MEDPAC | Medicare Payment Advisory Commission

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September 11, 2025

Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Attention: CMS-1832-P

Dear Dr. Oz:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled: "Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Coverage and Payment Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program" published in the *Federal Register,* vol. 90, no 134, pages 32352 to 33261 (July 16, 2025). We appreciate your staff's ongoing efforts to administer and improve Medicare's payment systems for physician and other health professional services (including the Quality Payment Program and Medicare Shared Savings Program), particularly given the many competing demands on the agency's staff.

Our comments address the following provisions in the proposed rule:

- Physician fee schedule update for calendar year (CY) 2026
- Development of strategies for updates to practice expense data collection and methodology
- Updates to practice expense methodology—site of service payment differential
- Use of outpatient prospective payment system (OPPS) data for rate setting
- Payment for services in urgent care centers
- Efficiency adjustment
- Comment solicitation on payment policy for software as a service
- Payment for skin substitutes
- Strategies for improving global surgery payment accuracy
- Rural health clinics and federally qualified health centers
- Part B drugs' average sales price.

Physician fee schedule update for CY 2026

As required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), starting in CY 2026, the physician fee schedule (PFS) will employ two conversion factors, depending on each clinician's participation in advanced alternative payment models (A–APMs). For CY 2026, CMS proposes that the PFS's conversion factor for CY 2025 be increased by a total of 3.8 percent for services furnished by qualifying A–APM participants, and by 3.3 percent for services furnished by all other clinicians. As required by statute, CMS determined the conversion factor updates for CY 2026 using a combination of three factors:

- statutorily determined updates of 0.75 percent for qualifying A–APM participants and 0.25 percent for all other clinicians,
- a statutorily determined one year update of 2.5 percent, applied to both conversion factors during CY 2026, and
- a budget-neutrality adjustment (which is based on proposed PFS payment policies) of 0.55 percent.

Comment

The proposed updates for CY 2026 align with the Commission's recommendation to update PFS payments by amounts greater than the 0.25 percent and 0.75 percent originally specified in MACRA. [1] While our measures of PFS payment adequacy remain mostly stable and relatively positive, the Commission is concerned about how recent high inflation will affect those measures, especially beneficiary access to care.

The Commission's recommended approach for updating payment rates in CY 2026 would have provided more targeted support for clinicians who treat low-income patients and would have replaced the differential updates with a single update.

Specifically, the Commission recommended that the Congress replace the two current-law updates with a single update equal to the Medicare Economic Index (MEI) (a measure of the growth in clinicians' input costs) minus 1 percentage point. Based on CMS's projections of the MEI in the proposed rule, the Commission's recommended update for 2026 would have raised 2025 payment rates by 1.7 percent. In contrast to recent temporary updates that only applied to a single year and then expired, the Commission recommended that this update be permanent and built into subsequent years' payment rates. The single update reflects the Commission's belief that incentivizing A–APM participation through differential payment-rate updates (such as 0.75 percent for A–APM participants and 0.25 percent for nonparticipants) is a flawed approach. Yet, the Commission believes that A–APMs continue to show promise. Policymakers thus may choose to include some form of a bonus as an important component of payment for

[1] Medicare Payment Advisory Commission. 2025. "Physician and other health professional services," in *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch4_MedPAC_Report_To_Congress_SEC-1.pdf.

clinician services as they seek policy changes to improve A–APM design and performance.

The Commission also recommended that the Congress establish new, permanent safety-net add-on payments for clinician services furnished to fee-for-service (FFS) Medicare beneficiaries with low incomes. We estimated that these add-on payments would increase the average clinician's fee schedule revenue by an additional 1.7 percent. The Commission determined that providing this additional financial support is warranted because clinicians often receive less revenue for treating low-income beneficiaries because of how Medicare's cost-sharing policies interact with state Medicaid payment policies. Yet the cost to clinicians of treating Medicare beneficiaries with low incomes is likely to be at least as much as, if not higher than, the cost of caring for other beneficiaries. As a result of less revenue and potentially higher treatment costs, these beneficiaries are likely to be less profitable to care for and therefore could have difficulty accessing care.

Development of strategies for updates to practice expense data collection and methodology

CMS currently relies on the American Medical Association's (AMA's) 2006 Physician Practice Information (PPI) survey for two high-level purposes: (1) to determine specialty-specific practice expense per hour to help calculate indirect practice expense (PE) RVUs and (2) to determine the overall share of relative value units (RVUs) allocated to work, practice expenses, and malpractice expense. In early 2025, the AMA released results from an updated PPI survey it fielded from 2022 to 2023.

In the proposed rule, CMS evaluates the new AMA PPI survey results to determine the appropriateness of incorporating them into the rate-setting process. CMS expresses several concerns about the new survey, including:

- low response rate and lack of representativeness,
- small sample size and sampling variation,
- lack of comparability to previous survey data,
- potential measurement error, and
- missing or incomplete data.

Given these concerns, CMS proposes not to use the new survey results to update indirect PE RVUs or to determine overall cost shares. Instead, the agency proposes taking more time to examine the survey results submitted by the AMA and consider alternatives to the survey data, such as Medicare claims data, hospital cost reports, and other data.

Comment

The Commission supports CMS's decision not to incorporate the AMA's new PPI survey results into the 2026 rate-setting process. In the Commission's June 2025 report to the Congress, we similarly highlighted some concerns we had regarding the AMA's most

recent survey, such as low response rates and results for some specialties being based on a small number of respondents (who may have volunteered to report their data rather than being part of a statically selected sample).[2]

While the Commission supports not incorporating the new survey data in 2026, the result of that decision is that the PE RVU methodology for 2026 substantially relies on data that were collected in 2006. Relying on data that are almost 20 years old is not optimal given the magnitude of changes that have occurred in the health care system over that time period, such as the increase in vertical consolidation, the growing reliance on nurse practitioners and physician assistants to provide care, and changes in medical technology, including the widespread adoption of electronic health record systems.

The Commission has emphasized the importance of updating the data used to establish RVUs and has recommended that the Secretary regularly collect such data.[3,4] However, we have recognized that regularly collecting practice expense data for dozens of different specialties is difficult. We note, too, that the AMA dedicated significant time, resources, and expertise to its most recent PPI survey. Concerns about the survey's sample size, response rate, and representativeness raises the question of whether the input data of the current PE RVU methodology can, as a practical matter, be updated on a routine basis. Therefore, as CMS continues to consider ways to modernize the methodology used to allocate PE RVUs, we encourage the agency to evaluate the extent to which the current methodology should be changed so that it relies only on data that can be routinely updated.

Narrowly, such changes could involve collecting practice expense data from broader groups of specialties or forgoing the use of specialty-specific practice expense data altogether. More broadly, in 2011, the Commission recommended a new process for collecting better data on work and practice expenses. We recommended collecting data from a cohort of efficient practices rather than trying to collect data through a voluntary survey. To avoid the issue of low response rates, we noted that participation would be required for practices selected to report their data. We said that practices could be paid to participate to compensate for the associated reporting costs.

In addition to the technical concerns raised by CMS, a key conceptual question for CMS to address when considering updating RVU shares is whether and how to incorporate data from clinicians whose practice expenses are paid for by a hospital (or other facility). The AMA's new survey included physicians who practiced in facilities and/or were directly employed by a hospital. To the extent that physicians' practice expenses were covered through other payment systems (e.g., the hospital outpatient prospective payment system), survey participants were instructed to exclude those expenses. Therefore, if a physician was employed by a hospital and most of their PE was financed by payments through another payment system, the expenses they reported in the AMA's survey should mostly

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[2] Medicare Payment Advisory Commission. 2025. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
[3] Medicare Payment Advisory Commission. 2011. *Moving forward from the sustainable growth rate (SGR) system.* Washington, DC: MedPAC.
[4] Medicare Payment Advisory Commission. 2025. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

be associated with work and malpractice insurance. The result is that the AMA's data suggesting that a lower share of physicians' costs were associated with practice expenses may not be because practice expenses as a share of total costs declined, but instead because the shifting of care to facility settings led to physicians (on average) bearing fewer of those costs. The Commission is concerned that using data for clinicians who do not rely on the PFS to cover their practice expenses may misrepresent the costs required to operate a nonfacility practice (e.g., an independent clinician office that is not owned by a hospital)—especially given the dramatic increase in vertical consolidation between hospitals and clinicians that has occurred since 2006.

Updates to practice expense methodology–site of service payment differential

When a clinician service is furnished in a facility, Medicare generally includes payments for indirect PE (i.e., overhead costs) in both the PFS payment and the facility payment (e.g., under Medicare's OPPS).[5] This arrangement assumes that all clinicians who furnish services in a facility should also be compensated for the costs of maintaining an independent, freestanding office outside the facility. Over the last few decades, an increasing portion of physicians have become employed by a hospital or now work in a practice that is owned by a hospital and can bill under both the PFS and the OPPS as a facility.[6] This trend suggests a growing share of physicians work mostly or exclusively in a facility and do not incur overhead costs to maintain a separate nonfacility office.

CMS therefore proposes to reduce the indirect PE portion of PFS payments for services furnished in a facility. Specifically, starting in 2026 CMS proposes to reduce the portion of facility indirect PE RVUs allocated based on work RVUs to half the amount allocated to nonfacility RVUs. Because of the zero-sum nature of how indirect PE RVUs are allocated, the proposed reduction in facility indirect PE RVUs would increase nonfacility indirect PE RVUs, resulting in higher payments for office-based clinicians.

CMS explains that its proposed indirect PE methodology is intended to better reflect the relative resources involved in furnishing services paid under the PFS in facility and nonfacility settings. It is worth noting that CMS proposes to reduce, but not completely eliminate, facility indirect PE RVUs. According to CMS, this approach is intended to recognize that many clinicians who furnish services in a facility have some indirect PE that the PFS should continue to cover.

Comment

The Commission shares CMS's view that facility indirect PE RVUs could be updated and adjusted to better reflect the current relationships between clinicians and facilities. In our June 2025 report to the Congress, we pointed out that facility indirect PE RVUs are

[5] The PFS also includes payment for direct PE (i.e., clinical staff costs, medical equipment, and medical supplies) when a service is furnished in a nonfacility setting. When a service is performed in a facility setting, the PFS payment generally does not include payment for direct PE because Medicare makes another payment (e.g., under the OPPS) for those expenses.
[6] Kane, C. K. 2025. *Physician practice characteristics in 2024: Private practices account for less than half of physicians in most specialties.* Chicago, IL: American Medical Association. https://www.ama-assn.org/system/files/2024-prp-pp-characteristics.pdf.

likely overvalued because many clinicians no longer have overhead costs for a separate office to finance. The fact that Medicare includes payment for indirect PE under facility payments such as the OPPS leads us to the conclusion that PFS payments for indirect PE costs are potentially duplicative and unnecessary. We agree that addressing this situation would help increase the accuracy of the PFS by reducing potential overpayment for facility services and increasing payments for nonfacility services, many of which are seen as undervalued. As such, although better data could be used to inform the magnitude of the proposed reduction and other approaches could be used to target the reductions (see our June 2025 report),[7] we are generally supportive of CMS's efforts to address potential overpayment by better aligning Medicare's payment for indirect PE with those costs in each setting.

Use of OPPS data for rate setting

For several service types, CMS proposes to forgo using AMA survey data and to instead use hospital OPPS data to set relative or absolute PFS rates. CMS proposes different methodologies for the use of OPPS data based on service type but seeks comment on whether it would be preferable to use a single methodology and, if so, how such a methodology would account for differences in practice expenses across services.

Comment

The Commission has long supported collecting accurate, timely data to set payment rates under the PFS. Therefore, the Commission generally supports CMS exploring the use of OPPS data to inform RVU values under the PFS but cautions that such methodology may not be appropriate for many services. Using OPPS data could be particularly useful to price services that are commonly performed in both hospital outpatient departments (HOPDs) and nonfacility settings, that have similar inputs when performed in HOPDs and nonfacility settings, that only have PE RVUs, that need to be priced on a temporary basis, or that are hard to price (e.g., services related to new technologies).

We offer a few, high-level comments on the use of OPPS data to set PFS payment rates:

- *Absolute hospital payment rates*: HOPDs often have higher cost structures than freestanding clinician offices. For example, hospitals tend to negotiate higher commercial insurance rates (which research has shown can, in turn, increase their costs) and have higher costs associated with maintaining 24/7 emergency capacity and treating a sicker mix of patients than are seen in doctors' offices. Those higher HOPD costs can lead to higher service-level costs in the OPPS. Therefore, CMS should be cautious about setting absolute payment rates under the PFS using OPPS cost data. For example, dividing the geometric mean costs for services by the PFS conversion factor to establish RVUs results in basing PFS rates on the absolute costs in hospitals, which may not be in the best interest of taxpayers and beneficiaries. Instead, OPPS data may be best used to set payment rate caps (an

[7] Medicare Payment Advisory Commission. 2025. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

approach that has been used in the past for certain services) or to identify instances of mispricing in the PFS.

- *Transparency*: Because using OPPS data to set PFS RVUs is a novel approach, CMS should be transparent with regard to the criteria that would be used to select services to be priced using OPPS data and how payment rates under the standard PFS RVU methodology would compare to the payment rates calculated under the OPPS methodology.
- *Interaction with standard PE RVU methodology*: CMS should detail how the RVUs set using OPPS data would be incorporated into the standard PE RVU methodology or not. The standard PE RVU methodology sums direct PE RVUs and indirect PE RVUs to determine total PE RVUs for a service. However, direct and indirect expenses are not currently separated out in OPPS data. Therefore, only aggregate PE RVUs can be derived from OPPS data. The lack of direct PE RVUs and indirect PE RVUs presents a challenge because of the different methodologies CMS uses to set and maintain direct PE RVUs and indirect PE RVUs. For example, CMS uses direct PE RVUs to allocate indirect PE RVUs, CMS applies different scaling factors to direct PE RVUs and indirect PE RVUs, and changes in direct PE RVUs and indirect PE RVUs are kept budget neutral within their respective pools (e.g., an increase in direct PE RVUs for one service results in decreases in direct PE RVUs for other services).
- *Continued need for better data:* Although we support exploring the use of OPPS data in PFS rate-setting for select groups of services or as a temporary stop-gap until better data can be collected, such a process would not obviate the need for better information on the costs of furnishing care in clinician offices. We continue to urge CMS to collect data on service volume, work time, and practice expenses from a cohort of efficient practices and to use it to set more accurate work and PE RVUs.[8]

Payment for services in urgent care centers

In response to a CY 2025 proposed rule solicitation of comments on urgent care centers, interested parties noted that some conditions that are often treated at hospital emergency departments can be treated effectively in less acute settings, such as urgent care centers. In addition, commenters noted that the current place of service code for urgent care centers does not adequately differentiate between those that offer services similar to a clinician's office and those that offer enhanced diagnostic and therapeutic services and operate for extended hours. Commenters stated that FFS Medicare payments to urgent care centers are not adequate and that urgent care centers that operate for extended hours and that have enhanced diagnostic and therapeutic capabilities incur additional costs. Therefore, interested parties have suggested adopting a new place of service code for "enhanced" urgent care centers as well as creating a new add-on code for all evaluation and management visits at "enhanced" urgent care centers.

[8] Medicare Payment Advisory Commission. 2011. Moving forward from the sustainable growth rate (SGR) system. October 14. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/10142011_MedPAC_SGR_letter.pdf.

CMS is seeking comments on whether separate coding and payment is needed for evaluation and management visits furnished at urgent care centers, including whether or not an add-on code would be appropriate or if a new set of visit codes would be more practical.

Comment

When clinically appropriate, shifting care from high-cost hospital emergency departments (EDs) to lower-cost settings is a laudable goal. However, more information is needed (1) to justify the need for a new add-on code or new (higher-paid) visit codes for urgent care centers and (2) to explain how any additional payments would be targeted to achieve their intended goals and avoid the unintended consequence of encouraging care to shift from clinician offices to urgent care centers. As such, we discourage adoption of a new coding scheme or additional payment mechanisms at this time.

Urgent care centers are growing rapidly, suggesting payment for care at these centers is adequate (rapid growth is generally not an indication of underpayment). From 2018 to 2023, PFS allowed charges billed with an urgent care place of service grew at an average of 11 percent per year compared with 2.7 percent per year for all PFS services. In addition, from 2014 to 2023, industry data suggest that the number of urgent care centers in the United States roughly doubled, going from about 7,000 to 14,000.[9] In addition, payment for diagnostics and therapeutic services are typically separately billable under the PFS, so, to the extent that certain urgent care centers furnish such services more than other clinician offices or urgent care centers, they would generate additional PFS payments. Establishing a clear evidentiary base for the need for an add-on payment (or higher-paid visit codes) would also help policymakers in the future when other providers suggest the need for other add-ons.

Establishing higher payments for urgent care centers could encourage more volume to shift from hospital EDs to urgent care centers. However, those higher payments could also encourage volume to shift from clinician offices to urgent care centers, which could be an unintended consequence of such a policy. Therefore, to the extent CMS proceeds with such a policy, targeting any additional payments to cases most likely to generate shifts from hospital EDs to urgent care centers (or other nonfacility settings) would be desirable. For example, while interested parties suggested allowing an add-on code to be billed with all evaluation and management office visits at "enhanced" urgent care centers, a more targeted approach could involve allowing clinicians at urgent care centers (or other nonfacility settings) to bill an add-on code only to the extent that care was furnished outside of normal business hours (when many clinician offices are closed).[10] More targeted approaches that pay based on the characteristics of the service (e.g., an after-hours service) rather than characteristics of the facility also have the benefit of not creating additional payment

[9] Trilliant Health. 2024. The marked shift in urgent care utilization: Two years later. https://www.trillianthealth.com/market-research/studies/the-marked-shift-in-urgent-care-utilization-two-years-later#:~:text=In%20the%20last%20two%20decades,declined%20over%20the%20same%20period.

[10] Payment for after-hours services, such as billing codes 99050 and 99051, are currently bundled under the PFS, so another alternative is to make these codes separately payable.

differentials in Medicare based on the site of care and are therefore more consistent with the Commission's long-held support for site-neutral payments.

Efficiency adjustment

CMS proposes applying an "efficiency adjustment" to thousands of non-time-based codes in the PFS in 2026. (Non-time-based codes include procedures, diagnostic tests, and radiology services.) CMS proposes to apply this new efficiency adjustment to work RVUs and to intraservice time inputs (which, in turn, affect the allocation of indirect practice expense RVUs) every three years.[11] In 2026, the first efficiency adjustment would equal –2.5 percent, reflecting the MEI's productivity adjustment for the last five years (2022–2026).[12] In 2029, the efficiency adjustment would only reflect MEI productivity adjustments for the prior three years (2027–2029). CMS states that reducing payment rates for non-time-based services will make them more accurate because studies have found that clinicians are able to perform many types of services more quickly over time as they gain more practice doing them.

In implementing this efficiency adjustment, CMS would increase the PFS's 2026 conversion factor by 0.55 percent to maintain budget neutrality, which would increase payment rates for primary care and behavioral health clinicians.

CMS states that, in the future, it may also apply the efficiency adjustment to direct PE inputs for clinical labor (which would reflect the premise that clinical staff such as nurses and medical assistants can provide services more quickly over time) and equipment costs (which would reflect the premise that nondisposable medical items such as EKG machines tend to come down in price over time).

CMS notes that if interested parties believed that the efficiency adjustment had led to an inaccurate number of work RVUs and physician time for a particular billing code, such parties could nominate a code for revaluation through CMS's Potentially Misvalued Codes process. CMS notes, however, that it will place greater emphasis on empirical data when considering such revaluations (e.g., electronic health record logs, operating room logs, and time-motion data).

Comment

The Commission supports the proposed efficiency adjustment, which (as CMS notes) is a policy option we discussed in our June 2018 report.[13] The Commission has a long history of concerns with the accuracy of non-time-based codes, based on studies that have found that clinicians spend less time delivering many types of services than the PFS assumes is

[11] "Intraservice time" refers to the number of minutes that CMS estimates a practitioner spends delivering a service to a patient (not including time spent before or after the service). Estimates of the amount of time spent delivering a service are used by CMS to allocate a fixed pool of indirect practice expense RVUs to different billing codes.
[12] The MEI productivity adjustment is calculated by CMS's Office of the Actuary (OACT) using the Bureau of Labor Statistics' most recent historical estimate of the 10-year moving average growth of private nonfarm business total factor productivity.
[13] Medicare Payment Advisory Commission. 2018. "Chapter 3: Rebalancing Medicare's physician fee schedule toward ambulatory evaluation and management services," in *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch3_medpacreport_sec.pdf.

needed.[14] For example, based on time-based anesthesia claims for 1,349 types of procedures, Crespin et al. found that clinicians took an average of 27 percent less time to deliver the procedures than billing codes assumed were needed.[15] And a systematic review of 12 studies of robotic thoracic surgery by Power et al. found that surgeons are able to perform procedures in less time, the more times they perform a procedure.[16] (Additional studies are summarized in the proposed rule and in our June 2024 report to the Congress.[17])

When the time and RVUs assigned to a billing code are higher than empirically justified, it results in "passive devaluation" of the other codes in the fee schedule. This is because it prevents a two-step process from occurring. If relatively overvalued services' RVUs had been reduced, it would have been accompanied by positive budget-neutrality adjustments to the fee schedule's conversion factor—which would have increased payment rates for all other services. When relatively overvalued services' RVUs are not revised downward, the remaining services in the fee schedule do not receive the payment increases they should have.

We support proceeding with the proposed efficiency adjustment for 2026 because it will help correct for the passive devaluation that has occurred in the fee schedule. Before proceeding with a second efficiency adjustment in 2029, we suggest that CMS analyze claims data to determine what impact the 2026 efficiency adjustment has had on beneficiaries' access to different types of services, to ensure beneficiaries' continued access. Regarding CMS's proposal to apply the efficiency adjustment only to work RVUs and intraservice time inputs for the time being, and not also to direct PE RVU inputs, we support this course of action, given the major change CMS proposes to PE RVU valuation elsewhere in this rule. Moving forward, CMS should take a holistic approach to revising PE RVU values—assessing how changes to PE RVU valuations in 2026 plus any other contemplated changes affect relative payment rates for different services and clinicians and monitoring how these changes affect utilization of different services in different settings—before contemplating applying an efficiency adjustment to direct PE RVU inputs. And to inform CMS's efforts to revalue PE RVUs, we reiterate our 2011

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[14] Medicare Payment Advisory Commission. 2006. "Chapter 3: Reviewing the work relative values of physician fee schedule services," in *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar06_Ch03.pdf.
Medicare Payment Advisory Commission. 2011. Moving forward from the sustainable growth rate (SGR) system. Letter to the House and Senate chairs of Medicare's committees of jurisdiction. October 14. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/10142011_MedPAC_SGR_letter.pdf.
Medicare Payment Advisory Commission. 2018. "Chapter 3: Rebalancing Medicare's physician fee schedule toward ambulatory evaluation and management services," in *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch3_medpacreport_sec.pdf.

[15] Crespin, D. J., T. Ruder, A. W. Mulcahy, et al. 2022. Variation in estimated surgical procedure times across patient characteristics and surgeon specialty. *JAMA Surgery* 157, no. 5 (May 1): e220099.

[16] Power, A. D., D. M. D'Souza, S. D. Moffatt-Bruce, et al. 2019. Defining the learning curve of robotic thoracic surgery: What does it take?" *Surgical Endoscopy* 33, no. 12: 3880–3888. https://pubmed.ncbi.nlm.nih.gov/31376007/.

[17] Medicare Payment Advisory Commission. 2024. "Chapter 1: Approaches for updating clinician payments and incentivizing participation in alternative payment models" in *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2024/06/Jun24_Ch1_MedPAC_Report_To_Congress_SEC.pdf.

recommendation that CMS regularly collect data on actual practice expenses from a cohort of efficient practices.[18]

Comment solicitation on payment policy for software as a service

Software-as-a-service (SaaS) technologies are algorithm-driven software that are either cleared or approved by the Food and Drug Administration (FDA) and help practitioners make clinical assessments. In recent years, there have been rapid developments in the use of SaaS items.

In this proposed rule, CMS indicates that as SaaS technologies have continued to evolve and diversify, interested parties have requested that CMS consider the development of a payment policy for these software devices that is stable and consistent across settings of care, payment systems, and types of services incorporating SaaS and AI-driven software. Additionally, because CMS is interested in paying accurately for the management of chronic disease and primary care services, the agency is seeking to understand how the use of SaaS and AI technology affects those services and how to incorporate these costs into CMS's current strategy for paying for evolving models of care delivery, such as Advanced Primary Care Management and risk-based payment arrangements generally. Therefore, CMS is requesting public comments on several questions related to payment for SaaS items in the PFS.

Comment

The goal of Medicare payment should be to obtain good value for the program's expenditures, which means maintaining beneficiaries' access to high-quality services while encouraging efficient use of resources. Anything less does not serve the interests of the taxpayers and beneficiaries who finance Medicare through their taxes and premiums. Regarding other new technologies such as drugs and biologicals, 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.[19]

Payment bundles are an integral part of FFS Medicare's payment systems. The Commission has repeatedly said that paying separately for items and services instead of packaging them into larger payment bundles would:

- undermine the integrity of the payment bundles;
- limit the competitive forces that generate price reductions among like services;
- possibly lead to overuse (to the extent clinically possible); and

[18] Medicare Payment Advisory Commission. 2011. Moving forward from the sustainable growth rate (SGR) system. Letter to the House and Senate chairs of Medicare's committees of jurisdiction. October 14. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/10142011_MedPAC_SGR_letter.pdf.
[19] Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

- shift financial burden from providers to the Medicare program, beneficiaries, and taxpayers.[20]

Because of the potential problems that arise from paying separately for technologies in lieu of larger payment bundles, the Commission encourages CMS to package ancillary items, such as SaaS technologies, into the payment bundles of the related primary services as long as beneficiaries' access is not adversely affected. For example, under the OPPS, CMS had packaged several SaaS items such as LiverMultiScan through CY 2022 before changing policy and paying separately for these items beginning in CY 2023. The Commission recognizes the need to ensure beneficiaries' access to new technologies that improve outcomes while preserving the incentives for efficiency that can be achieved through packaging. Combining a primary service with related ancillary items into a single payment encourages efficiency because the combination of inputs used to treat a beneficiary determines whether the provider experiences a financial gain or loss. Broader bundles also foster competition among similar items and services, which generates pressure on manufacturers and suppliers to reduce prices. The Commission has long supported larger payment bundles because they offer providers opportunities to find flexibility in providing care and incentives to use the most cost-efficient methods. In addition, packaging SaaS items—relative to separate payment for specific SaaS items—creates more desirable incentives for providers because it encourages them to choose technologies based on what is most effective in their own operations and does not create or distort financial incentives for items that may not be efficacious or efficient.

In contrast, separate payment for SaaS items would leave Medicare with few pricing tools that would help the program strike a balance between maintaining incentives for innovation and ensuring affordability for beneficiaries and taxpayers. In addition, SaaS developers would face little competitive pressure when making pricing decisions, allowing them to set prices based on what they believe the U.S. health care market will bear for their products. Moreover, paying for SaaS items on a per use basis could lead to overuse of these technologies and could have significant fiscal implications for Medicare, particularly as the FDA clears or approves more of these technologies.

Payment for skin substitutes

According to CMS, skin-substitute products are a heterogeneous group that includes nonautologous human cellular or tissue products, nonhuman cellular and tissue products, or biological products that are used to treat chronic wounds (e.g., venous leg ulcer and diabetic foot ulcers).[21] The agency explains that the FDA regulates skin substitutes according to their product composition, mode of action, and intended use as: (1) human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated under section 361 of the Public Health Service (PHS) Act (herein referred to as *self-determined 361*

[20] Medicare Payment Advisory Commission. 2024. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.
[21] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2025. Skin-substitute grafts/cellular and tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35041.

HCT/Ps);[22] (2) devices approved or cleared under a 510(k) premarket notification submission, a premarket approval application (PMA), or a De Novo classification request; or (3) biologicals approved under section 351 of the PHS Act.

In the nonfacility setting, CMS has historically paid for most skin substitutes under section 1847A of the Social Security Act based on each product's average sales price (ASP) plus 6 percent.[23] Using this methodology, each skin substitute product receives a unique billing code and payment limit. By contrast, under the 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 2025, 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." This payment policy is also used in the ambulatory surgical center payment system.

In this proposed rule, CMS reports significant growth in the nonfacility setting in the use of expensive skin-substitute products and describes "profiteering practices" that have occurred in this industry, including a dramatic increase in launch prices that do not appear to be driven by real change in resource costs.[24] CMS also reports "several novel industry practices" that have resulted in a significant increase in spending for skin-substitute products in the nonfacility setting, from approximately $250 million in 2019 to over $10 billion in 2024, a nearly 40-fold increase, while the number of patients receiving these products only doubled.[25] To reduce incentives for such behavior, beginning CY 2026, CMS proposes to separately pay for provision of skin-substitute products (that are not approved by the FDA under section 351 of the PHS Act as biological products) as incident-to supplies when such products are used as part of a covered application procedure under the PFS in the nonfacility setting or under the OPPS in the hospital outpatient department setting.[26] Under the PFS, CMS would continue to pay for any skin-substitute products that are approved by the FDA under section 351 of the PHS Act as biological products based on each product's ASP plus 6 percent (per section 1847A of the Act). For skin substitutes that are not biologicals under section 351 of the PHS Act, CMS proposes beginning CY 2026 to:

- Classify each skin substitute into one of three payment categories based on each product's FDA regulatory pathway: (1) devices approved under FDA's PMA pathway; (2) devices cleared under FDA's 510(k) or De Novo process; and (3)

[22] Establishments that manufacture 361 HCT/Ps, as defined by 21 CFR 1271.3(e), must register and list their 361 HCT/Ps in the FDA's electronic Human Cell and Tissue Establishment Registration System (eHCTERS), but premarket review and approval by FDA is not needed.
[23] If manufacturers do not report ASP data to CMS, then payment is based either on the wholesale acquisition cost (WAC) or invoices.
[24] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2025. Medicare and Medicaid programs; CY 2026 payment policies under the physician fee schedule and other changes to Part B payment and coverage policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program. *Federal Register* 90, no. 134 (July 16): 32352–33261.
[25] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2025. Medicare and Medicaid programs; CY 2026 payment policies under the physician fee schedule and other changes to Part B payment and coverage policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program. *Federal Register* 90, no. 134 (July 16): 32352–33261.
[26] Incident-to services and supplies are those provided as an integral, although incidental, part of the physician's or nonphysician practitioner's personal professional services during diagnosis and treatment.

products that are human cells, tissues, and cellular and tissue-based (i.e., self-determined 361 HCT/Ps).

- Apply the same initial payment rate (and thus PE RVUs) to all skin-substitute products across the three payment categories. The proposed payment rate would reflect the highest volume-weighted average payment of the three payment categories. CMS would calculate the initial payment using ASP pricing data and OPPS cost data weighted by OPPS volume.
- Establish a single payment rate of approximately $125.38/cm^2 (prior to the application of geographic adjustments) for all skin-substitute products.[27] This payment rate reflects the volume-weighted payment of the 361 HCT/P payment group.
- Codify the definition of "biological" as "a product licensed under section 351 of the Public Health Service Act" at §§ 414.802 and 414.902.
- Update the payment rate for the skin-substitute payment categories annually through the rulemaking process using each product's most recently available calendar quarter of ASP data, when available.[28] [29]

CMS seeks comment on whether the agency should establish the skin-substitute billing codes in CY 2026 as an add-on service or a standalone service under the PFS. In addition, the agency is seeking comments on how to update the payment rates for skin-substitute products under the PFS in the future.

Comment

The Commission applauds the agency's attention to the significant increase in Medicare program spending on skin-substitute products in the nonfacility setting and strongly supports the changes the agency proposes to how Medicare pays for skin substitutes in the nonfacility setting under the PFS. In the Commission's comment letter on the CY 2025 PFS proposed rule, we said that the Secretary should explore opportunities to reform the payment method for skin-substitute products that ensure both beneficiary access to services that improve care and provider efficiency.[30] We noted that between 2021 and 2023, Medicare Part B spending on skin-substitute products grew from $1.0 billion to $4.2 billion. According to our recent update, 2024 Part B spending on skin-substitute products more than doubled to $10.2 billion compared to the prior year's spending.[31,32] In terms of

[27] CMS proposed skin-substitute products as stand-alone billing codes that include 0.01 malpractice (MP) RVU. If CMS were to treat these codes as add-on codes to the application codes, the agency would assign 0 MP RVUs to them.
[28] In the event ASP is not available for a particular product, CMS would use the hospital outpatient mean unit cost (MUC) data, and if MUC is not available, CMS would propose to use the product's WAC or 89.6 percent of average wholesale price (AWP) if WAC is also unavailable.
[29] CMS is also proposing to review HCPCS Level II coding applications for all skin substitutes marketed as 361 HCT/Ps through the biannual coding cycle for non-drugs and non-biological products, rather than on a quarterly basis for drug and biological products.
[30] Medicare Payment Advisory Commission. 2024. https://www.medpac.gov/wp-content/uploads/2024/09/09062024_2025_PFS_MedPAC_comment_SEC.pdf.
[31] Medicare spending data for CY 2024 claims data represent claims processed through week 20 of 2025.
[32] Medicare Payment Advisory Commission. 2025. *Data book: Health care spending and the Medicare program.* Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_Sec10_SEC.pdf.

Part B drug spending by therapeutic class, the skin-substitute class rose sharply in rank by total Medicare spending from tenth in 2021 to second in 2024. In last year's comment letter, the Commission also noted that, 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.[33]

The Commission supports CMS's proposal to separately pay for skin-substitute products not regulated by the FDA as biologicals under section 351 of the PHS Act as incident-to supplies under the PFS.[34] The agency's proposal balances the need to maintain beneficiary access to care while promoting the efficiency of providers and ensuring good value and affordability for beneficiaries and taxpayers. Although CMS has historically paid for skin-substitute products in the nonfacility setting according to each product's ASP plus 6 percent per section 1847A of the Social Security Act, this payment policy applies to drugs and biologicals regulated under sections 505 and 351 of the PHS Act, respectively. Importantly, under the PFS, the proposed payment policy would only apply to products regulated as other products including devices and self-determined 361 HCT/Ps. Skin-substitute products that the FDA approves as drugs and biologicals would continue to be paid per section 1847A of the Act.

As we explain in our letter to the Secretary on the CY 2026 proposed rule for the hospital outpatient prospective payment and ambulatory surgical center payment systems, the Commission does not support applying this proposed payment approach in the OPPS, which would unbundle skin substitutes in the facility setting. As CMS indicates, the issue with increased FFS Medicare spending for skin substitutes resides in the nonfacility setting—not within the OPPS. The Commission has repeatedly said that paying separately for items and services instead of packaging them:

- undermines the integrity of the payment bundles;
- limits the competitive forces that generate price reductions among like services;
- can lead to overuse (to the extent clinically possible); and
- shifts financial burden from providers to the Medicare program, beneficiaries, and taxpayers.[35]

With regard to the PFS, CMS's proposed approach to calculate the CY 2026 payment rate for skin-substitute products in the nonfacility setting that are devices or self-determined 361 HCT/Ps is reasonable, including using the 361 HCT/P volume-weighted average

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[33] Due to MACs' inability to find sufficient literature showing the effects of these products on beneficiaries' health outcomes, the contractors 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-coveragedatabase/view/lcd.aspx?lcdId=39827&ver=4.)

[34] In 2024, among the top 10 skin-substitute products that accounted for nearly 65 percent of total Medicare spending for these products, most are registered with the FDA as 361 HCT/Ps, while the remainder were cleared by the FDA as a device. None of the top 10 skin substitute products in 2024 were approved by the FDA under section 351 of the Public Health Service Act as a biological product.

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

payment amount to set an initial payment rate in CY 2026 that would apply to products in all three payment categories. We support CMS's approach that sets the payment rate for skin-substitute products using an empirical analysis.

The Commission strongly supports grouping skin-substitute products into categories of clinically similar products in CY 2026 and beyond. Such an approach spurs price competition among clinically similar products. In our June 2023 report to the Congress, the Commission recommended that the Congress should give the Secretary the authority to establish a single ASP–based payment rate for drugs and biologics with similar health effects.[36]

We support using OPPS utilization data to calculate the nonfacility volume-weighted payment rate in CY 2026. As explained in the proposed rule, the OPPS utilization data is likely a better predictor of use patterns under the proposed approach for nonfacility settings because these products are already grouped together under the OPPS. By grouping skin substitutes into high- and low-cost groups in the OPPS, providers are incentivized to choose either the lowest-cost, clinically appropriate product in the low-cost group or the lowest-cost, clinically appropriate product in the high-cost group. By contrast, no similar incentive currently exists in the nonfacility setting.

With regard to CMS's request for comments about whether to establish the skin-substitute codes in CY 2026 as an add-on service or a standalone service, paying for these products as a standalone service would require that CMS assign 0.01 MP RVU to the payment for each unit of the skin substitute the clinician applies. While 0.01 is a small amount per unit, these products are often billed in multiple units, which could result in too many malpractice (MP) RVUs being allocated to these products.

The Commission supports paying for skin-substitute products as an add-on service rather than as a standalone service. As the agency explains, doing so would indicate that the products are supplies that clinicians furnish during the primary procedure of applying skin-substitute products to a wound (which is assigned its own work, practice expense, and MP RVUs).[37] As an add-on code, the service would have its own PE RVUs but, according to CMS, would be assigned 0 MP RVUs to them.

With regard to updating the payment rates for skin-substitute products in the future, we urge CMS to consider the following:

- To avoid any potential for what CMS has called "profiteering practices" by manufacturers, CMS should use a longer timeframe, such as the most recently available four calendar quarters, of ASP data if available, otherwise mean unit cost data (which uses hospital charges on claims and adjusts them to cost using hospital cost-to-charge ratios from hospitals' cost reports) to establish the PE RVUs for the skin-substitute payment categories. The agency should not rely on wholesale

[36] Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare and the health care delivery system.* https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch1_MedPAC_Report_To_Congress_SEC.pdf.
[37] For example, CPT code 15271 describes the application of a skin-substitute graft to the trunk, arms, or legs. This code specifically applies to the initial 25 square centimeters or less of the treated area.

average cost or average wholesale price, because these data are not net of discounts or rebates.

- CMS should continue to assign skin-substitute products into payment categories of clinically similar products.
- Once updated use patterns reflecting this policy in the nonfacility setting are available to calculate rates, CMS should use all relevant products and the product utilization patterns from the nonfacility setting to determine a weighted average per unit cost by category to set separate payment rates for each payment category.
- To the greatest extent possible, CMS should calculate the PE RVUs for skin-substitute products using the same method as all other supplies paid under the PFS. Consequently, CMS should apply PE scaling factors (which are essentially budget-neutrality adjustments applied to all services' PE RVUs) to skin-substitute PE data once these products are incorporated into PFS data used for rate setting (in CY 2028); otherwise the PE RVUs for these products would not be affected by the same budget-neutrality constraints that affects the PE RVUs of all other services.

Strategies for improving global surgery payment accuracy

For many PFS 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. Currently, about 4,200 procedures have 10- or 90-day global periods, most of which include postoperative evaluation and management (E&M) visits. 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 or has a different specialty, both the proceduralist and the other clinician are supposed to report a transfer-of-care modifier on their claims. In such cases, the global payment is then shared between the two clinicians. When this transfer-of-care modifier is used, it prevents CMS from double-paying for postoperative visits[38]—but CMS reports that this modifier is "rarely" used.

For CY 2026, CMS asks for feedback about ways to improve valuation of global codes. The agency expressed a specific interest in improving the accuracy of procedure shares (i.e., the portion of each global payment that is paid to the proceduralist in cases where he/she uses a transfer-of-care modifier to transfer postoperative care to another clinician). CMS points out that the procedure shares currently in use were developed decades ago and may not accurately reflect contemporary practice patterns.

[38] CMS double-pays for postoperative visits when a proceduralist bills CMS for a 10- or 90-day global surgical code and improperly fails to use the transfer-of-care modifier and then refers their patient to another clinician (e.g., the patient's primary care provider) for some or all of their postoperative care. In such a scenario, CMS pays the proceduralist for postoperative visits that CMS assumes the proceduralist is providing and also pays the primary care provider for E&M visits that CMS does not know are actually postoperative visits. The proceduralist benefits from the overpayment in this scenario.

Comment

Determining RVUs for global surgical codes involves making assumptions about the number and intensity of postoperative visits a patient typically receives over the 10- or 90-day postoperative period. Studies have found large differences between the number of postoperative visits that the PFS assumes clinicians will deliver after a surgical procedure and the number they actually deliver. For instance, according to a study for CMS by RAND using Medicare claims data, on average only 47 percent of the postoperative visits that are assumed in 90-day global surgical codes are actually provided, and only 17 percent of the postoperative visits assumed in 10-day global surgical codes are provided.[39,40] Allowing surgical global codes to continue to be assigned too many RVUs results in payment rates for all other services being passively devalued (since they are denied the positive budget-neutrality adjustments that would have occurred if global codes' RVUs had been reduced to more empirically justifiable levels).

Given strong evidence that 10- and 90-day global codes are overvalued relative to other codes, the Commission views current payment policies for global surgical codes as inherently problematic. We reiterated our concerns about the accuracy of payment rates for global surgical codes in our June 2025 report to the Congress.[41]

Given MACRA's prohibition on converting 10- and 90-day global codes to 0-day codes, we have noted that an alternate approach CMS could use to improve the accuracy of 10- and 90-day codes is to revalue them to reflect the actual average number of postoperative visits furnished according to claims data. RAND has estimated that revaluing 10- and 90-day global surgical codes to remove work RVUs, physician time, and direct PE inputs for visits that were assumed but not provided would reduce total RVUs for global surgical codes by 28.5 percent. When including the PFS's budget-neutrality adjustment, RAND estimated that total Medicare payments for certain surgical specialties would decline by up to 18 percent, while payments to specialties such as primary care would increase by just under 3 percent.[42]

Some stakeholders have argued that simply subtracting work RVUs for postoperative visits 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

[39] 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.
[40] 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.
[41] Medicare Payment Advisory Commission. 2025. "Reforming physician fee schedule updates and improving the accuracy of relative payment rates," in *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_Ch1_MedPAC_Report_To_Congress_SEC.pdf.
[42] Mulcahy, A., H. Liu, T. Ruder, et al. 2021. *Using claims-based estimates of post-operative visits to revalue procedures with 10- and 90-day global periods*. Santa Monica, CA: RAND. https://www.rand.org/pubs/research_reports/RR3035-1.html.

intensity.[43] Given this concern, CMS could holistically reassess the work RVUs used in 10- and 90-day global surgical 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. (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.[44]) If revaluing 10- and 90-day codes rather than replacing them with 0-day codes, the number of postoperative visits observed in claims data could be used, rather than the number that surgeons estimate will be needed in surveys.

Rural health clinics and federally qualified health centers

Medical visits paid under the federally qualified health center (FQHC) prospective payment system (PPS) and rural health clinic (RHC) all-inclusive rate (AIR) payment systems are typically required to be face-to-face (that is, in person).[45] However, through a series of time-limited provisions passed since the COVID-19 public health emergency (PHE) began in 2020, Congress has allowed FQHCs and RHCs to furnish medical visits via telehealth and be paid at rates that are similar to the payment rates for comparable telehealth services billed under the PFS. In 2025, Medicare's PFS-equivalent rate for medical visits furnished via telehealth and billed by FQHCs and RHCs is $94.45.

CMS proposes to allow FQHCs and RHCs to continue to furnish and bill for medical visits furnished via telehealth and be paid at PFS-equivalent rates through December 31, 2026. CMS also seeks feedback on an alternative of allowing FQHCs and RHCs to bill for medical visits furnished via telehealth at the higher FQHC PPS and RHC AIR payment system rates.

Comment

The Commission supports continuing to allow FQHCs and RHCs to furnish medical visits via telehealth and be paid at PFS-equivalent rates to maintain beneficiary access to telehealth services.

In response to CMS's solicitation on an alternative option of paying these services at the higher FQHC PPS and RHC AIR payment system rates, the Commission agrees with CMS that this option could raise some issues.

Medicare pays higher rates for clinician services provided at FQHCs and RHCs to help ensure access to care in medically underserved areas or areas with clinician shortages:

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[43] American Medical Association. 2015. Letter to Sean Cavanaugh regarding the response to the Centers for Medicare & 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-global-unbundling-policy.pdf.

[44] 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.

[45] Beginning in 2022, CMS began paying for mental health visits furnished via telehealth services through the FQHC PPS and RHC AIR payment systems rather than at a PFS-equivalent rate.

- Medicare pays FQHCs using a PPS. In 2025, the FQHC PPS payment rate is $202.65; the rate is updated annually based on the FQHC market basket, and individual FQHC rates are adjusted based on geography.
- Medicare's RHC payment system generally bundles all professional services furnished in a single day into one payment. Medicare pays RHCs a facility-specific cost-based AIR, subject to payment limits. The AIRs for independent RHCs, provider-based RHCs that are part of a hospital with 50 or more beds, and RHCs of any type that enrolled in Medicare after December 31, 2020, are subject to the national statutory payment limit. In 2025, the national statutory payment limit is $152 per visit (and set in statute to increase to $190 per visit by 2028). The payment limit per visit for RHCs that are part of a hospital with fewer than 50 beds and were enrolled as of December 31, 2020, is equal to the greater of their 2020 AIR, increased annually by MEI growth, or the national statutory payment limit. We estimate that, as of 2020, the average AIR for these RHCs was $255 per visit.

Paying for medical visits furnished via telehealth would often result in beneficiaries and taxpayers paying much more for the same service than they currently do because the FQHC PPS and RHC AIR payment system rates are higher than the PFS-equivalent rate. In addition, because beneficiary coinsurance for services billed under the RHC AIR methodology is set based on RHC *charges* and not payment rates, rural beneficiaries would experience especially high increases in coinsurance if CMS switched from paying PFS-equivalent rates to those based on the RHC AIR methodology. In the Commission's June 2025 report to the Congress, we found that charge-based coinsurance at RHCs is often high and varies considerably across RHCs, leaving beneficiaries vulnerable.[46] While we cannot determine the exact increase in beneficiary coinsurance if CMS paid medical telehealth visits under the RHC AIR methodology (because we do not yet know providers' charges for 2026), if beneficiary coinsurance follows average charges we observe for all other RHC AIR services, we would expect coinsurance to increase by at least 100 percent on average. For example, in 2025, beneficiary coinsurance for a telehealth visit paid at the PFS-equivalent rate is capped at 20 percent of the payment rate or about $19 ($94.45 × 20%). In contrast, the average coinsurance for AIR services at independent RHCs in 2022 was $38—a difference of about $19 per visit, or 100 percent.[47] Moreover, the Commission found that RHC charges (and therefore coinsurance) varied widely across RHCs, so some beneficiaries would likely experience even higher increases in coinsurance.

The Commission is also concerned that paying medical telehealth visits higher-than-PFS rates under the FQHC PPS and RHC AIR payment systems could create unintended incentives for providers. For example:

- RHCs may have an incentive to furnish telehealth visits to beneficiaries outside their local areas (including urban areas) because it is substantially profitable.[48] For

[46] Medicare Payment Advisory Commission. 2025. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
[47] This estimate may be conservative for multiple reasons. For example, RHC charges have likely increased since 2022 (which was the most recent year of data the Commission analyzed), and we used independent RHCs in the example but provider-based RHCs furnish a majority of RHC services and have higher coinsurance per visit.
[48] While the RHC AIR payment system only pays RHCs their costs up to a limit, furnishing telehealth services under the AIR system could nonetheless generate profits because RHCs are allowed set their charges above the AIR and beneficiary

example, in 2025, if an RHC had a cost per visit that was equal to the national statutory payment limit of $152 and set their charges at twice that amount ($304 per visit, which was well within the range we observed in in our June 2025 report to the Congress), the RHC would generate 17 percent profit margins on such services.[49]

- Because clinicians do not have to be physically located at an RHC to bill a telehealth visit under the RHC AIR payment system, clinicians who might not be located in rural areas would have an incentive to contract with a higher-paid RHC (rather than bill under the PFS or at a lower-paid RHC).
- Paying FQHC PPS and RHC AIR payment system rates for telehealth visits will result in paying substantially more for an FQHC- or RHC-provided telehealth service than if the same service were provided in-person by a clinician billing under the PFS, which could create an incentive to reduce providing in-person care.

Therefore, without further reforms or safeguards, the Commission contends that allowing FQHCs and RHCs to bill for medical visits performed via telehealth at PFS-equivalent rates is a preferable approach that balances the goals of ensuring beneficiary access and being a prudent fiscal steward of the Medicare program, without undue beneficiary cost-sharing burden.

Part B drugs' average sales price

Medicare generally pays for Part B drugs based on the manufacturer-reported ASP plus 6 percent. In the proposed rule, CMS makes several proposals concerning the manufacturer's calculation of ASP—particularly, related to the treatment of price concessions and bona fide service fees (BFSFs) in the calculation of ASP. CMS states its proposals seek to ensure accurate calculation and reporting of ASP by manufacturers and reduce the potential for overpayments by the FFS Medicare program and beneficiaries if ASP is not accurate.

Bundled price concessions

The Social Security Act requires manufacturers to deduct price concessions from ASP, which means that price concessions lower ASP. Sometimes manufacturers offer bundled price concessions, in which the price concessions for one or more of their products are contingent on the purchase of one or more other products. To date, Medicare has not issued guidance on how manufacturers should allocate price concessions across products in bundled arrangements. In the absence of guidance, CMS expects manufacturers to make reasonable assumptions.

In this year's proposed rule, CMS proposes to define bundled arrangements and establish guidance on how manufacturers should allocate price concessions across products in a bundled arrangement.

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coinsurance is based on charges. Therefore, total payments (program payments plus beneficiary cost sharing) can exceed provider costs.

[49] Profits were calculated as follows: ($152*0.8 + $304*0.2) – $152 / ($152*0.8 + $304*0.2)

- *Definition of bundled arrangement.* CMS proposes that a bundled arrangement is "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs or biologicals been purchased separately or outside the bundled arrangement.''
- *Methodology for allocation of discounts in bundled arrangements.* CMS proposes to adopt the allocation approach utilized under the Medicaid drug rebate program for the calculation of average manufacturer price where "discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement."
- *Bundles including noncovered products.* CMS proposes for bundled sales containing both Medicare Part B drugs and noncovered products (meaning products without an ASP reporting requirement), manufacturers allocate discounts proportionally across all products.
- *Value-based purchasing arrangements.* CMS proposes not to adopt Medicaid policy that value-based arrangements may qualify as bundled sales and states that they will continue to evaluate the issue and seek comment.

Bona fide service fees

Drug manufacturers may pay entities in the supply chain fees for certain services (e.g., distribution services, data sharing, patient adherence programs). If service fees meet the criteria for BFSFs, they are not considered price concessions and are not deducted from ASP. In the 2007 PFS final rule CMS defined BFSFs with a four-part definition [numbers added for clarity]:

> "(1) "fees paid by a manufacturer to an entity that represents fair market value (2) for a bona fide, itemized service actually performed on behalf of the manufacturer (3) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (4) that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug."

If a fee meets the first three parts of the BFSF criteria, CMS has permitted manufacturers to assume that a fee is not passed on (meets fourth part of criteria) absent evidence or notice to the contrary.

In the CY 2026 proposed rule, CMS makes several proposals concerning BFSFs.

- *Fees that do not vary based on the quantity or price of the drug.* CMS proposes that fair market value (FMV) can be determined based on either comparable market transactions, or the cost of the service plus a reasonable markup.

- *Fees that vary with the quantity or price of the drug (e.g., percentage fees).* CMS proposes that FMV must be determined using the cost of the service plus a reasonable markup, and the FMV analysis must be conducted by a third-party evaluator without a conflict of interest.
- *Updates to FMV.* CMS proposes that manufacturers must update FMV for a service arrangement at least as frequently as the arrangement's renewal frequency.
- *Evidence that BFSFs are not passed on.* CMS proposes that manufacturers can no longer presume BFSFs are not passed on and must on a quarterly basis submit certification letters from any entity receiving a BFSF that the fee is not passed on.
- *Submission of reasonable assumptions.* CMS proposes to require manufacturers to submit the reasonable assumptions they use to calculate ASP (currently submission is voluntary), and that the submission include documentation of the methodology used to determine FMV and periodic reviews of FMV.
- *Guidance on specific fees that are not or may not be BFSFs.* CMS proposes a nonexhaustive list of fees the agency does not consider to be BFSFs (e.g., covering credit card fees for drug purchasers, tissue procurement payments for gene therapies). CMS also indicates certain data sharing fees or certain distribution fees may exceed FMV or otherwise not be BFSFs.

Comment

We agree with CMS that it is important that ASP is calculated accurately. In 2023, the Medicare program and beneficiaries spent $54 billion on Part B drugs and biologics and other products paid under the ASP payment system.[50] We support CMS's efforts to provide more guidance and safeguards concerning price concessions and BFSFs in the calculation and reporting of ASP to ensure FFS Medicare program payments and beneficiaries' cost sharing are accurate.

Bundled price concessions

The Commission supports CMS's efforts to establish guidance on the allocation of bundled price concessions in the ASP calculation. In 2007, the Commission recommended that CMS clarify how bundled discounts should be allocated when manufacturers calculate ASP.[51] In 2023, the Office of Inspector General also encouraged CMS to provide more guidance concerning bundled price concessions and the ASP calculation.[52] CMS's proposal to use the Medicaid approach to proportionally allocate discounts across Part B drugs in a bundled arrangement is reasonable and will promote

[50] Medicare Payment Advisory Commission. 2025. *Data book: Health care spending and the Medicare program*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf.
[51] Medicare Payment Advisory Commission. 2007. *Report to the Congress: Impact of changes in Medicare payments for Part B drugs.* Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2025/08/January2007_MedPAC_PartBDrugs_MandatedReport.pdf.
[52] Office of Inspector General, Department of Health and Human Services. 2022. *Manufacturers may need additional guidance to ensure consistent calculations of average sales prices.* OEI-BL-21-0033. Washington, DC: OIG. https://www.oversight.gov/sites/default/files/documents/reports/2023-01/OEI-BL-21-00330.pdf.

consistency in how ASP is calculated across manufacturers. Below we comment on a few areas where there may be a need for further guidance or monitoring.

It is important that the adoption of an allocation methodology for bundled price concessions does not enable manufacturers to develop bundling arrangements that shift discounts from Part B drugs to other noncovered products, raising ASP for Part B drugs. For bundles that involve Part B drugs and other noncovered products, CMS proposes to apply the proportional methodology across all products in bundled arrangements, including products that are not Part B drugs. The agency notes that this may not always result in accurate ASPs for Part B drugs and seeks comment.

Table 1 shows a simplified illustrative example of how proportionally allocating price concessions in a bundle that includes a Part B drug and other product could lead to a higher ASPs for Part B drugs.

Table 1 | Illustrative example of bundle arrangement including a Part B drug and other item

Products in bundle	List price	Bundled price	Price concessions	Units sold	Total value of products (percent value of total)	Allocation of total price concessions	Average sale price if discounts allocated proportionally
Part B drug	$100	$70	$30	200	$20,000 (67%)	$4,000 (0.67 * $6,000)	$80 ($20,000–$4,000)/200
Other product (not a Part B drug)	$50	$50	$0	200	$10,000 (33%)	$2,000 (0.33 * $6,000)	Not applicable
Total	–	–	–	400	$30,000 (100%)	$6,000 ($30 * 200)	–

In the hypothetical example, the Part B drug receives a discount contingent on the purchase of another product that is not a Part B drug, while the price of the other product is the same regardless of whether purchased separately or in the bundle. The Part B drug has a list price of $100 and a price of $70 under the bundled arrangement. The other product (not Part B drug) is priced at $50 regardless of whether purchased separately or in the bundle. As shown in table, the proportional allocation of discounts across the Part B drug and other product results in ASP for the Part B drug being $80, which is $10 higher than ASP would have been ($70) if the discounts had not been proportionally allocated from the Part B drug to the other product that is not paid under the ASP system. In this example, allocating the price concessions proportionally among the Part B drug and non-Part B drug inflates the Part B drug's ASP and raises Medicare program payments and beneficiary cost sharing for the Part B drug. However, this hypothetical example is only one of many ways that a manufacturer could structure a bundled arrangement involving

both Part B drugs and other products. In some structures, apportioning discounts among Part B drugs and other products might result in lower ASPs for Part B drugs.

Given the array of potential structures for bundled arrangements involving Part B drugs and other products, we encourage CMS to consider additional guidance for allocating price concessions for these types of bundles to help ensure the accuracy of the ASP calculation and limit the potential for distortions. For example, CMS could consider using a "lower-of approach" to prevent the allocation of discounts from Part B drugs to other products (not paid based on ASP) from increasing ASP for Part B drugs. That is, ASP could be the lower of (1) ASP with price concessions allocated across all products in the bundle or (2) ASP with price concessions allocated only among Part B drugs in the bundle that are required to report ASP data. For example, in the context of our previous hypothetical example, this approach would result in ASP for the Part B drug equaling $70—the lower of (1) $80 or (2) $70.

We also encourage the agency to monitor the issue of bundled price concessions in the context of products without an alternative. In our 2007 report, we discussed concerns that had been raised about bundled price concessions for a product that involved no alternatives and the potential use of those bundled price concessions by the manufacturer to create a competitive advantage for another product in the bundle that faced competition.[53] We noted at the time that an approach of allocating bundled price concessions based on the total dollar value of the products in the bundle might not address distortions caused by the bundling arrangement when there is a product without alternatives. We suggest that CMS monitor for this type of issue going forward and consider revisiting guidance should this scenario arise.

Lastly, we note that CMS has indicated it is still studying the issue of value-based purchasing arrangements and proposes not to adopt Medicaid's definition that value-based purchasing arrangements may be part of bundled arrangements. We encourage CMS to monitor value-based purchasing arrangements going forward to help ensure this policy does not have unintended effects. CMS could consider monitoring for the prevalence of value-based purchasing arrangements via the reasonable assumptions manufacturers submit to CMS.

Bona fide service fees

We support CMS's efforts to provide more guidance, accountability, and transparency concerning BFSFs. We agree with CMS that FFS Medicare and beneficiaries have an interest in ensuring that price concessions are not misclassified as BFSFs, which could otherwise artificially raise ASP and inflate Medicare program payments and beneficiary cost sharing.

We support CMS's effort to establish additional guidance for assessing whether percentage service fees meet the BFSF criteria. The Commission has long had a concern about Medicare paying providers a percentage add-on (6 percent) to ASP for Part B drugs

[53] Medicare Payment Advisory Commission. 2007. *Report to the Congress: Impact of changes in Medicare payments for Part B drugs.* Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/2025/08/January2007_MedPAC_PartBDrugs_MandatedReport.pdf.

and the potential for the spread between Medicare's payment and providers' acquisition costs to create incentives for the use of Part B drugs, especially higher-priced products. In our June 2023 report, the Commission recommended that Medicare reduce add-on payments for costly Part B drugs paid based on ASP in order to minimize the relationship between ASP and add-on payments and improve incentives.[54] Similarly, with services fees—especially those that are based on a percentage of a drug's sales—there is potential that if such fees are misclassified as BFSFs when they are actually price concessions, they could increase the spread between Medicare's payment and provider acquisition costs, creating greater incentives for use of particular products. Given these concerns, we support CMS's efforts to ensure accurate classification of service fees by establishing more specific guidance on when fees meet the BFSF criteria, including requiring that manufacturers obtain an assessment of the FMV of percentage service fees based on an evaluation of the cost of the service plus a reasonable markup conducted by an independent, third-party evaluator.

It is important for the integrity of Medicare's ASP payment system that ASP is calculated accurately and consistently across manufacturers. We support CMS's proposal to require manufacturers to submit the reasonable assumptions they use to calculate ASP, as well as the assumptions used for FMV and frequency of the FMV determinations. Doing so would give CMS increased visibility into how ASP is calculated and greater ability to monitor for differences in approaches across manufacturers and the potential need for future guidance. While these proposals would involve additional reporting requirements for manufacturers, the benefit of these proposals for the Medicare program and beneficiaries warrant their adoption.

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

[54] Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.