DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).*]

Issued: December 12, 2024

Posted: December 17, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-11 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding the provision of free meningococcal vaccinations to eligible patients prescribed one of two drugs manufactured by Requestor (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts

described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor, a pharmaceutical manufacturer, manufactures [redacted] and [redacted] (the "Products"). The U.S. Food and Drug Administration ("FDA") has approved each of the Products for the treatment of several different rare disorders. The Products are administered by health care professionals via intravenous infusion. Both Products carry a black box warning, which cautions of the risk of serious and life-threatening meningococcal infections in patients treated with the Products. According to Requestor, patients taking one of the Products are at 1,000 to 2,000 times greater risk of contracting meningococcal disease, as compared to otherwise healthy people living in the United States. To address this risk, the FDA-approved literature (i.e., the Products' labels, the Medication Guides distributed with the Products, and the Risk Evaluation and Mitigation Strategy ("REMS") Patient Safety Information Card for each of the Products) directs health care professionals to complete or update meningococcal vaccination at least 2 weeks prior to administering the first dose of one of the Products, unless the risks of delaying therapy outweigh the risks of developing a meningococcal infection. The Products' prescribing information states that patients who initiate treatment with one of the Products less than 2 weeks after receiving a meningococcal vaccination also should be prescribed prophylactic antibiotics.

Requestor certified that each of the Products is subject to a REMS with Elements to Assure Safe Use ("ETASU") to manage the elevated risk of meningococcal infections associated with using the Products. Under the REMS program, prescribers of the Products must be certified to prescribe and dispensers must be certified to dispense each Product.[2] In addition, prescribers must, among other requirements, counsel patients about the risk of meningococcal infection and the need for vaccination, provide patients with REMS-required educational materials, and assess patients' meningococcal vaccine status.

The U.S. Centers for Disease Control and Prevention Advisory Committee on Immunization Practices ("ACIP") recommends that patients undergoing treatment with the Products should be vaccinated against meningococcal serogroups A, B, C, W, and Y. In order to be vaccinated against all serogroups, a patient would need to receive either a pentavalent vaccine covering all

[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] The certification process requires prescribers and dispensers to review educational materials about the Products and enroll in the REMS program for the Products.

five serogroups—at present there is one such FDA-approved vaccine—or a combination of vaccines covering a subset of the serogroups. Currently there are two vaccines approved for serogroup A, C, W, and Y, and two separate vaccines approved for serogroup B, as well as the pentavalent vaccine mentioned above. Each vaccine requires a two- or three-dose course to complete the primary series.

According to Requestor, since the Products were approved, the FDA has expressed concern that the REMS programs are insufficient to ensure patients receive the recommended vaccinations, and the FDA has urged Requestor to update and improve its REMS programs.[3] Although meningococcal vaccinations typically are covered by commercial insurance and Federal health care programs,[4] Requestor certified that many patients prescribed one of the Products experience practical and logistical barriers to accessing the vaccines before beginning therapy with one of the Products. Patients may face challenges accessing meningococcal vaccinations from their treating physicians, primary care physicians, and pharmacies.

With respect to barriers at the prescribing physician level, prescribers treating patients for certain of the Products' indications may practice in a specialty that generally has less familiarity with meningococcal vaccines and may be less likely to stock the vaccines in their clinics. For example, some patients prescribed the Products may be treated by neurologists who, according to Requestor, are unlikely to be familiar with meningococcal vaccines. In addition, because any given neurologist is unlikely to treat a significant number of patients taking the Products, neurologists may be reluctant to purchase and stock meningococcal vaccines, which typically are sold in multipacks that could go to waste if unused. Therefore, patients prescribed the Products who are treated by neurologists may face challenges accessing meningococcal vaccines from their prescribers. By contrast, other patients prescribed the Products may be treated by hematologists, hemato-oncologists, and nephrologists—specialists who, according to Requestor, likely have more extensive training in internal medicine and, by extension, in infectious diseases. Those patients may be more likely to be able to access meningococcal vaccines from their prescribers. A patient unable to receive vaccinations from their treating physicians could visit a primary care physician—if the patient has one—although this presents an additional logistical obstacle to receiving the recommended vaccinations.

Another barrier identified by Requestor exists at the pharmacy level, where pharmacies may be unwilling to administer meningococcal vaccines to individuals who fall outside the vaccines' FDA-approved age ranges. Although the FDA-approved prescribing information and REMS for

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[3] In 2024, Requestor developed a revised REMS program that builds on requirements of the existing REMS programs and aims to improve patient safety through additional requirements focused on education about the risk for meningococcal infections and addressing FDA-identified gaps in vaccine data collection. According to Requestor, the updated REMS does not facilitate patient access to the vaccinations themselves.

[4] As of January 1, 2023, pursuant to the Inflation Reduction Act, Medicare Part D enrollees are exempt from out-of-pocket costs relating to ACIP-recommended vaccines for adults (including meningococcal vaccines). Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11401, 11405, 136 Stat. 1818, 1896-98, 1900-01 (2022).

each Product recommends that all patients receive meningococcal vaccines before being treated with one of the Products, the FDA-approved prescribing information for the vaccines themselves dictates a limited approved age range for the vaccines.[5] Accordingly, some patients may not be able to receive the vaccines from pharmacies unwilling to administer the vaccine outside the indicated age range for the vaccines.

Given these barriers, Requestor has implemented the Arrangement as part of its efforts to facilitate compliance with the Products' REMS program by removing barriers to vaccination of patients prescribed one of the Products. Under the Arrangement, Requestor offers free meningococcal vaccinations to patients who: (i) have been prescribed one of the Products for an on-label indication; (ii) enroll in Requestor's patient support program; and (iii) have a prescription for a meningococcal vaccine (or vaccines). There are no financial eligibility requirements for the Arrangement. Requestor certified that the Arrangement is available to patients regardless of their selection of prescriber (as long as the prescriber enrolls in the REMS).

After a patient enrolls in Requestor's patient support program, Requestor contacts the patient, via a case manager, to discuss options for vaccination (i.e., vaccination by the prescriber, the patient's primary care physician, a retail pharmacy, or potentially through the Arrangement (if the patient is eligible for the Arrangement)). The case manager assesses the most expeditious way for the patient to be vaccinated. If the Arrangement is the most expeditious way for the patient to be vaccinated and the case manager has confirmed patient eligibility, Requestor then arranges for the patient's vaccination through one of two methods: (i) via a third-party vendor with which Requestor contracts for this purpose (the "Vendor"); or (ii) by shipping the appropriate vaccines directly to the patient's prescriber or other health care professional who will administer the vaccinations.

Under the Arrangement, Requestor covers the full cost of the vaccines and vaccine administration conducted by the Vendor. Requestor's contract with the Vendor prohibits the Vendor from billing Federal health care programs or any other payor for the vaccinations administered pursuant to the Arrangement, including the costs of the vaccines and the costs of administration. According to Requestor, in most cases the prescriber ordering one of the Products is not the same provider who administers the vaccines. In cases where a patient receives vaccinations under the Arrangement from their treating physician or another health care professional, Requestor ships the appropriate vaccines to the physician or health care professional (at no cost to them) and does not pay the physician or health care professional an administration fee or any other payment associated with providing the vaccinations. In that circumstance, a physician or health care professional must attest that they will not bill any payor, including any Federal health care program, for the cost of the vaccines they receive. Those

[5] The one FDA-approved pentavalent vaccine is indicated for individuals 10 through 25 years of age. Of the two serogroup A, C, Y, and W vaccines, one is indicated for individuals age 2 months through 55 years, and the other is indicated for individuals age 2 years and older. The two serogroup B vaccines are approved for use in individuals 10 through 25 years of age. As a result, in order to satisfy the REMS-recommended regime of vaccination with either the pentavalent vaccine or a combination of two vaccines, a Medicare enrollee age 65 or older would need to receive at least one vaccine on an off-label basis.

providers may, however, bill payors, including Federal health care programs, an administration fee of approximately $20.

Requestor certified that it has no financial relationships related to meningococcal vaccines with any of the manufacturers of meningococcal vaccines. In addition, Requestor certified that it neither covers any patient costs for either Product in connection with the Arrangement nor provides any remuneration to the physicians who prescribe either Product in connection with the Arrangement, other than the opportunity to bill an administration fee.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[6] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[7] For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.[8] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care

[6] Section 1128B(b) of the Act.

[7] Id.

[8] E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

1. Federal Anti-Kickback Statute

Under the Arrangement, Requestor provides free meningococcal vaccinations to eligible patients, including Federal health care program enrollees, who are prescribed one of the Products. The Arrangement also offers some health care professionals the opportunity to bill an administration fee for the vaccines. At the outset, we recognize that the Arrangement has the potential to increase compliance with FDA-recommended safety protocols for patients taking the Products and to address the FDA's concerns about insufficient efforts by Requestor to ensure patients receive the recommended vaccinations. Because Medicare Part D enrollees are exempt from out-of-pocket costs relating to meningococcal vaccines, absent the Arrangement, enrollees either would receive the vaccines without cost-sharing obligations or would not receive the vaccines at all. To the extent the Arrangement enables a higher proportion of patients using the Products to receive meningococcal vaccines, the value to enrollees is the reduced likelihood of contracting serious and life-threatening meningococcal infections. By providing the vaccines for free, and in some cases facilitating administration via the Vendor, the Arrangement removes practical obstacles to patients receiving the recommended vaccinations. Accordingly, the most significant impacts of the Arrangement are to enhance compliance with FDA-recommended safety protocols for patients taking the Products and to address concerns raised by the FDA about insufficient use of meningococcal vaccines among patients taking the Products.

Nevertheless, the free vaccinations constitute remuneration under the Federal anti-kickback statute. This remuneration could induce eligible patients who are Federal health care program enrollees to purchase one of the Products or to purchase other federally reimbursable items manufactured by Requestor. Similarly, the opportunity to bill an administration fee could induce a prescriber to order one of the Products. No safe harbor applies to the Arrangement. For the combination of the following reasons, however, we believe the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, although the Arrangement could induce eligible patients who are Federal health care program enrollees to purchase one of the Products, the Arrangement is unlikely to be a significant factor in that determination. As noted above, the chief value to patients is in the form of convenience and safety rather than in the form of financial value because, even absent the Arrangement, Medicare enrollees would not incur out-of-pocket expenses related to the vaccinations. In addition, Requestor certified it does not cover any other patient costs associated with the Products in connection with the Arrangement. Accordingly, the provision of free

vaccinations is unlikely to be a significant factor inducing any patient to choose one of the Products.

Second, the Arrangement is unlikely to result in inappropriately increased costs to Federal health care programs because the vaccines are not billed to any payors, and health care professionals administering the vaccines may bill Federal health care programs only for an administration fee. To the extent those administration fees increase costs to Federal health care programs, those are costs that the government—through the FDA—has actively encouraged through its REMS with ETASU. Moreover, under the Arrangement, Federal health care programs likely incur lower costs with respect to patients prescribed the Products because Requestor provides the vaccines themselves—which otherwise would be billable to Federal health care programs—for free.

Finally, the Arrangement is unlikely to corrupt medical decision-making. The only potential remuneration flowing to a prescriber of one of the Products is in the form of the opportunity to bill a nominal administration fee, which is unlikely to persuade a prescriber to order one of the Products. Moreover, Requestor certified that, in most cases, the prescriber ordering one of the Products is not the same provider who administers the vaccine, so the prescriber ordering one of the Products would not be in a position to receive an administration fee as part of the Arrangement.

2. Beneficiary Inducements CMP

In evaluating the Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor knows or should know that the remuneration it offers to beneficiaries is likely to influence their selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. Under the Arrangement, all patients, including Federal health care program beneficiaries, are eligible to receive the free vaccinations regardless of which physician prescribed the Products, and the vaccinations are offered only after a physician has prescribed one of the Products. As such, the Arrangement does not influence Federal health care program beneficiaries to choose a particular physician for the order or receipt of one of the Products. Whether the Arrangement could influence a beneficiary to select Requestor for the order or receipt of one of the Products is moot because Requestor, a pharmaceutical manufacturer that does not own or operate, directly or indirectly, any providers or suppliers of the Product, is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP. Accordingly, because the Arrangement is not likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier, we conclude that the remuneration offered by Requestor under the Arrangement does not generate prohibited remuneration under the Beneficiary Inducements CMP.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts

described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded

only if the relevant and material facts have not been fully, completely, and accurately disclosed to OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs