MEDPAC | Medicare Payment Advisory Commission

425 I Street, NW • Suite 701
Washington, DC 20001
202-220-3700 • www.medpac.gov

Michael E. Chernew, Ph.D., Chair
Amol Navathe, M.D., Ph.D., Vice Chair
Paul B. Masi, M.P.P., Executive Director

September 6, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Attention: CMS-1807-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled: "Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments" published in the *Federal Register*, vol. 89, no. 147, pages 61596 to 62648 (July 31, 2024). We appreciate your staff's ongoing efforts to administer and improve Medicare's payment systems for physician and other health professional services (including implementing the Quality Payment Program and the Medicare Shared Savings Program), particularly given the many competing demands on the agency's staff. We hope that the comments we offer below are helpful.

Our comments address the following provisions in the proposed rule:

- Physician fee schedule update for calendar year (CY) 2025,
- Payment for skin substitutes,
- Strategies for improving global surgery payment accuracy,
- Digital mental health treatment,
- Medicare Shared Savings Program, and
- Part B drug supplying fee.

Proposed CY 2025 update to physician fee schedule conversion factor

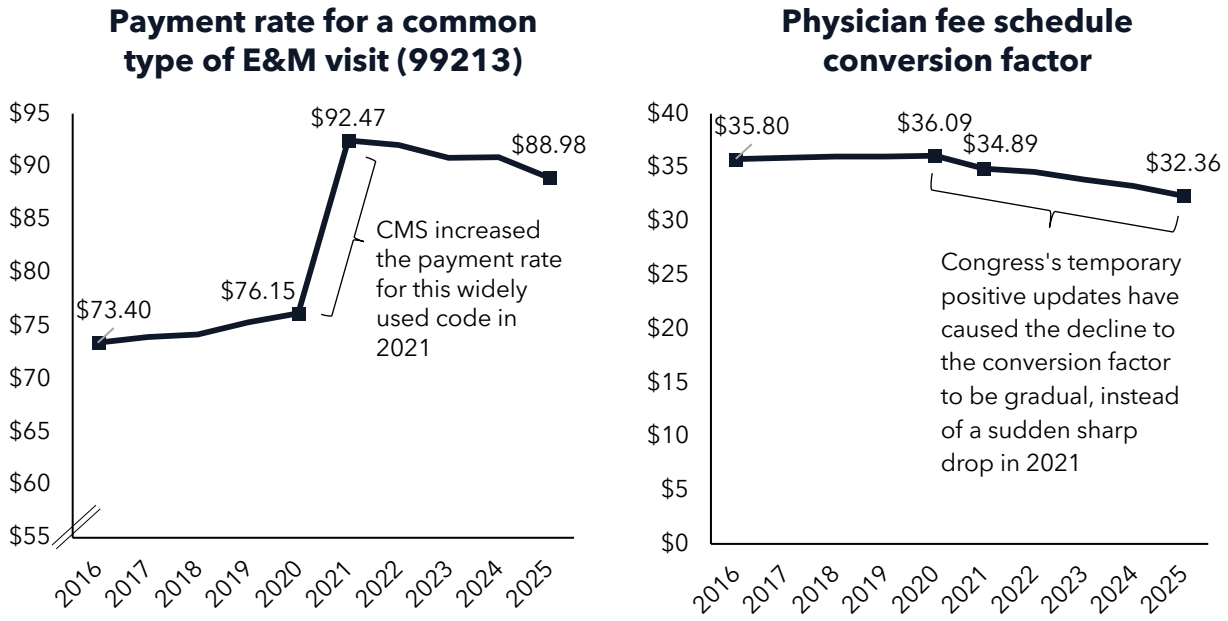
For CY 2025, CMS proposes a 2.8 percent decrease in the physician fee schedule's conversion factor, relative to the CY 2024 level. The CY 2024 conversion factor would have been lower (and the CY 2025 decrease not necessary) had the Congress not enacted a temporary increase in the conversion factor to counteract budget-neutrality reductions resulting from changes in coding and payment rates (described below). As required by statute, CMS determined the update for CY 2025 using a combination of three factors:

- A statutorily determined update of 0.0 percent for CY 2025,
- the expiration of a temporary statutory update that had increased the conversion factor for the latter part of CY 2024 by 2.93 percent,[1] and
- a budget-neutrality adjustment (which is based on fee schedule payment policies CMS has proposed) of +0.5 percent for CY 2025. [2]

In CY 2025, a reduction to the conversion factor, triggered by a policy change in 2021, will be fully phased in. In 2021, CMS increased payment rates for a widely used set of billing codes for office/outpatient evaluation and management (E&M) visits. Since changes in spending resulting from changes to the mix and value of billing codes in the fee schedule are required to be budget neutral, CMS proposed to offset changes to office/outpatient E&M codes with a large decrease to the fee schedule's conversion factor in CY 2021. Instead, due to a series of temporary positive updates enacted by the Congress in 2021, 2022, 2023, and 2024, the decline in the conversion factor has been gradually phased in over multiple years (Figure 1). The result of these combined policies (the increased payment rates for E&M visits, the budget-neutrality adjustment in 2021, and the temporary updates) is a rebalancing of payments toward E&M services (which is what was intended). Specifically, some clinicians (e.g., primary care providers) have seen meaningful increases to their total Medicare payments over the last few years. Clinicians who provide fewer E&M visits (e.g., some specialists) may have seen decreases.

[1] The 2.93 percent temporary update applied to physician fee schedule payment rates from March 9, 2024, through December 31, 2024. This update replaced a 1.25 percent temporary update that was in effect during the earlier part of CY 2024.
[2] CMS proposes to update the conversion factor for anesthesia services by 2.1 percent. The smaller reduction is due to an additional 0.7 percent increase to reflect adjustments in practice expenses and malpractice insurance for these services.

Figure 1 | CMS's increase to the payment rates for office/outpatient E&M visits in 2021 required an offsetting reduction to the conversion factor, which has been gradually phased in



Note: E&M (evaluation and management).

Comment

The Commission recognizes that CMS is required by law to implement its proposed update for CY 2025. However, in our March 2024 report to the Congress, we expressed concerns about the effects of using current law (a 0.0 percent statutory update) in the fee schedule's conversion factor in CY 2025. While our measures of payment adequacy for clinician services remain mostly stable and relatively positive, the Commission is concerned about how recent high inflation will affect those measures, especially beneficiary access to care. Continued increases in costs could be difficult for clinicians to absorb when payment rates are reduced, which could have negative effects on beneficiary access.

As such, the Commission recommended that for CY 2025 the Medicare payment rate be updated by the amount specified in current law plus 50 percent of the projected increase in the Medicare Economic Index (MEI). Based on CMS's projections of the MEI in the proposed rule, the Commission's recommended update for 2025 would be equivalent to 1.6 percent above current law. The Commission intended that this update be permanent; that is, it would be built into subsequent years' payment rates, in contrast to the temporary updates specified under current law for 2021 through 2024, which have each increased payment rates for one year only and then expired.

Payment for skin substitutes

Under the physician fee schedule (PFS), Medicare's payment rate for skin substitutes is generally the average sales price (ASP) + 6 percent. If manufacturers do not report ASP data to CMS, then payment is based either on the wholesale acquisition cost (WAC) or invoices.[3] By contrast, under the outpatient prospective payment system (OPPS), Medicare's payment for skin substitutes that do not qualify for pass-through status are packaged into the payment for the associated service (i.e., treatment of a wound). In CY 2024, the OPPS packages wound care, including supplies such as skin substitutes, into two groups: (1) "high-cost skin substitute products," and (2) "low-cost skin substitute products."[4] This payment policy is also used in the ambulatory surgical center payment system.

Over several rulemaking cycles, CMS has considered whether and how to incorporate skin substitutes (biological and synthetic skin substitutes) as supplies under the PFS rate-setting methodology.[5]

- In the CY 2023 PFS rulemaking, the agency proposed but did not finalize a policy to treat skin substitutes as incident-to supplies when furnished in nonfacility settings and to include the costs of these products as resource inputs in establishing practice expense (PE) relative value units (RVUs) for associated clinician services effective January 1, 2024.[6]
- In the CY 2024 PFS rulemaking, CMS solicited comments about approaches to identify and establish direct cost inputs for the skin substitute products to establish PE RVUs.
- In the CY 2025 proposed rule, CMS does not propose any changes to how Medicare pays for skin substitutes but reports that the agency continues to examine ways to treat skin substitute products as incident-to supplies under the PFS rate-setting methodology.

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[3] Office of Inspector General. 2023. *Some skin substitute manufacturers did not comply with new ASP reporting requirements.* OEI-BL-23-00010. Washington, DC: OIG.
[4] In CY 2024, CMS assigns new skin substitute HCPCS codes into the "low-cost skin substitute products" group unless the agency's OPPS pricing data show the cost of the product is above either the mean unit cost of $47 or the per day cost for CY 2024 of $807. (Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2024. *CMS Manual System. Transmittal 12439*. Baltimore MD: CMS.)
[5] Skin substitutes are typically divided into two main classes, biological and synthetic substitutes. CMS generally considered skin substitute products to be biologicals in the initial implementation of the ASP methodology. However, with the introduction of synthetic skin substitute products, the agency began reviewing their categorization of these products, starting with the proposed rule for CY 2023.
[6] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare and Medicaid Programs; CY 2023 payment policies under the physician fee schedule and other changes to Part B Payment policies; Medicare Shared Savings Program requirements; Medicare and Medicaid provider enrollment policies, including for skilled nursing facilities; conditions of payment for suppliers of durable Medicaid equipment, prosthetics, orthotics, and supplies (DMEPOS); and implementing requirements for manufacturers of certain single-dose container or single-use package drugs to provide refunds with respect to discarded amounts. Proposed rule. *Federal Register* 87, no. 145 (July 29): 45860–46834.

Comment

We encourage CMS to continue to explore reforming Medicare's payment for skin substitutes. According to the Commission's analysis, total spending on separately payable skin substitutes billed by physicians has grown rapidly. Between 2021 and 2022, Medicare spending on skin substitutes grew by 52 percent, from $1.0 billion to $1.6 billion. Medicare spending grew even more rapidly in 2023 to $4.4 billion, a 175 percent increase from the prior year. In 2023, Medicare spending on one skin substitute product (Dual Layer Impax Membrane) exceeded $1.4 billion (with annual spending per beneficiary of $279,000), making it among the top 10 highest expenditure Part B drugs in 2023. In terms of Part B drug spending by therapeutic class, the skin substitute class increased in rank by total Medicare spending from 10th in 2021 to 7th in 2022 to 3rd in 2023. This increase in Part B drug spending is particularly notable given CMS's observation that there has been an increase in Healthcare Common Procedure Coding System (HCPCS) Level II coding request applications for newly developed skin substitute products. While spending growth is a concern, we also acknowledge the importance of beneficiary access to services that improve outcomes. However, according to a draft local coverage determination proposed by CMS's Medicare administrative contractors (MACs), there is a need for better evidence about the outcomes associated with some skin substitute treatment.[7] The Secretary should continue to: (1) monitor the substantial growth in spending on skin substitutes, (2) explore opportunities to reform the payment method that ensures both patient access to services that improve care and provider efficiency, and (3) ensure that the use of such products is "reasonable and necessary for diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member" for the individual patient (per Section 1862(a)(1)(A) of the Social Security Act).

Strategies for improving global surgery payment accuracy

For many procedures, CMS uses global surgical codes that pay a bundled rate to clinicians for performing the procedure and associated preoperative care and postoperative care furnished during the 10- or 90-day period following the procedure. When beneficiaries receive an associated preoperative or postoperative service from a practitioner who does not work in the same practice as the proceduralist who furnished the beneficiary's surgical procedure, the external clinician is eligible to receive a portion of the global payment. To be eligible for a portion of the global payment, the nonperforming clinician must have a formal transfer-of-care agreement with the clinician who performed the procedure, and modifiers must be included on claims to indicate that such an arrangement exists. These modifiers are intended to ensure that the proceduralist and the external practitioner each receive an appropriate share of the payment associated with the global

[7] Due to MACs' inability to find sufficient literature showing the effects of these products on beneficiaries' health outcomes, the contractors have proposed (via local coverage determinations) that Medicare not cover a subset of skin substitute products, including some of the highest expenditure products in 2023. (Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2024. Proposed LCD: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL39828). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39827&ver=4.)

surgical code. In cases where transfer-of-care modifiers are not used, the proceduralist and external clinicians essentially both receive payment for the same service.

Since CMS reports that the transfer-of-care modifiers are "rarely" used, the agency proposes to make these modifiers easier to use. For 90-day global codes, CMS proposes to drop the requirement that the clinician who did not perform the procedure obtain a formal transfer-of-care agreement to bill for a portion of the global payment. The agency states that claims for follow-up care furnished by clinicians who did not perform the procedure should still include the appropriate modifiers, but CMS proposes that for 90-day codes these modifiers can be submitted without the existence of a formal transfer-of-care arrangement. CMS asks for comment on whether to also apply this policy to 10-day global codes.

CMS also proposes an add-on HCPCS code for postoperative office/outpatient E&M visits furnished by a practitioner who is not the proceduralist who performed the surgical procedure (or in the same group practice), and who does not have the same specialty as that proceduralist. (CMS mentions that these external practitioners are sometimes primary care providers, for example.) The add-on code would be billable when there is no transfer-of-care arrangement between the proceduralist and the external practitioner. The add-on code would pay for the extra time and resources involved in these postoperative visits, including obtaining and reviewing the patient's surgical notes and surgical history, researching the postoperative course of a surgical procedure, and asking the proceduralist questions if needed. CMS assumes this extra effort will add 5.5 minutes to E&M visits and values this add-on code at 0.16 RVUs (worth about $5). The add-on code would be billable once per 90-day global period since CMS assumes this extra effort would only be needed at the first postoperative visit. The add-on code would not be available for postoperative visits provided during 10-day global periods.

CMS also seeks input on improving the accuracy of the shares of global code payments that constitute preoperative care, the surgical procedure, and postoperative care.

Comment

Given the current global payment policy, the Commission supports CMS's attention to improving the accuracy of payments for surgical procedures and related care. At the same time, however, the Commission views current payment policies for global surgical codes as being inherently problematic. CMS already has robust evidence that Medicare is overpaying for postoperative visits: According to a report prepared for CMS by RAND using Medicare claims data, on average only 47 percent of postoperative visits assumed in

90-day global surgical codes are actually provided, and only 17 percent of postoperative visits assumed in 10-day global surgical codes are provided.[8,9]

Given this evidence, the Commission has asserted that CMS should move away from the use of 10- and 90-day surgical global codes. In four prior comment letters, the Commission has supported using 0-day surgical global codes instead; we reiterate our support for that policy here.[10] Under 0-day global codes, proceduralists would receive a lump sum payment for all services provided on the day of a procedure, including preoperative and postoperative care provided that day as well as the procedure itself; visits on other days would be billed separately using E&M visit codes. In 2014, CMS attempted to act on this issue by proposing to replace 10- and 90-day global codes with 0-day codes that would pay for each service separately.[11] However, the Medicare Access and CHIP Reauthorization Act of 2015 prohibited the agency from implementing that year's proposal (P.L. 114-10, sec 523). Instead, the law required CMS to collect additional information about postoperative visits, which could be used to improve the accuracy of global payments.

We previously suggested that CMS could shift to 0-day global codes by estimating work RVUs for postoperative visits and subtracting them from global codes' total work RVU values, but some stakeholders have argued that this action would result in inappropriate work RVU values for some procedures, with nearly half of minor and major surgical procedures having work RVUs that reflect a low intensity.[12] Given this concern, an alternative approach would be for CMS to ask the RVS Update Committee (RUC) to propose new values for 0-day global codes in tranches—for example, prioritizing those 10- and 90-day codes that generate the largest amount of spending and/or are billed most frequently.

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[8] Crespin, D. J., A. M. Kranz, T. Ruder, et al. 2021. *Claims-based reporting of post-operative visits for procedures with 10- or 90-day global periods: Updated results using calendar year 2019 data.* Santa Monica, CA: RAND Corporation. https://www.cms.gov/ files/document/rand-cy-2019-claims-report-2021.pdf.

[9] We report results of a sensitivity analysis by RAND that was restricted to the subset of clinicians who billed for any postoperative visits during 90-day global periods. We report these results, rather than RAND's main results, because some specialty societies contend that the reason some clinicians did not bill for any postoperative visits was that their billing system did not allow them to submit the 99024 no-pay billing code that was used by RAND to identify postoperative visits. However, we caution that it is also possible that some clinicians did not report any postoperative visits because they did not provide any. The results we report should therefore be interpreted as conservative and possibly overrepresenting how many postoperative visits were provided.

[10] Medicare Payment Advisory Commission. 2014. MedPAC comment letter on CMS's proposed rule for the CY 2015 physician fee schedule. August 24. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08282014_comment_letter_2015_pt_b_rule_final.pdf.
Medicare Payment Advisory Commission. 2018. MedPAC comment letter on CMS's proposed rule for the CY 2019 physician fee schedule. September 4. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09042018_macra_feeschedule_1693p_medpac_comment_v2_sec.pdf.
Medicare Payment Advisory Commission. 2019. MedPAC comment letter on CMS's proposed rule for the CY 2020 physician fee schedule. September 13. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09132019_cms_1715p_physician_medpac_comment_v2_sec.pdf.
Medicare Payment Advisory Commission. 2023. MedPAC comment letter on CMS's proposed rule for the CY 2024 physician fee schedule. September 11. https://www.medpac.gov/wp-content/uploads/2023/09/09112023_MedPAC_Physician_Comment_v2_SEC.pdf.

[11] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Medicare program; revisions to payment policies under the physician fee schedule, clinical laboratory fee schedule, access to identifiable data for the Center for Medicare and Medicaid Innovation Models & other revisions to Part B for CY 2015. *Federal Register* 79, no. 219 (November 13): 67548–68010.

[12] American Medical Association. 2015. Letter to Sean Cavanaugh re: response to the Centers for Medicare and Medicaid Services (CMS) concerning the transition from surgical global periods to 000-day global period. March 3. https://www.ama-assn.org/ system/files/2019-12/ruc-recommendation-for-surgical-globalunbundling-policy.pdf.

(About 300 global codes account for 94 percent of spending on 10-day global codes and 72 percent of spending on 90-day global codes.[13])

Digital mental health treatment

CMS proposes new billing codes for digital mental health treatment (DMHT) in CY 2025, including a code that would pay practitioners for furnishing Food and Drug Administration (FDA)–cleared DMHT devices: HCPCS code GMBT1 (supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan). GMBT1 would be payable only if the device has been FDA-cleared under 21 CFR 882.5801 and the billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary.[14] Furnishing of the DMHT device must be incident to the billing practitioner's professional services in association with ongoing treatment under a plan of care by the billing practitioner, and the patient could use the DMHT device at home or perhaps in an office or other outpatient setting. CMS also proposes two additional codes (GMBT2 and GMBT3) that would pay clinicians to monitor use of a DMHT device and support a treatment plan related to use of the device.

Comment

The Commission is in the initial stages of considering how Medicare should pay for medical software.[15] However, we have long maintained that the goal of Medicare payment is to obtain good value for the program's expenditures, which means maintaining beneficiaries' access to high-quality services while encouraging efficient use of resources. With respect to new and innovative services, the Commission has said that Medicare should establish payment in a way that (1) promotes access to new technologies that meaningfully improve the diagnosis or treatment of beneficiaries, (2) ensures technologies' affordability for beneficiaries and taxpayers, and (3) creates incentives for the development of new technologies that lead to substantial clinical improvement (as opposed to incentives for developing technologies that have only marginal benefits).

Paying for a new software technology under its own billing code could lead to overuse of such technology and may have significant fiscal implications for Medicare, particularly as the FDA clears or approves more and more such technologies over time. According to CMS,

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[13] Crespin, D. J., A. M. Kranz, T. Ruder, et al. 2021. *Claims-based reporting of post-operative visits for procedures with 10- or 90-day global periods: Updated results using calendar year 2019 data.* Santa Monica, CA: RAND Corporation. https://www.cms.gov/ files/document/rand-cy-2019-claims-report-2021.pdf.

[14] According to 21 CFR 882.5801: A computerized behavioral therapy device for psychiatric disorders is a prescription-only device intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician-supervised outpatient treatment to patients with psychiatric conditions. The digital therapy is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes.

[15] Medicare Payment Advisory Commission. 2024. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

"the number of FDA approved or cleared 'machine learning' or 'AI' clinical software programs has rapidly increased in the past few years".[16]

We therefore encourage the agency to look for opportunities to include software services as part of larger payment bundles. Providers make decisions about the use of software in many aspects of their operations, and they optimize these decisions given their own circumstances and the existing technologies and contractual relationships already in place. In such complex situations, bundled payment, rather than separate payment for specific software products, creates more desirable incentives, encouraging providers to choose technologies based on what is most effective in their own operations and not creating or distorting financial incentives for items that may not be optimal in terms of efficacy or efficiency.

If CMS elects to pay for digital mental health treatment using non-bundled codes such as GMBT1, the agency should ensure that, per Medicare's statute, such services are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Some have raised concerns about whether prescription digital therapeutics (PDTs) improve health outcomes. In a cross-sectional analysis of clinical studies of FDA-authorized PDTs (as of November 29, 2022), Kumar and colleagues found important limitations in the rigor of evidence. For example, 40 percent of prescription PDTs had clinical studies that were not blinded, and the clinical studies frequently excluded older adults and people not proficient in English.[17]

CMS seeks comment as to whether payment should be made if the practitioner furnishes a digital device that has not been cleared by the FDA for mental health treatment for a specific use, even if the digital device has been cleared by the FDA for another specific use. The agency could consider giving the Parts A/B Medicare administrative contractors (MACs) the discretion to cover use of digital devices for purposes other than what has been approved by the FDA (i.e., "off-label use") if the A/B MAC determines the use to be medically accepted. Such an approach would be similar to MACs' ability to cover non-cancer drugs for off-label indications.

Medicare Shared Savings Program

Shared savings and losses for accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP) are determined by comparing per capita Part A and Part B expenditures of beneficiaries assigned to an ACO with the ACO's financial benchmark. CMS estimates a benchmark for each ACO in each agreement period, and ACOs whose beneficiaries spend sufficiently below the benchmark share in a portion of savings. ACOs may also share in losses depending on the program track the ACO selected. CMS has

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[16] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program: hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; organ acquisition; rural emergency hospitals: payment policies, conditions of participation, provider enrollment, physician self referral; new service category for hospital outpatient department prior authorization process; overall hospital quality star rating; COVID–19. Final rule with comment period; final rules. *Federal Register* 87, no. 225 (November 23): 71748–72310.
[17] Kumar, A., J. S. Ross, N. A. Patel, et al. 2023. Studies of prescription digital therapeutics often lack rigor and inclusivity. Health Affairs 42, no. 11 (November): 1559-1567.

adjusted the method for calculating the financial benchmark over the years to address concerns about unequal benchmarks for ACOs in the same market, encourage ACOs that have decreased spending to remain in the program (otherwise these ACOs might see their benchmarks continually fall—the "rachet effect"), and encourage participation by ACOs that have higher baseline spending (and thus more potential to save). Current program guidelines calculate the benchmark as a blend of the ACO's historical spending and the fee-for-service (FFS) spending for all assignable beneficiaries (i.e., those with at least one qualifying primary care visit) in an ACO's region (including the spending of the ACO's assigned population). Recently, CMS implemented benchmark policies to mitigate the impact of the negative regional adjustment, cap the risk score growth in the regional trend calculation, and add a prior-savings adjustment (ACOs can receive the higher of the regional adjustment or the prior-savings adjustment).

CMS seeks input on strategies to improve the ENHANCED track (the track with the greatest risk and reward in which 43 percent of ACOs now participate).[18] CMS contemplates policy changes such as 100 percent savings/loss rates and eliminating the minimum savings/loss rates while recognizing the need to prevent increased program spending. Thus, CMS considers reduction or removal of the regional adjustment to the benchmark, especially given the prior-savings adjustment and CMS's proposal to add an equity adjustment to the benchmark.

Comment

As we have noted in prior years, including both the prior-savings adjustment and the regional adjustment maintains undesirable participation incentives and distorts the calculation of the prior-savings adjustment.[19,20] We urge CMS to phase out the regional adjustment to an ACO's benchmark baseline expenditures. The regional adjustment has coincided with ACOs selectively including physician practices to participate in the ACO and contributes to higher benchmarks without necessarily demonstrating efficiency gains during an ACO's MSSP participation. According to CMS, among participating ACOs in 2024, 85 percent received a positive regional adjustment to their benchmarks (including 95 percent of ACOs in the ENHANCED track). We are increasingly concerned that risk adjustment does not adequately account for an ACO's regional efficiency. For example, the Commission recently examined the FFS spending of beneficiaries who later enrolled in a

[18] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2024. Shared Savings Program Fast Facts – As of January 1, 2024. https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf
[19] Medicare Payment Advisory Commission. 2022. Comment letter on the Centers for Medicare & Medicaid Services' (CMS's) 2023 payment policies under the physician fee schedule and other changes to Part B payment policies; Medicare Shared Savings Program requirements; Medicare and Medicaid provider enrollment policies, including for skilled nursing facilities; conditions of payment for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and implementing requirements for manufacturers of certain single-dose container or single-use package drugs to provide refunds with respect to discarded amounts. September 2. https://www.medpac.gov/wpcontent/uploads/2022/09/09022022_Part_B_2023_CMS1770P_MedPAC_COMMENT_v2_SEC.pdf 2023 and 2024 medpac letters
[20] Medicare Payment Advisory Commission. 2023. Comment letter on the Centers for Medicare & Medicaid Services' (CMS's) CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. September 11. https://www.medpac.gov/wp-content/uploads/2023/09/09112023_MedPAC_Physician_Comment_v2_SEC.pdf

Medicare Advantage (MA) plan.[21] We found that beneficiaries who were favorable relative to their regional risk-standardized spending average remained favorable for the entire duration of their FFS enrollment—even if their continuous FFS enrollment spanned more than a decade. ACOs can create this favorable bias in regional benchmarks by being particularly selective about identifying physician practices that serve assignable beneficiaries with low risk-adjusted spending.

As an alternative, CMS should consider eliminating the regional adjustment to benchmarks entirely (not just for the ENHANCED track)—including any involvement in the prior-savings adjustment calculation—and scaling up the prior-savings factor (currently 50 percent for ACOs) based on an ACO's regional efficiency (i.e., baseline expenditures relative to the average baseline expenditures in the ACO's region). For example, an ACO that would have qualified for a 2 percent positive regional adjustment could receive a 60 percent factor to its prior-savings adjustment, while an ACO that would have qualified for a 5 percent positive regional adjustment could receive a 75 percent factor to its prior-savings adjustment. In this way, both inflation to benchmarks and ratchet effects would be mitigated because the regional adjustment would be removed from both the performance-year benchmarks and the prior-savings adjustment. At the same time, CMS could provide incentives for current ACO participants to remain in the program by scaling up the shared savings rates based on regional "efficiency" and assuring protection from shared losses up to an amount equivalent to the current regional adjustment calculation.

Part B drug supplying fee

CMS proposes how Medicare Part B will pay for drugs covered as additional preventive services (DCAPS) under Section 1833 of the Social Security Act. CMS has not yet paid for a drug as a preventive service under this authority, but it has issued a proposed national coverage determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus. CMS proposes to pay for DCAPS according to the standard average sales price (ASP) methodology it uses to pay for other Part B drugs under Section 1847A of the Social Security (and under an alternative approach if ASP data are not available). With respect to DCAPS that are furnished by pharmacies, the agency proposes to pay the same supplying fee that Medicare pays for certain other Part B–covered pharmacy supplied drugs (i.e., certain oral anticancer, antiemetic, and immunosuppressive drugs).

Comment

The Commission supports ensuring beneficiary access to preventive services that offer significant benefit to beneficiaries' health. With respect to CMS's proposal to pay the Part B drug supplying fee for DCAPS, we note that in 2016 the Commission recommended that the Part B supplying fees (for Part B oral drugs) and dispensing fees (for Part B inhalation drugs) be reduced to rates similar to other payers.[22] We find that Medicare pays

[21] Medicare Payment Advisory Commission. 2024. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[22] Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

substantially higher supplying fees than other payers, and we urge the agency to revisit its Part B drug supplying and dispensing fee rates and reduce them to levels similar to other payers.

The Part B supplying fee is $24 for the first prescription and $16 for each subsequent prescription in a 30-day period, with a higher amount for the first immunosuppressive prescription ever. The inhalation drug dispensing fee is $33 per 30-day supply of drugs, with higher fees for 90-day supplies and for the first supply a beneficiary receives. These supplying and dispensing fee rates have been in effect since 2006; were set by CMS based on limited data; and exceed those of other federal programs, such as Medicare Part D and Medicaid. A 2014 OIG report found that in 2011, Medicare Part D plans paid an average dispensing fee of about $4.60 for inhalation drugs and about $1.80 for immunosuppressive, oral anticancer, and oral antiemetic drugs; Medicaid paid about $4.60 per prescription across these different types of drugs.[23] More recent data suggest the Part B supplying and dispensing fees continue to be above fees paid by other federal programs. For example, in 2022, we estimate the average Part D dispensing fee for inhalation drugs was about $4 and for oral drugs was $1; typical Medicaid retail pharmacy dispensing fee rates for most states ranged from $10 to $12 as of the third quarter 2022.[24].

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please contact Paul B. Masi, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair

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[23] Office of Inspector General, Department of Health and Human Services. 2014. *Medicare Part B prescription drug dispensing and supplying fee payment rates are considerably higher than the rates paid by other government programs*. A-06-12-00038. Washington, DC: OIG.

[24] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicaid covered outpatient prescription drug reimbursement information by state quarter ending September 2022. https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/medicaid-covered-outpatient-prescription-drug-reimbursement-information-state/index.html.