P–17–437, P–17–438, P–17–439, and P–17–440

Chemical names and CAS Numbers:

Chemical name	CAS No.
Benzoic acid, 2-chloro-3-methyl-, sodium salt (1:1) (P–17–424)	1708942–16–8
Benzoic acid, 3-chloro-2-methyl-, sodium salt (1:1) (P–17–425)	1708942–17–9
Benzoic acid, 3-chloro-4-methyl-, sodium salt (1:1) (P–17–426)	1708942–15–7
Benzoic acid, 2-chloro-5-methyl-, sodium salt (1:1) (P–17–427)	118537–88–5
Benzoic acid, 4-chloro-2-methyl-, sodium salt (1:1) (P–17–428)	203261–42–1
Benzoic acid, 3-fluoro-2-methyl-, sodium salt (1:1) (P–17–429)	1708942–24–8
Benzoic acid, 3-fluoro-4-methyl-, sodium salt (1:1) (P–17–430)	1805805–74–6
Benzoic acid, 4-fluoro-2-methyl-, sodium salt (1:1) (P–17–431)	1708942–23–7
Benzoic acid, 2-fluoro-4-methyl-, sodium salt (1:1) (P–17–432)	1708942–19–1
Benzoic acid, 2-fluoro-3-methyl-, sodium salt (1:1) (P–17–433)	1708942–18–0
Benzoic acid, 2-fluoro-3-(trifluoromethyl)-, sodium salt (1:1) (P–17–435)	1701446–41–4
Benzoic acid, 2-fluoro-4-(trifluoromethyl)-, sodium salt (1:1) (P–17–436)	1708942–20–4
Benzoic acid, 2-fluoro-6-(trifluoromethyl)-, sodium salt (1:1) (P–17–437)	1708942–21–5
Benzoic acid, 3-fluoro-5-(trifluoromethyl)-, sodium salt (1:1) (P–17–438)	1535169–59–5
Benzoic acid, 4-fluoro-3-(trifluoromethyl)-, sodium salt (1:1) (P–17–439)	1701446–39–0
Benzoic acid, 4-fluoro-2-(trifluoromethyl)-, sodium salt (1:1) (P–17–440)	1708942–22–6

Effective date of TSCA section 5(e) Order: May 7, 2018.

Basis for TSCA section 5(e) Order: The PMNs state the use of the substances will be as tracer chemicals used as a tracer in water solution, or in a solid blend with polymer, or in a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata. Based on test data for an analogous chemical, and physical/chemical properties, EPA has identified toxicity concerns for reproductive toxicity, developmental toxicity, neurotoxicity (ataxia), lung effects, and skin irritation. Based on SAR analysis of test data, EPA identified ecotoxicity hazards at concentrations that exceed 300 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Refrain from manufacturing (excluding import) the PMN substances in the United States;

2. Refrain from using the PMN substances other than as tracers in aqueous solution, or in a solid blend with polymer, or in a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata;

3. Limit the amount of the PMN substances handled at processing and use sites to no more than 50 kg/day/site in aggregate for the solid formulations that generate a dust;

4. Provide personal protective equipment to its workers to mitigate dermal exposure to the PMN substances where there is potential for dermal exposure;

5. Establishment and use of a hazard communication program, including

human health precautionary statements on each label and in the SDS; and

6. No release of the PMN substances resulting in surface water concentrations that exceed 300 ppb;

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects, reproductive/developmental toxicity testing and acute aquatic toxicity testing would help characterize the potential health and environmental effects of the PMN substances. Although the Order does not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11217.

PMN Numbers: P–17–434 and P–17–443

Chemical name: Benzoic acid, 2,3,6-trifluoro, sodium salt (1:1).

CAS Number: 1803845–07–9.

Effective date of TSCA section 5(e) Orders: May 11, 2018.

Basis for TSCA section 5(e) Orders: PMN P–17–434 states that the use of the substance is as a tracer chemical (1) used as a tracer in water solution, (2) when in a solid blend with polymer, or (3) in a solid proppant bead form, all to measure flow in deep oil or gas bearing strata. PMN P–17–443 states that the generic (non-confidential) use of the substance will be to monitor well performance. Based on test data for a structurally analogous chemical and physical/chemical properties, EPA has identified concerns for reproductive toxicity, development toxicity, and neurotoxicity (ataxia), lung effects, and skin irritation. The Orders were issued for under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Orders require:

1. Submission of certain toxicity testing before exceeding the confidential production volume limit in the Order for P–17–443;

2. Manufacture the PMN substance only as a liquid formulation with the engineering controls specified in the Order for P–17–443;

3. Refrain from using the PMN substance other than as a tracer in aqueous solution, a solid blend with polymer, or a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata (non-confidential uses specified in the Order for P–17–434), or for the confidential use specified in the Order for P–17–443. The Order for P–17–434 allows processing and use of solid forms of the PMN substance but no more than 50 kg/site/day for those forms that generate a dust. Other manufacturers and processors would need to submit a SNUN to manufacture or process solid forms of the PMN substance.

4. Use of personal protective equipment to mitigate dermal exposure to the PMN substance where there is potential for dermal exposure; and

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. The submitter for P–17–443 has agreed not to exceed a certain aggregated production volume limit without performing specific pulmonary effects testing. EPA has also determined that the results of pulmonary effects and reproductive/developmental toxicity testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this testing, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citations: 40 CFR 721.11218.

PMN Number: P–18–3

Chemical name: Fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: April 10, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be as a lubricant for metal working applications. Based on SAR analysis of test data on analogous esters, EPA has identified concerns for sensitization and skin and eye irritation. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the PMN substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Provide personal protective equipment to its workers to prevent dermal exposure where there is potential for dermal exposure; and

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the health effects of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of specific sensitization testing would help characterize the potential health effects of the PMN substance. Although the Order does not require this test, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or relevant information.

CFR citation: 40 CFR 721.11219.

PMN Number: P–18–22

Chemical Name: Substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis (isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed (generic).

CAS Number: Not available.

Effective date of TSCA section 5(e) Order: April 20, 2018.

Basis for TSCA section 5(e) Order: The PMN states that the use of the substance will be used as a primer coating used for corrosion protection. Based on the physical/chemical properties of the PMN substance, available PMN data, and comparing the substance to structurally analogous chemical substances, EPA identified concerns for dermal and ocular

irritation and sensitization for the low molecular weight fraction of the PMN substance. EPA also identified concerns for ecotoxicity if the substance was manufactured differently. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(l)(A)(ii)(I) of TSCA, based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

1. Refraining from domestic manufacture in the United States (*i.e.,* import only);

2. Use of the PMN substance only for primer coating for corrosion protection;

3. Import the PMN substance with an average molecular weight greater than 1026 daltons and with low weight fractions no more than 15.3% less than 500 daltons and 25% less than 1000 daltons;

4. Use of personal protective equipment where there is a potential for dermal exposure;

5. Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure; and

6. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about environmental effects and health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has also determined that the results of skin sensitization, fate property testing, and acute and chronic aquatic toxicity testing would help characterize the potential human and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

CFR citation: 40 CFR 721.11220.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for all 66 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The proposed SNURs would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA would receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA would be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.
- EPA would identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.*

VI. Applicability of the Proposed Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which would be designated as significant new uses. The identities of 42 of the 66 chemical substances subject to this proposed rule have been claimed as confidential and EPA has not received any post-PMN *bona fide* submission (per §§ 720.25 and 721.11) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, EPA designates November 15, 2018 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule. In developing this proposed rule, EPA has recognized that, given EPA's general practice of posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before **Federal Register** publication of the proposed rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the

notice, and has taken such actions as are required with that determination.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information identified by EPA that would help characterize the potential health and/or environmental effects of the PMN/SNUN substance for all of the listed SNURs. EPA recognizes that the 2016 Lautenberg Amendments have led to modifications in our approach to testing requirements, including an increased consideration of alternatives to vertebrate testing. Descriptions of tests/information needs are provided for informational purposes only and EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the potentially useful information. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org.*

In certain of the TSCA section 5(e) Orders for the chemical substances that would be regulated under this proposed rule, EPA has established production limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Listings of the tests specified in the TSCA section 5(e) Orders are included in Unit IV. The proposed SNURs contain the same production limits as the TSCA section 5(e) Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

Any request by EPA for the testing described in the Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing/information request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information listed in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in § 720.40 and § 721.25. E–PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2018–0650.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing

respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, and 14 in FY2017, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $16,000 to $2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This proposed rule would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045

This proposed rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 24, 2018.

Jeffery T. Morris,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Amend Subpart E by adding § 721.11194 through § 721.11220 to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

Sec.

§ 721.11202 Amine- and hydroxy-functional acrylic polymer (generic).
§ 721.11203 Hydroxy acrylic polymer, methanesulfonates (generic).
§ 721.11204 Alkyl perfluorinated acryloyl ester (generic).
§ 721.11205 Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy-.
§ 721.11206 Alkylidene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (generic).
§ 721.11207 Aluminum boron cobalt lithium nickel oxide.
§ 721.11208 Aluminum boron cobalt lithium magnesium nickel oxide.
§ 721.11209 Heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (generic).
§ 721.11210 (Substituted-dialkyl(C=1~7)silyl)alkanenitrile (generic).
§ 721.11211 Substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (generic).
§ 721.11212 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts.
§ 721.11213 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16-18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, potassium salts.
§ 721.11214 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile.
§ 721.11215 Halogenated benzoic acid ethyl ester (generic).
§ 721.11216 Halogenated benzoic acid (generic).
§ 721.11217 Certain halogenated sodium benzoate salts.
§ 721.11218 Benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1).
§ 721.11219 Fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (generic).
§ 721.11220 Substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis (isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed, (generic).

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

§ 721.11194 Alkene reaction and distillation by-products and residues (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkene reaction and distillation by-products and residues (P–15–106) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iii), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10), (when determining which persons are reasonable likely to be exposed as required for § 721.63 (a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(v), (vi), (b)(concentration set at 1.0%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 2 mg/m^3 as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (ix), (g)(2)(i), (ii), (iv), (v), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 2 mg/m^3), (g)(3)(ii), (g)(4)(do not release to water at concentrations that exceed 1 ppb), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4) where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11195 Oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, monobutyl ether, monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer (P–15–726, CAS No. 1644400–33–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(ii), (2)(ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that generates a vapor, dust, mist, or aerosol.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11196 Aliphatic acrylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic acrylate (P–16–337) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section

do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified § 721.63(a)(1), (2)(i), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (ii), (iv), (vii), (ix), (g)(2)(i), (ii), (iii), (iv), (v), (g)(3)(i), (ii), (g)(4)(release restrictions apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), (c)(4) where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11197 Flue dust, glass manufg. Desulfurization. Definition: The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na2S04, Na2CO3, and Na4(SO4)(CO3).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as flue dust, glass manufg. Desulfurization. Definition: The dust produced from the flue gas exhaust cleaning of a glass manufacturing process using carbonate containing substances. It consists primarily of Na2S04, Na2CO3, and Na4(SO4)(CO3) (P–16–421, CAS No. 1916486–36–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely incorporated into a glass product.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3), (4), (5)(respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 50 or when the PMN substance is in a mixture at a concentration below 1.0 percent by weight, an APF of 10), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(v), (vi), (particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(iii), (iv), (vi), (ix), (cardiovascular effects), (g)(2)(i), (ii), (iii), (iv), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(h). It is a significant new use to modify the processes or uses described in the premanufacture notice such that occupational exposure is increased. It is a significant new use to manufacture the substance with an elemental composition different from that described in the PMN.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (d) and (f) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11198 Organo-titanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organo-titanate (P–16–600) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3), (when determining which persons are reasonable likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(vii), (g)(2)(i), (v), (g)(3)(ii), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to process or use the substance involving an application method that generates a vapor, mist, or aerosol.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11199 Dialkyl 7,10-dioxa, dithiahexadeca diene (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as dialkyl 7,10-dioxa, dithiahexadeca diene (P–17–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in

§ 721.63(a)(1), (2)(i), (iii), (iv), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(3), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(iv), (vi), (vii), (ix), (skin sensitization), (respiratory sensitization), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(i), (g)(5). Alternative hazard warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g). It is a significant new use to manufacture, process, or use the substance involving an application method that generates a vapor, mist, dust, or aerosol.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 67.

(b) *Specific requirements.* The provision of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11200 Haloalkyl substituted carbomonocycle (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as haloalkyl substituted carbomonocycle (P–17–49) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified § 721.63(a)(1), (2)(i),(ii), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 10), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (a)(6)(particulate) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(ix), (irritation), (sensitization), (liver toxicity), (mutagenicity), (g)(2)(i), (ii), (iii), (iv), (v), (g)(4)(i), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to use the substance without the confidential engineering controls specified in the Order.

(iv) *Disposal.* Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1).

(v) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (k).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11201 Amine- and hydroxy-functional acrylic polymer, neutralized (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amine- and hydroxy-functional acrylic polymer, neutralized (P–17–249), is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in dried coating.

(2) The significant new uses are:

(i) *Hazard communication* Requirements as specified in § 721.72(a) through (e)(concentration set at 1%), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), (do not release to water without pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to use the substance without the confidential engineering controls specified in the Order. It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

(iii) *Disposal requirements.* Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1).

(iv) *Release to water.* Requirements as specified in § 721.90. It is a significant new use to release to water without pretreatment at an on-site wastewater treatment plant with at least 96% efficiency.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11202 Amine- and hydroxy-functional acrylic polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amine- and hydroxy-functional acrylic polymer (P–17–380), is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in dried coating.

(2) The significant new uses are:

(i) *Hazard communication* Requirements as specified in § 721.72(a) through (e)(concentration set at 1%), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), (do not release to water without pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally

Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to use the substance without the confidential engineering controls specified in the Order. It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

(iii) *Disposal requirements.* Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1).

(iv) *Release to water.* Requirements as specified in § 721.90. It is a significant new use to release to water without pretreatment at an on-site wastewater treatment plant with at least 96% efficiency.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11203 Hydroxy acrylic polymer, methanesulfonates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hydroxy acrylic polymer, methanesulfonates (P–17–381), is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained in dried coating.

(2) The significant new uses are:

(i) *Hazard communication* Requirements as specified in § 721.72(a) through (e)(concentration set at 1%), (f), (g)(1)(ii), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), (do not release to water without pre-treatment of water releases at an onsite waste water treatment plant with at least 96% efficiency), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to use the substance without the confidential engineering controls specified in the Order. It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

(iii) *Disposal requirements.* Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1).

(iv) *Release to water.* Requirements as specified in § 721.90. It is a significant new use to release to water without pretreatment at an on-site wastewater treatment plant with at least 96% efficiency.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11204 Alkyl perfluorinated acryloyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl perfluorinated acryloyl ester (P–17–270) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11205 Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propen-1-yl)-.omega.-hydroxy- (P–17–271, CAS No. 31497–33–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substances after they have been reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii), (g)(2)(ii), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the substance other than as a polymer intermediate. It is a significant new use to manufacture, process or use the substance in a manner that generates a vapor, mist, or aerosol, or that results in inhalation exposure.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11206 Alkylidene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylidene dicarbomonocycle, polymer with halo-substituted heteromonocycle and disubstituted alkyl carbomonocycle alkenedioate alkylalkenoate (P–17–304) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after it has been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified

§ 721.63(a)(1), (a)(2)(i), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii),(skin sensitization), (g)(2)(i), (ii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the substance other than as an intermediate for thermoset plastic material. It is a significant new use to manufacture (includes importing) the substance to contain more than 0.1% residual isocyanate by weight.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11207 Aluminum boron cobalt lithium nickel oxide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as aluminum boron cobalt lithium nickel oxide (P–17–337, CAS No. 207803–51–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (ii), (a)(3)(i), (ii), (a)(4), (a)(5), (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1,000), (when determining which persons are reasonable likely to be exposed as required for § 721.63 (a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 0.1%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL 0.000092 mg/m^3 as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e), (concentration set at 0.1%), (f), (g)(1)(i), (vii), (damage to the lung, kidney, and spleen), (g)(2)(i), (iii), (iv), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.000092 mg/m^3), (avoid breathing substance in the dust form), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond two years. It is a significant new use to manufacture or process the substance at any facility unless all process air streams containing the substances pass through control technology such as a high-efficiency particulate air filter with a rated removal efficiency of at least 99.99%.

(iv) *Disposal.* Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(2). It is a significant new use to dispose of the substances by metal reclamation unless the person reclaiming metal containing the substances complies with this section. It is a significant new use to release the substances to air unless the chemical transfer and air ventilation processes specified in the order are followed.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (j) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iv) of this section.

§ 721.11208 Aluminum boron cobalt lithium magnesium nickel oxide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as aluminum boron cobalt lithium magnesium nickel oxide (P–17–338, CAS No. 2087499–33–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (ii), (a)(3)(i), (ii), (a)(4), (a)(5), (respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1,000), (when determining which persons are reasonable likely to be exposed as required for § 721.63 (a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (b)(concentration set at 0.1%), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL 0.000092 mg/m^3 as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e), (concentration set at 0.1%), (f), (g)(1)(i), (vii), (damage to the lung, kidney, and spleen), (g)(2)(i), (iii), (iv), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.000092 mg/m^3), (avoid breathing substance in the dust form), and (g)(5). Alternative hazard and warning statements that meet the criteria of the

Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond two years. It is a significant new use to manufacture or process the substances at any facility unless all process air streams containing the substances pass through control technology such as a high-efficiency particulate air filter with a rated removal efficiency of at least 99.99%.

(iv) *Disposal.* Requirements as specified in § 721.85(a)(2), (b)(2), and (c)(2). It is a significant new use to dispose of the substances by metal reclamation unless the person reclaiming metal containing the substances complies with this section. It is a significant new use to release the substances to air unless the chemical transfer and air ventilation processes specified in the order are followed.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (j) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iv) of this section.

§ 721.11209 Heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteropolycyclic-alkanol carbomonocycle-alkanesulfonate (PMN P–17–343) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (vi), (ix), (eye irritation), (systemic effects), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture, process or use the substance in a manner that results in inhalation exposure to a vapor, mist, dust or aerosol.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725 (b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11210 (Substituted-dialkyl(C=1~7)silyl)alkanenitrile (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as (substituted-dialkyl(C=1~7)silyl) alkanenitrile (PMN P–17–354) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(ii), (iv), (vi), (ix), (skin and eye irritation), (sensitization), (mutagenicity), (g)(2)(i), (ii), (iii), (iv), (v), (use eye protection), (g)(3)(i), (ii), (g)(4)(i), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(iv) *Disposal.* Requirements as specified in § 721.85(a)(1), (b)(1), and (c)(1)(waste streams from use must be disposed of only by incineration with no less than 99.9% efficiency).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (j) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11211 Substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted heteromonocycle, polymer with diisocyanato alkane and alkanediol, substituted heteromonocycle homopolymer ester with substituted alkylacrylate; blocked (P–17–361) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (3), (4), (5), (respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor (APF) of at least 50 or an APF of at least 1,000 if spray applied), (when determining which persons are

reasonable likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (vii), (ix), (sensitization), (systemic effects), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance containing greater than 0.25% residual isocyanate or an average molecular weight less than 2,280 daltons. It is a significant new use to use the substance other than as a dual-cure adhesion coating or barrier.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11212 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16–18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as glycolipids, sophorose-contg., candida bombicola-fermented, from C16–18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts (P–17–401, CAS No. 2102535–74–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (eye irritation), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance in any manner that results in generation of a vapor, dust, mist or aerosol.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11213 Glycolipids, sophorose-contg., candida bombicola-fermented, from C16–18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, potassium salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as glycolipids, sophorose-contg., Candida bombicola-fermented, from C16–18 and C18-unsatd. glycerides and D-glucose, hydrolyzed, sodium salts (P–17–402, CAS No. 2102536–64–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (2)(i), (iii), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (eye irritation), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture, process, or use the substance for consumer use or for commercial uses that could introduce the substance into a consumer setting. It is a significant new use to manufacture, process, or use the substance in any manner that results in generation of a vapor, dust, mist or aerosol.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11214 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester, polymer with 1,3-butadiene and 2-propenenitrile (PMN P–17–404, CAS No. 2058302–39–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. It is a significant new use to manufacture, process, or use the substance in any manner that results in the generation of spray, mist, aerosol, or respirable particles.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in

§ 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11215 Halogenated benzoic acid ethyl ester (generic).

(a)(1) The chemical substances identified generically in the table of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

TABLE—HALOGENATED BENZOIC ACID ETHYL ESTERS

PMN No.	Chemical name
P–17–405 ...	Halogenated benzoic acid ethyl ester.
P–17–406 ...	Halogenated benzoic acid ethyl ester.
P–17–407 ...	Halogenated benzoic acid ethyl ester.
P–17–408 ...	Halogenated benzoic acid ethyl ester.
P–17–409 ...	Halogenated benzoic acid ethyl ester.
P–17–410 ...	Halogenated benzoic acid ethyl ester.
P–17–411 ...	Halogenated benzoic acid ethyl ester.
P–17–412 ...	Halogenated benzoic acid ethyl ester.
P–17–423 ...	Halogenated benzoic acid ethyl ester.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (2)(i), (iv), (3), (4), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to use the substances other than for oil and gas well performance. It is a significant new use to manufacture or process the substances without the engineering controls specified in the Order. It is a significant new use to exceed the kilograms per day limit specified in the Order of the substances handled at processing and use sites.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 8.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725 (b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11216 Halogenated benzoic acid (generic).

(a)(1) The chemical substances identified generically in the table of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

TABLE—HALOGENATED BENZOIC ACIDS

PMN No.	Chemical name
P–17–414 ...	Halogenated benzoic acid.
P–17–415 ...	Halogenated benzoic acid.
P–17–416 ...	Halogenated benzoic acid.
P–17–417 ...	Halogenated benzoic acid.
P–17–418 ...	Halogenated benzoic acid.
P–17–420 ...	Halogenated benzoic acid.
P–17–421 ...	Halogenated benzoic acid.
P–17–422 ...	Halogenated benzoic acid.
P–17–441 ...	Halogenated sodium benzoate.
P–17–442 ...	Halogenated sodium benzoate.
P–17–444 ...	Halogenated sodium benzoate.
P–17–445 ...	Halogenated sodium benzoate.
P–17–446 ...	Halogenated sodium benzoate.
P–17–447 ...	Halogenated sodium benzoate.
P–17–448 ...	Halogenated sodium benzoate.
P–17–449 ...	Halogenated sodium benzoate.
P–17–450 ...	Halogenated benzoic acid.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), (a)(4), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(5) (respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (respirators are only required for P17–414 to P17–418, P17–420 to P17–422, and P17–450), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for the substances. The NCEL is 0.0184 mg/m3 as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved].

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (v), (iv)(use respiratory protection or maintain workplace airborne concentration at or below an 8-hour time-weighted average of 0.0184 mg/m^3) (This statement only required for P17–414 to P17–418, P17–420 to P17–422, and P17–450), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q) and (t). It is a significant new use to use the substances other than for monitoring well performance. It is a significant new use to manufacture or process the substances without the engineering controls specified in the Order. It is a significant new use to exceed the kilograms per day limit specified in the Order of the substances handled at processing and use sites. It is a significant new use to use P17–441 to 442 and P17–444 to P17–449 other than in a liquid formulation.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 460.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725 (b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11217 Certain halogenated sodium benzoate salts.

(a)(1) The chemical substances listed in the table of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

TABLE—HALOGENATED SODIUM BENZOATE SALTS

PMN No.	CAS No.	Chemical name
P–17–424	1708942–16–8	Benzoic acid, 2-chloro-3-methyl-, sodium salt (1:1).
P–17–425	1708942–17–9	Benzoic acid, 3-chloro-2-methyl-, sodium salt (1:1).
P–17–426	1708942–15–7	Benzoic acid, 3-chloro-4-methyl-, sodium salt (1:1).
P–17–427	118537–88–5	Benzoic acid, 2-chloro-5-methyl-, sodium salt (1:1).
P–17–428	203261–42–1	Benzoic acid, 4-chloro-2-methyl-, sodium salt (1:1).
P–17–429	1708942–24–8	Benzoic acid, 3-fluoro-2-methyl-, sodium salt (1:1).
P–17–430	1805805–74–6	Benzoic acid, 3- fluoro-4-methyl-, sodium salt (1:1).
P–17–431	1708942–23–7	Benzoic acid, 4- fluoro-2-methyl-, sodium salt (1:1).
P–17–432	1708942–19–1	Benzoic acid, 2- fluoro-4-methyl-, sodium salt (1:1).
P–17–433	1708942–18–0	Benzoic acid, 2- fluoro-3-methyl-, sodium salt (1:1).
P–17–435	1701446–41–4	Benzoic acid, 2- fluoro-3-(trifluoromethyl)-, sodium salt (1:1).
P–17–436	1708942–20–4	Benzoic acid, 2- fluoro-4-(trifluoromethyl)-, sodium salt (1:1).
P–17–437	1708942–21–5	Benzoic acid, 2- fluoro-6-(trifluoromethyl)-, sodium salt (1:1).
P–17–438	1535169–59–5	Benzoic acid, 3- fluoro-5-(trifluoromethyl)-, sodium salt (1:1).
P–17–439	1701446–39–0	Benzoic acid, 4- fluoro-3-(trifluoromethyl)-, sodium salt (1:1).
P–17–440	1708942–22–6	Benzoic acid, 4- fluoro-2-(trifluoromethyl)-, sodium salt (1:1).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to handle at a processing or use site more than 50 kilograms per day per site in aggregate of the PMN substances for solid formulations that generate a dust. It is a significant new use to use the substances other than as tracers in aqueous solution, in solid blends with polymers, or in a solid proppant bead forms to measure flow in deep oil-bearing or gas-bearing strata.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 300.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11218 Benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified benzoic acid, 2, 3, 6-trifluoro, sodium salt (1:1) (P–17–434 and P–17–443, CAS No. 1803845–07–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), (when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (iii), (iv), (vi), (ix), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q). It is a significant new use to manufacture the substance other than in a liquid formulation and without the confidential engineering controls specified in the Order for P–17–443. It is a significant new use to use the substance other than as a tracer in aqueous solution, a solid blend with polymer, or a solid proppant bead form to measure flow in deep oil-bearing or gas-bearing strata or for the confidential use specified in the Order for P–17–443.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725 (b)(1) apply to paragraph (a)(2)(iii) of this section.

§ 721.11219 Fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acids, diesters with dihydroxyalkane, fatty acids, esters with dihydroxyalkane (PMN P–18–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), (when determining which persons are

reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible), (a)(6)(v), (vi), (particulate), (b)(concentration set at 1.0%) and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 1.0%), (f), (g)(1), (skin and eye irritation and sensitization), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11220 Substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis (isocyanatocarbomonocycle) bis (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed, (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted carbomonocycle, polymer with halo substituted heteromonocycle and polyoxyalkylene polymer with alkylenebis(isocyanatocarbomonocycle) his (carbomonocycledicarboxylate), reaction products with alkylamines, hydrolyzed, (P–18–22) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), (a)(4), (a)(5)(respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor of at least 50), (when determining which persons are reasonable likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposures, where feasible), (a)(6)(particulate), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1)(ii), (irritation to skin, eyes, lungs, and mucous membranes), (g)(2)(i), (ii), (iii), (iv), (v), (avoid eye contact), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to use the substance other than as primer coating used for corrosion protection. It is a significant new use to import the substance with an average molecular weight greater less than 1026 daltons, and with low weight fractions greater than 15.3% less than 500 daltons and 25% less than 1000 daltons.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

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The President

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Title 3—

The President

Proclamation 9822 of November 9, 2018

Addressing Mass Migration Through the Southern Border of the United States

By the President of the United States of America

A Proclamation

The United States expects the arrival at the border between the United States and Mexico (southern border) of a substantial number of aliens primarily from Central America who appear to have no lawful basis for admission into our country. They are traveling in large, organized groups through Mexico and reportedly intend to enter the United States unlawfully or without proper documentation and to seek asylum, despite the fact that, based on past experience, a significant majority will not be eligible for or be granted that benefit. Many entered Mexico unlawfully—some with violence—and have rejected opportunities to apply for asylum and benefits in Mexico. The arrival of large numbers of aliens will contribute to the overloading of our immigration and asylum system and to the release of thousands of aliens into the interior of the United States. The continuing and threatened mass migration of aliens with no basis for admission into the United States through our southern border has precipitated a crisis and undermines the integrity of our borders. I therefore must take immediate action to protect the national interest, and to maintain the effectiveness of the asylum system for legitimate asylum seekers who demonstrate that they have fled persecution and warrant the many special benefits associated with asylum.

In recent weeks, an average of approximately 2,000 inadmissible aliens have entered each day at our southern border. In Fiscal Year 2018 overall, 124,511 aliens were found inadmissible at ports of entry on the southern border, while 396,579 aliens were apprehended entering the United States unlawfully between such ports of entry. The great number of aliens who cross unlawfully into the United States through the southern border consumes tremendous resources as the Government seeks to surveil, apprehend, screen, process, and detain them.

Aliens who enter the United States unlawfully or without proper documentation and are subject to expedited removal may avoid being promptly removed by demonstrating, during an initial screening process, a credible fear of persecution or torture. Approximately 2 decades ago, most aliens deemed inadmissible at a port of entry or apprehended after unlawfully entering the United States through the southern border were single adults who were promptly returned to Mexico, and very few asserted a fear of return. Since then, however, there has been a massive increase in fear-of-persecution or torture claims by aliens who enter the United States through the southern border. The vast majority of such aliens are found to satisfy the credible-fear threshold, although only a fraction of the claimants whose claims are adjudicated ultimately qualify for asylum or other protection. Aliens found to have a credible fear are often released into the interior of the United States, as a result of a lack of detention space and a variety of other legal and practical difficulties, pending adjudication of their claims in a full removal proceeding in immigration court. The immigration adjudication process often takes years to complete because of the growing volume of claims and because of the need to expedite proceedings for detained aliens. During that time, many released aliens fail to appear for hearings, do not

comply with subsequent orders of removal, or are difficult to locate and remove.

Members of family units pose particular challenges. The Federal Government lacks sufficient facilities to house families together. Virtually all members of family units who enter the United States through the southern border, unlawfully or without proper documentation, and that are found to have a credible fear of persecution, are thus released into the United States. Against this backdrop of near-assurance of release, the number of such aliens traveling as family units who enter through the southern border and claim a credible fear of persecution has greatly increased. And large numbers of family units decide to make the dangerous and unlawful border crossing with their children.

The United States has a long and proud history of offering protection to aliens who are fleeing persecution and torture and who qualify under the standards articulated in our immigration laws, including through our asylum system and the Refugee Admissions Program. But our system is being overwhelmed by migration through our southern border. Crossing the border to avoid detection and then, if apprehended, claiming a fear of persecution is in too many instances an avenue to near-automatic release into the interior of the United States. Once released, such aliens are very difficult to remove. An additional influx of large groups of aliens arriving at once through the southern border would add tremendous strain to an already taxed system, especially if they avoid orderly processing by unlawfully crossing the southern border.

The entry of large numbers of aliens into the United States unlawfully between ports of entry on the southern border is contrary to the national interest, and our law has long recognized that aliens who seek to lawfully enter the United States must do so at ports of entry. Unlawful entry puts lives of both law enforcement and aliens at risk. By contrast, entry at ports of entry at the southern border allows for orderly processing, which enables the efficient deployment of law enforcement resources across our vast southern border.

Failing to take immediate action to stem the mass migration the United States is currently experiencing and anticipating would only encourage additional mass unlawful migration and further overwhelming of the system.

Other presidents have taken strong action to prevent mass migration. In Proclamation 4865 of September 29, 1981 (High Seas Interdiction of Illegal Aliens), in response to an influx of Haitian nationals traveling to the United States by sea, President Reagan suspended the entry of undocumented aliens from the high seas and ordered the Coast Guard to intercept such aliens before they reached United States shores and to return them to their point of origin. In Executive Order 12807 of May 24, 1992 (Interdiction of Illegal Aliens), in response to a dramatic increase in the unlawful mass migration of Haitian nationals to the United States, President Bush ordered additional measures to interdict such Haitian nationals and return them to their home country. The Supreme Court upheld the legality of those measures in *Sale v. Haitian Centers Council, Inc.,* 509 U.S. 155 (1993).

I am similarly acting to suspend, for a limited period, the entry of certain aliens in order to address the problem of large numbers of aliens traveling through Mexico to enter our country unlawfully or without proper documentation. I am tailoring the suspension to channel these aliens to ports of entry, so that, if they enter the United States, they do so in an orderly and controlled manner instead of unlawfully. Under this suspension, aliens entering through the southern border, even those without proper documentation, may, consistent with this proclamation, avail themselves of our asylum system, provided that they properly present themselves for inspection at a port of entry. In anticipation of a large group of aliens arriving in the coming weeks, I am directing the Secretary of Homeland Security to commit additional resources to support our ports of entry at the southern border

to assist in processing those aliens—and all others arriving at our ports of entry—as efficiently as possible.

But aliens who enter the United States unlawfully through the southern border in contravention of this proclamation will be ineligible to be granted asylum under the regulation promulgated by the Attorney General and the Secretary of Homeland Security that became effective earlier today. Those aliens may, however, still seek other forms of protection from persecution or torture. In addition, this limited suspension will facilitate ongoing negotiations with Mexico and other countries regarding appropriate cooperative arrangements to prevent unlawful mass migration to the United States through the southern border. Thus, this proclamation is also necessary to manage and conduct the foreign affairs of the United States effectively.

NOW, THEREFORE, I, DONALD J. TRUMP, by the authority vested in me by the Constitution and the laws of the United States of America, including sections 212(f) and 215(a) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(f) and 1185(a), respectively) hereby find that, absent the measures set forth in this proclamation, the entry into the United States of persons described in section 1 of this proclamation would be detrimental to the interests of the United States, and that their entry should be subject to certain restrictions, limitations, and exceptions. I therefore hereby proclaim the following:

Section 1. *Suspension and Limitation on Entry.* The entry of any alien into the United States across the international boundary between the United States and Mexico is hereby suspended and limited, subject to section 2 of this proclamation. That suspension and limitation shall expire 90 days after the date of this proclamation or the date on which an agreement permits the United States to remove aliens to Mexico in compliance with the terms of section 208(a)(2)(A) of the INA (8 U.S.C. 1158(a)(2)(A)), whichever is earlier.

Sec. 2. *Scope and Implementation of Suspension and Limitation on Entry.* (a) The suspension and limitation on entry pursuant to section 1 of this proclamation shall apply only to aliens who enter the United States after the date of this proclamation.

(b) The suspension and limitation on entry pursuant to section 1 of this proclamation shall not apply to any alien who enters the United States at a port of entry and properly presents for inspection, or to any lawful permanent resident of the United States.

(c) Nothing in this proclamation shall limit an alien entering the United States from being considered for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. 1231(b)(3)) or protection pursuant to the regulations promulgated under the authority of the implementing legislation regarding the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, or limit the statutory processes afforded to unaccompanied alien children upon entering the United States under section 279 of title 6, United States Code, and section 1232 of title 8, United States Code.

(d) No later than 90 days after the date of this proclamation, the Secretary of State, the Attorney General, and the Secretary of Homeland Security shall jointly submit to the President, through the Assistant to the President for National Security Affairs, a recommendation on whether an extension or renewal of the suspension or limitation on entry in section 1 of this proclamation is in the interests of the United States.

Sec. 3. *Interdiction.* The Secretary of State and the Secretary of Homeland Security shall consult with the Government of Mexico regarding appropriate steps—consistent with applicable law and the foreign policy, national security, and public-safety interests of the United States—to address the approach of large groups of aliens traveling through Mexico with the intent of entering the United States unlawfully, including efforts to deter, dissuade, and return

such aliens before they physically enter United States territory through the southern border.

Sec. 4. *Severability.* It is the policy of the United States to enforce this proclamation to the maximum extent possible to advance the interests of the United States. Accordingly:

(a) if any provision of this proclamation, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this proclamation and the application of its other provisions to any other persons or circumstances shall not be affected thereby; and

(b) if any provision of this proclamation, or the application of any provision to any person or circumstance, is held to be invalid because of the failure to follow certain procedures, the relevant executive branch officials shall implement those procedural requirements to conform with existing law and with any applicable court orders.

Sec. 5. *General Provisions.* (a) Nothing in this proclamation shall be construed to impair or otherwise affect:

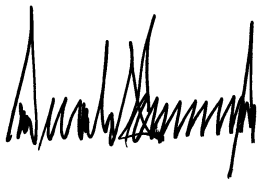
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This proclamation shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This proclamation is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of November, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2018–25117
Filed 11–14–18; 11:15 am]
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Presidential Documents

Proclamation 9823 of November 9, 2018

American Education Week, 2018

By the President of the United States of America

A Proclamation

During American Education Week, we reaffirm our commitment to ensuring that all Americans have access to an affordable, high-quality education. We also recognize the hard work of our Nation's dedicated parents, guardians, teachers, and school leaders to ensure that every child is prepared to join today's growing workforce. To maintain our country's competitiveness, our students deserve a good education that empowers them with the knowledge, skills, and character necessary to reach their full potential.

Education is a lifelong process of learning and discovery that begins at home. Parents are a child's first teacher. By actively engaging with educators, mentors, coaches, faith leaders, and community members, parents are best equipped to shape their child's education. My Administration has worked to empower States and local communities with greater control and flexibility over their schools. We are also protecting and expanding parents' access to a wide range of high-quality educational choices, including effective public, charter, magnet, private, parochial, online, and homeschool options.

Each student is unique, with their own distinct experiences, needs, learning styles, and dreams. Thus, education must be customized and individualized as there is no single approach to education that works for every student. My Administration encourages parents, guardians, educators, and school leaders to rethink the way students learn in America to ensure that every American receives a high-quality education that meets their needs. We empower teachers to create learning environments that are challenging, relevant, and engaging. When families are free to choose where and how their children learn, and when teachers are free to do their best work, students are able to grow and explore their talents and passions.

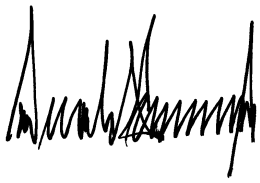
High-quality education also paves the way for a thriving workforce in America. My Administration acknowledges that our economy requires dynamic approaches to education and workforce development. Today's students will enter an economy that is stronger than ever before. With consumer confidence at a record high and unemployment at the lowest rate in almost 50 years, bringing our workforce development efforts into the 21st century is exceedingly critical. In July, I established the President's National Council for the American Worker and the American Workforce Policy Advisory Board to harness the expertise of the education and business communities, and to allow private- and public-sector collaboration to resolve pressing issues related to workforce development. Additionally, I was pleased to sign a reauthorization of the Carl D. Perkins Career and Technical Education Act. This legislation increases access to programs that will help provide students with the skills they need to succeed in our 21st century economy while enabling more flexibility for States to meet the unique needs of their students, educators, and employers. My Administration is committed to ensuring that America's students and workers have access to education and job training that will equip them to compete and win in the global economy.

This week, we are reminded of our great responsibility to empower our Nation's students to develop the skills needed to pursue meaningful careers.

We must continue our efforts to expand freedom and opportunity in education, with the knowledge that our country's future relies on today's students.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 11 through November 17, 2018, as American Education Week. I commend our Nation's schools, their teachers and leaders, and the parents of students across this land. And I call on States and communities to support high-quality education to meet the needs of all students.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of November, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2018–25122
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Presidential Documents

Proclamation 9824 of November 9, 2018

National Apprenticeship Week, 2018

By the President of the United States of America

A Proclamation

Under my Administration's policies, our Nation's economy is booming and Americans have more opportunities than ever before. Men and women from all walks of life are moving off the sidelines and into the workforce. In this economic context, our country needs workers with world-class skills and abilities to fill vacant positions in the labor force. During National Apprenticeship Week, we recognize the importance of apprenticeships in helping our country's hardworking people develop the competencies that enable success in today's dynamic, 21st century economy.

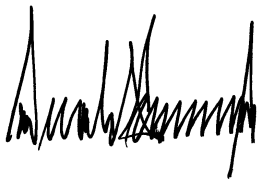
As a lifelong businessman who has hired thousands of workers, I am a strong believer in the apprenticeship model, and my Administration is committed to expanding apprenticeship opportunities. Apprenticeship programs, when implemented effectively, provide workers with an opportunity to ''earn and learn'' on the job, and pair workplace education with classroom instruction, accelerating the learning process for participants and increasing their marketability. Since I took office, American employers have hired over 400,000 apprentices. In 2018 alone, we committed $145 million to diversify and scale apprenticeship programs, and we provided an additional $150 million in grant opportunities to promote apprenticeships in industries where they have not traditionally existed, including advanced manufacturing, banking and finance, information technology, and healthcare. In addition, as a result of our Pledge to America's Workers, in just 3 months, we have secured commitments from more than 160 companies and associations to provide jobs, education, and workforce development opportunities to 6.4 million American workers.

In June of last year, I signed an Executive Order creating the Task Force on Apprenticeship Expansion, which focused on identifying proposals to cultivate apprenticeships across all sectors of the economy and reform ineffective education and workforce development programs. The Task Force was composed of representatives from business, the trades, labor and industry groups, and educational institutions; each participant contributed a unique set of insights and experiences. The Task Force helped my Administration map out a strategy for creating new, industry-recognized apprenticeship programs that will encourage employers and industries to adopt the apprenticeship model.

In addition to supporting apprenticeships, I am advancing tax and regulatory policies that are increasing opportunities for all Americans. Last month, the unemployment rate dropped to 3.7 percent, its lowest point in nearly 50 years, and more Americans are working today than ever before in our history. At the same time, right now, there are 7 million unfilled jobs in our country. By successfully deploying the apprenticeship model, the United States can build a workforce strong enough to quickly fill all of those jobs and better compete on the global stage. This week, I encourage all participants in our economy, from business leaders to government officials to educators, to join in our efforts to expand apprenticeship programs. Together, we can build and educate our Nation's workforce, securing American economic greatness for future generations.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 12 through November 18, 2018, as National Apprenticeship Week.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of November, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2018–25126
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Presidential Documents

Proclamation 9825 of November 9, 2018

Veterans Day, 2018

By the President of the United States of America

A Proclamation

On November 11, 1918, the United States and its allies signed an armistice with Germany to end hostilities in World War I. The Great War exacted a tremendous toll on our Nation. More than 100,000 American service members perished in the war, and the lives of countless others were forever altered. In 1919, to honor and memorialize these sacrifices, President Woodrow Wilson proclaimed November 11 as Armistice Day, the precursor to Veterans Day, expressing ''solemn pride in the heroism of those who died in the country's service.'' This year, as we commemorate the 100th anniversary of the Armistice, we again salute the generations upon generations of American heroes who have sacrificed so much to secure the blessings of freedom for their fellow Americans.

We will never be able to repay the debt we owe the brave men and women who have served in the Army, Navy, Air Force, Marines, and Coast Guard. To the 20 million veterans alive today: this Veterans Day, we recommit ourselves to providing you with the care you deserve. In June, I signed into law the VA MISSION Act of 2018, enacting some of the most substantial reforms to the Department of Veterans Affairs (VA) in a generation. This landmark legislation made Veterans Choice permanent, ensuring that our Nation's veterans have timely access to the highest quality of care possible and the flexibility to receive care either at the VA or at a private healthcare facility. The VA MISSION Act is removing barriers to telemedicine and expanding access to walk-in clinics. And it is giving veterans who were catastrophically injured in World War II, the Korean War, the Vietnam War, and the Gulf War the same access to caregiver assistance that veterans of more recent conflicts already enjoy. My Administration is also processing veteran claims and appeals more quickly than ever before, and veterans can now use their GI Bill benefits at any point in their lives. And, for the first time in history, the Department of Defense and the VA will share electronic health records, improving accessibility and easing the healthcare burden on our veterans.

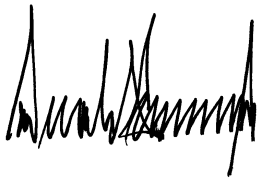
For many service members, the transition into civilian life can be fraught with challenges. To enhance their access to critical resources and support, I signed an Executive Order that directs the Secretaries of Defense, Veterans Affairs, and Homeland Security to develop and implement a Joint Action Plan that provides seamless access to mental health treatment and suicide prevention resources for service members in the year following the conclusion of their military service.

As we mark the centennial of the Armistice, we remember the countless sacrifices that our country's heroic veterans have made throughout our history to preserve our liberty and prosperity. Our veterans embody the values and ideals of America and the timeless virtue of serving a greater cause. With respect for, and in recognition of, the contributions our service members have made to the advance of peace and freedom around the world, the Congress has provided (5 U.S.C. 6103(a)) that November 11 of each year shall be set aside as a legal public holiday to honor our Nation's veterans. As Commander in Chief of our heroic Armed Forces, I humbly thank our

veterans and their families for their selflessness and love of country as we remember their service and their sacrifice. Today, and every day, we pay tribute to those who have worn the uniform, and we pray for the safety of all currently serving in harm's way.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim November 11, 2018, as Veterans Day. I encourage all Americans to recognize the fortitude and sacrifice of our veterans through public ceremonies and private thoughts and prayers. I call upon Federal, State, and local officials to display the flag of the United States and to participate in patriotic activities in their communities. I call on all Americans, including civic and fraternal organizations, places of worship, schools, and communities to support this day with commemorative expressions and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of November, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



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Reader Aids

Federal Register

Vol. 83, No. 221

Thursday, November 15, 2018

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

54861–55092 1
55093–55246 2
55247–55452 5
55453–55600 6
55601–55812 7
55813–55930 8
55931–56254 9
56255–56698 13
56699–57306 14
57307–57670 15

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
13850 55243
Proclamations:
9814 55453
9815 55455
9816 55457
9817 55459
9818 55461
9819 55463
9820 57303
9821 57305
9822 57661
9823 57665
9824 57667
9825 57669
Administrative Orders:
Memorandums:
Memorandum of October 29, 2018 56697
Notices:
Notice of October 31, 2018 55239
Notice of November 8, 2018 56251
Notice of November 8, 2018 56253
Presidential Determinations:
No. 2019–01 of October 4, 2018 55091

5 CFR

250 55931
Ch. XIV 54862
Ch. CI 54861

7 CFR

906 55931
927 56255
1728 55465
Proposed Rules:
981 56742
987 55111

8 CFR

208 55934
1003 55934
1208 55934

10 CFR

72 55601
Proposed Rules:
50 56156
72 55643
170 55113
171 55113
430 ..... 54883, 56746
431 54883

12 CFR

652 55093
700 55467
701 55467
702 55467
703 55467
713 55467
723 55467
747 55467
Proposed Rules:
Ch. II 57351
268 57343
701 56640
1281 55114

13 CFR

120 55478

14 CFR

25 55247
39 ..... 55249, 55252, 55255, 55258, 55606, 55610, 55614, 55617, 55619, 55813, 55816, 55953, 56699, 56702, 56704, 56709
71 ..... 54864, 55479, 56711
91 55263
97 ..... 55818, 55821
Proposed Rules:
39 ..... 55294, 55297, 55299, 55303, 55496, 55498, 55502, 55825, 55828, 55830, 55833, 57364
71 ..... 55306, 55308, 55310
93 ..... 55133, 55134

15 CFR

740 55099
742 55099
744 55099
772 55099
774 55099
922 55956

17 CFR

1 56666
232 55264
240 55486
249 56257

20 CFR

418 55626
Proposed Rules:
620 55311
655 ..... 55977, 55985
401 57366
404 57368
416 57368

21 CFR

73 ..... 54869, 56258
101 55266
862 (2 documents) 54873, 54875

Proposed Rules:
15.....55318
50.....57378
101.....55323
112.....54888
175.....56750
176.....56750
177.....56750
178.....56750
179.....54891
312.....57378
807.....54891
812.....57378
1002.....54891
1010.....54891
1040.....54891

23 CFR

625.....54876
Proposed Rules:
630.....56758
635.....56758

25 CFR

23.....55267

26 CFR

1.....55632
54.....57336, 57592
Proposed Rules:
1 .....55324, 55646, 56763
53.....55653

29 CFR

1926.....56198
2590.....57336, 57592
4022.....57307
Proposed Rules:
Ch. I.....55329
570.....57386

31 CFR

App. A to Ch.V 55269
547.....57308
560.....55269

32 CFR

Proposed Rules:
111.....55329

33 CFR

100.....55271, 55967
117 .....55099, 55100, 55967, 55969
147.....55967
164.....55272
165 .....55101, 55282, 55284, 55488, 55967, 55969, 56258, 57318, 57319, 57321, 57322
Proposed Rules:
165.....55332, 56768

37 CFR

1.....55102
Proposed Rules:
Ch. III.....55334
201.....57386

38 CFR

4.....54881

40 CFR

51.....56713, 57324
52 .....56734, 56736, 57324
55.....56259
60.....56713
63.....56713
180 .....55491, 55970, 56262, 57333
282.....55286
Proposed Rules:
49.....55994
52 .....55335, 55338, 55656, 55994, 56002, 56770, 56773, 56775, 56777, 56781
60.....56015, 57387
81.....56781
86.....55837
282.....55340
355.....56791
721.....57634
770.....54892

42 CFR

409.....56406
413.....56922
414.....56922
424.....56406
484.....56406
486.....56406
488.....56406
Proposed Rules:
10.....55135
422.....54982
423.....54982
438.....54982, 57264
457.....57264
482.....55105
484.....55105
485.....55105
498.....54982

44 CFR

64.....56269

45 CFR

147.....57336, 57592
Proposed Rules:
155.....56015
156.....56015
1148.....55504

46 CFR

35.....55272, 56271
Proposed Rules:
10.....56272

47 CFR

20.....55106
Proposed Rules:
1.....56031
73.....56031, 56038

48 CFR

509.....56739
Proposed Rules:
16.....54901
52.....54901
501.....55838
536.....55838
552.....55838

49 CFR

171.....55792
172.....55792
173.....55792
176.....55792
178.....55792
180.....55792
Proposed Rules:
192.....57388

50 CFR

218.....57076
300.....55636
622 .....55107, 55292, 55293, 55975, 57339
635 .....55108, 55638, 57340
648.....55640
665.....55641
679 .....54881, 55109, 55641, 55823, 56740, 57341
Proposed Rules:
17.....55341
253.....55137
600.....56039
622.....55850, 56039
648 .....54903, 55665, 57389, 57395
697.....56039

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 7, 2018

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