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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

July 29, 2025

Background & Summary

On July 14, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2026 Medicare payment and policies for the Physician Fee Schedule (PFS) (hereinafter, "Proposed Rule"). The Proposed Rule revises payment polices under the Medicare PFS, including changes related the use of different data sources for ratesetting, a new efficiency adjustment which would reduce payments for most services and significant changes to the agency's approach to covering skin substitutes. Also, CMS proposes a policy to implement the Medicare Inflation Rebate Program and changes related to manufacturers' reporting of Average Sales Price (ASP).

In addition, CMS proposes the Ambulatory Specialty Model (ASM), which is a new mandatory payment model, and proposes updates to the Medicare Shared Savings Program (SSP) and Quality Payment Program (QPP).

Comments are due **September 12, 2025**, with most policies going into effect January 1, 2026. Vizient looks forward to working with clients to inform our comments to CMS.

Calculation of the Proposed CY 2026 PFS Conversion Factor

There are three components that must be considered to value each service under the PFS – work, practice expense (PE) and malpractice (MP) relative value units (RVUs). Each component is adjusted by geographic price cost indices (GPCIs), which reflect variations in the costs of furnishing services compared to the national average cost for each component. Then, the RVUs are converted to dollar amounts via the application of a conversion factor (CF), which is calculated by CMS's Office of the Actuary (OACT). Finally, the Medicare PFS payment amount (based on the below formula) for a given service and fee schedule area is calculated based on the previously discussed metrics.

PFS Payment = [(WorkRVU x WorkGPCI) + (PE RVU x PE GPCI) + (MP RVU x MP GPCI)] x CF

Beginning CY 2026, as required by statute[1], there will be two separate CFs: one for items and services furnished by a qualifying Advanced Alternative Payment Model participant (qualifying APM CF) and another for other items and services furnished by a non-qualifying APM participant (referred to as the non-qualifying APM conversion factor). The proposed qualifying APM CF is 33.5875 and the proposed non-qualifying APM conversion factor is 33.4209, as shown in Table 1 and 2. Both conversion factors are an increase from the CY 2025 CF of

[1] Section 1848(d)(1)(A) of the Social Security Act

33.3465. This increase is largely driven by a 2.50 percent statutory boost to the CF that was provided in recently passed legislation.[2] The payment impact of the proposed policies by specialty is shown in Table 92 of the Proposed Rule (pg. 452).

Calculation of the Proposed CY 2026 PFS Qualifying APM Conversion Factor		
CY 2025 Conversion Factor		**33.3465**
CY 2026 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2026 RVU Budget Neutrality Adjustment	0.55 percent (1.0055)	
CY 2026 2.50 Percent Increase	2.50 percent (1.0250)	
CY 2026 Conversion Factor		**33.5875**

Table 1. Calculation of the CY 2026 PFS Qualifying APM Conversion Factor

Calculation of the Proposed CY 2026 PFS Non-Qualifying APM Conversion Factor		
CY 2025 Conversion Factor		**32.3465**
CY 2026 Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2026 RVU Budget Neutrality Adjustment	0.55 percent (1.0055)	
CY 2026 2.50 Percent Increase	2.50 percent (1.0250)	
CY 2026 Conversion Factor		**33.4209**

Table 2. Calculation of the CY 2026 PFS Non-Qualifying APM Conversion Factor

Practice Expense Relative Value Units

The PE is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses. To establish PE RVUs for specific services, CMS must also establish the direct PE (e.g., clinical labor, supplies, equipment) and indirect PE (e.g., administrative labor, office expenses, and all other expenses) associated with each service.

To determine the direct portion of the PE RVU, CMS considers the sum of direct cost resources and refines this information for each CPT code based on recommendations from the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC). Alternatively, for the indirect portion of the PE RVU, CMS considers the direct portion of the PE RVU, either the clinical labor costs or the work RVUs (whichever is more), and uses survey data (e.g., AMA Physician Practice Information Survey (PPIS)) on indirect PEs incurred per hour worked to determine how to allocate a service's direct and indirect costs.[3] For procedures that can be furnished in a physician's office or facility setting, CMS establishes two separate PE RVUs: facility and non-facility.

CMS notes that when the PFS was established, the methodology for allocating indirect practice expense was based in part on an assumption that the physician maintained an office-based practice even when also practicing in a facility setting. In that context, the PE methodology has allocated the same amount of indirect costs per work RVU, without regard to setting of care.

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[2] https://www.congress.gov/bill/119th-congress/house-bill/1/text

[3] As noted in the Proposed Rule, CMS allocates the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. CMS also incorporates survey data to develop the indirect portion of the PE RVU.

In calculating the PE RVUs for services furnished in a facility, CMS excludes resources that physicians would not provide for the service (e.g., staff, supplies). For this reason, the facility PE RVUs are generally lower than the non-facility PE RVUs. CMS proposes changing how it allocates the indirect PE between facility and non-facility settings given the agency's concerns about potential duplicative payment under the current PE methodology for allocating indirect costs of physicians practicing in the facility setting. Specifically, for each service valued in the facility setting under the PFS, CMS proposes reducing the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to the non-facility PE RVUs beginning in CY 2026. CMS notes that this proposed change would occur in in step 8 of the PE RVU methodology which is described in the Proposed Rule (pg. 8). **CMS seeks comments on whether this proposal is an appropriate reduction or whether the agency should consider a different percentage reduction for CY 2026 or in future years. Additional questions related to the proposed PE RVU changes are included in the Proposed Rule (pg. 23).**

Medicare Economic Index

The Medicare Economic Index (MEI) reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index comprised of two broad categories: (1) physicians' own time (compensation); and (2) physicians' practice expense (PE). Additionally, it includes an adjustment for the change in economy-wide, total factor productivity (TFP) (which recently replaced the term multifactor productivity). While the MEI annual percentage change increase is not directly used to update the PFS CF, the MEI cost weights are used to update the GPCI (e.g., weighting the four components of the practice expense GPCI (employee compensation, the office rent, purchased services and medical equipment, supplies and other miscellaneous expenses)). The MEI is also used to recalibrate the relativity adjustment to ensure that the total pool of aggregate PE RVUs remains stable relative to the pool of work and MP RVUs, as noted above.

In the CY 2023 PFS Final Rule, CMS rebased and revised the MEI, which was based on 2017 data, to reflect more current market conditions faced by physicians, but did not implement this rebased and revised MEI for ratesetting purposes. In subsequent rulemaking, CMS continued to believe that delaying the implementation of the finalized 2017-based MEI cost share weights for the RVUs was consistent with the agency's efforts to balance payment stability and predictability with incorporating new data through more routine updates. Further, CMS decided to delay implementation as the AMA was working to collect practice expenses costs data from physician practices as historically, this information was relevant for the MEI.

As noted in the Proposed Rule, the AMA shared data from its Physician Practice Information (PPI) and Clinician Practice Information (CPI) Surveys with CMS for consideration when implementing the PE per hour (PE/HR) data and cost shares in the PFS ratesetting for CY 2026. However, CMS notes concern with the accuracy and suitability of the PPI and CPI surveys and is not proposing to implement the PE/HR cost shares from the AMA's survey data. Instead, CMS proposes to maintain the current PE/HR and 2006-based MEIs for CY 2026 ratesetting.

In addition, CMS notes that it has an ongoing contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. CMS also indicates that it intends to work with interested parties, including the AMA, to understand whether and how such data should be used in PFS ratesetting in future rulemaking.

Geographic Practice Cost Indices

By statute, CMS must develop separate GPCIs to measure the relative cost difference among localities compared to the national average for the work, PE and MP fee schedule components. CMS is required to review and potentially adjust the GPCIs at least every 3 years. There are also certain statutory requirements if more than one year has elapsed since the last update. The last GPCI updates were implemented in CY 2023 and CY 2024.

In accordance with statutory requirements, CMS proposes to phase in one half of the proposed GPCI adjustment in CY 2026 and the remaining half of the adjustment for CY 2027. Table 31 of the Proposed Rule (pg. 183) provides the proposed cost share weights for CY 2026 which are based on the 2006-based MEI weights to maintain stability. Addenda D and E of the Proposed Rule, which are available on the CMS website, provided the proposed GPCIs and summarized geographic adjustment factors (GAFs) for CY 2026.

New, Revised and Potentially Misvalued Codes

In the Proposed Rule, consistent with prior years, CMS reviews the work RVUs for new, revised and potentially misvalued codes. For CY 2026 CMS received 11 requests concerning various codes as potentially misvalued. Additional information regarding these codes is available in the Proposed Rule (pg. 26-35).

Valuation of Specific Codes: Proposed Efficiency Adjustment

Establishing RVUs for newly created and revised CPT codes is a routine part of maintaining the PFS. CMS has historically relied on survey data from the AMA/Specialty Society Relative Value Scale (RVS) Update Committee (RUC) to estimate practitioner time, work intensity and practice expense for the purpose of establishing RVUs for the codes used for payment under the PFS. Due to the agency's concerns about the quality of the survey data and the agency's belief that work RVUs have not adequately accounted for certain efficiencies (e.g., technology, procedural workflows, practitioner experience) for non-time-based services, CMS proposes a new methodology to account for efficiency gains which would be reflected in the valuation of work RVUs. The proposed methodology is detailed in the Proposed Rule (pg. 50-51) and the methodology relies on the MEI productivity adjustment, using a five-year look-back period. Based on this methodology, CMS proposes an efficiency adjustment of -2.5 percent for CY 2026.

CMS seeks comments on the initial look-back period and the use of the MEI productivity adjustment percentage values for calculation of the efficiency adjustment for 2026. Also, CMS seeks comments on whether adjustments should be made in future rulemaking to also adjust the direct PE inputs for clinical labor and equipment time that correspond with the physician time inputs.

If finalized for CY 2026, CMS proposes to apply the efficiency adjustment to the intra-service portion of physician time and work RVUs every 3 years. This timing would imply that the next efficiency adjustment after CY 2026 would be calculated and applied in CY 2029 PFS rulemaking, reflecting efficiency gains measured from 2027 through 2029. CMS proposes to update and apply the proposed efficiency adjustment with a cadence of every 3 years to align with the other updates under the PFS, including updates to the GPCI and MP RVUs, to allow for streamlining so that interested parties can expect updates on a similar timeframe.

CMS proposes to apply this efficiency adjustment to non-time-based services that it expects will accrue efficiencies over time. Additional information regarding the proposed codes is available in the Proposed Rule (pg. 52). **CMS seeks comments on the codes expected to accrue efficiencies over time.**

Also, CMS proposes that the public may nominate a code for review via the ''Potentially Misvalued Codes'' process if they believe the efficiency adjustment will lead to inaccurate physician time and work RVUs for the nominated code.

Payment for Services in Urgent Care Centers

In the CY 2025 PFS Proposed Rule, CMS requested feedback regarding urgent care centers and whether the current "Urgent Care Facility" Place of Service (POS) code (POS 20) adequately identifies and defines the scope of services furnished in such settings. In response, CMS received recommendations to create a new POS describing "enhanced" urgent care centers that offer specific diagnostic and therapeutic services and that operate outside typical business hours. More recently, CMS notes that one stakeholder recommended that CMS consider adopting a new POS code for ''enhanced'' urgent care centers and create a new add-on G-code.[4] The new G-code would describe the resource costs involved when practitioners furnish certain services in enhanced urgent care centers that offer extended hours and certain diagnostic and therapeutic services.

In the Proposed Rule, CMS seeks comments on whether separate coding and payment is needed for evaluation and management (E/M) visits furnished at urgent care centers, including whether an add-on code would be appropriate or if a new set of visit codes would be more practical. CMS is also interested in feedback regarding how either the code set, or the PE methodology, might be improved to better recognize the relative resources involved in furnishing services across different kinds of settings.

Use of Outpatient Prospective Payment System (OPPS) Data for PFS Ratesetting

As noted in the Proposed Rule, CMS has concerns with the quality of recent AMA survey data (i.e., AMA's PPI and CPI Surveys). As a result, CMS proposes to use hospital OPPS data to either set relative or absolute rates, especially for technical services paid under the PFS (i.e., radiation treatment delivery and superficial radiation therapy services, remote patient monitoring and remote therapeutic monitoring services and skin substitutes).

In the Proposed Rule, CMS further details this proposal as it reviews specific services, such as its proposal to establish PE RVUs for Radiation Oncology Treatment Delivery, Superficial Radiation Treatment and Proton Beam Treatment Delivery (e.g., pg. 73- 80) using OPPS data. Additional information and a comment solicitation regarding the methodology for remote

[4] The interested party suggested to CMS the following descriptor: ''Visit complexity inherent to evaluation and management associated with medical care services that serve as the immediate focal point for all needed urgent, non-emergent health care services and/or with urgent, nonemergent medical care services that are related to diagnosis and treatment of an unscheduled, ambulatory patient's urgent, non-emergent conditions. (Add-on code, list separately in addition to office/outpatient evaluation and management visits, new or established)'' and recommended that it be valued based on a crosswalk to HCPCS code G2211 (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (addon code, list separately in addition to office/outpatient evaluation and management visit, new or established) and made billable with all levels of office/outpatient E/M visits for both new and established patients when services are furnished in an enhanced urgent care center.

patient monitoring and remote therapeutic monitoring valuation is available in the Proposed Rule (pg. 85-87). Also, information regarding the proposed changes related to skin substitutes is available in the Proposed Rule (pg. 161-171) and below.

CMS seeks comment on whether it should adopt a single ratesetting methodology, such as a scaler, and how such a methodology would account for differences in practice expenses between services (e.g., services with extensive clinical staff time versus services where the valuation is primarily dependent on equipment costs).

Medicare Telehealth Services

Several conditions, such as patient eligibility, originating site, scope of distant site practitioners and communications methods, must be considered before Medicare will make payments for telehealth services under the PFS. In the Proposed Rule, CMS proposes several changes related to telehealth services, as outlined below.

Proposals to Modify the Medicare Telehealth Services List and Review Process

CMS maintains a Medicare telehealth services list, where services are assigned either a "permanent" or "provisional"[5] status after a 5-step review process. For CY 2026, CMS proposes to eliminate Step 4 (Consider whether the service elements of the requested service map to the service elements of services on the list that has a permanent status described in previous final rulemaking) and Step 5 (Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system) from the review criteria. CMS would retain Steps 1 through 3 of the existing process, which are listed in the Proposed Rule (pg. 37-38).

In addition, CMS proposes to remove the "permanent" and "provisional" designations so that all services on the Medicare Telehealth Services List would be included on a permanent basis. **CMS welcomes comments regarding safety and quality concerns regarding removal of Steps 4 and 5 and of these designations.** CMS emphasizes that a service's presence on the Medicare telehealth list does not indicate that CMS believes that telehealth may be appropriate in all circumstances; instead, the agency relies on providers to use their professional judgment to make appropriate determinations based on the needs of the individual patient.

For CY 2026, CMS received requests to add many categories of services to the Medicare Telehealth Services List, including Telemedicine E/M services, as noted in the Table 8 of the Proposed Rule (pg. 39). However, CMS proposes to add only the following categories of services to the Medicare Telehealth List for CY 2026, as noted in Table 9 of the Proposed Rule (pg. 41): Multiple-Family Group Psychotherapy, Group Behavioral Counseling for Obesity, Infectious Disease Add-on and Auditory Osseointegrated Sound Processor. CMS makes clear that it is not accepting the request to add Telemedicine E/M services (CPT codes 98000-98015) to the telehealth list since these services do not satisfy the agency's first

[5] A "provisional" status is assigned if there is not enough evidence to demonstrate that the service is of clinical benefit, but there is enough evidence to suggest that further study may demonstrate such benefit.

telehealth review step, which is that the services are not separately payable when furnished in person under the Medicare PFS.

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List, CMS includes certain frequency restrictions on how often practitioners may furnish the service via Medicare telehealth (e.g., one subsequent hospital care service furnished through telehealth every 3 days; one subsequent nursing facility visit furnished through telehealth every 14 days; and one critical care consultation service furnished through telehealth per day). While CMS provided additional flexibility related to frequency limitations during and after the COVID-19 Public Health Emergency (PHE), for CY 2026 CMS proposes to permanently remove frequency limitations on the following services furnished via telehealth: Subsequent Inpatient Visits (CPT 99231-99233), Subsequent Nursing Facility Visits (CPT 99307-99310) and Critical Care Consultation Services (G0508-G0209).

Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests and services incident to a physician's (or other practitioner's) professional service (incident-to services), are required to be furnished under specific minimum levels of supervision by a physician or other practitioner. The types of supervision are General Supervision, Direct Supervision and Personal Supervision. Before the COVID-19 PHE, for Direct Supervision, CMS required the supervising practitioner to be physically present in the office, but not necessarily in the same room. As a result of experiences during the COVID-19 PHE, in the CY 2025 PFS Final Rule, CMS permanently allowed virtual direct supervision via two-way audio/video communications technology for certain incident-to services and for a type of E/M visit (i.e., CPT Code 99211).

Due to stakeholder support to expand this policy to more types of services, CMS proposes to permanently adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all incident-to services[6], except for services that have a global surgery indicator of 010 or 090.[7] **CMS also seeks comment on patient safety and quality of care concerns for services that have a 000 global surgery indicator[8] and if it is necessary to exclude these services from allowing the presence of the physician (or other practitioner) to include virtual presence through audio/video real-time communications technology (excluding audio-only).**

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[6] CMS proposes to expand the policy to all services described under 42 CFR 410.26 (Services and supplies incident to a physician's professional services: Conditions)

[7] These global surgery indicators are defined in IOM Pub. 100–04, chapter 23, section 50.6 as 010 ''Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable'' and 090 ''Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount.''

[8] Endoscopies or some minor surgical procedures

CMS also seeks comments on applying the proposed definition of Direct Supervision to diagnostic x-ray tests, diagnostic laboratory tests and other diagnostic tests,[9] and the applicable cardiac, pulmonary and intensive cardiac rehabilitation services.

Proposed Changs to Teaching Physicians' Billing for Services Involving Residents with Virtual Presence

In prior rulemaking, due to changes related to the COVID-19 PHE, CMS permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location. For CY 2026, CMS is not proposing to extend this policy. Rather, CMS proposes that for services provided within Office of Management and Budget (OMB)-defined metropolitan statistical areas (MSAs), physicians must maintain physical presence during critical portions of all resident-furnished services to qualify for Medicare payment, not just in-person services. CMS proposes this policy only for those within MSAs to provide greater flexibility for rural healthcare providers.

Telehealth Originating Site Facility Fee Payment Amount Update

As required under statute, the telehealth originating site facility fee is increased by the percentage increase of the MEI. The proposed MEI increase for CY 2026 is 2.7 percent. Although more recent data may be used when the final rule is published, the proposed payment amount for CY 2026 for telehealth originating site facility fee (HCPCS code Q3014) is $31.85.

Evaluation and Management Visits: Office/ Outpatient (O/O) Evaluation and Management (E/M) Visit Complexity Add-on

In the CY 2024 PFS Final Rule, CMS finalized separate payment for the O/O E/M visit complexity add-on code (HCPCS code G2211[10]) but provided limitations on its use. For CY 2026, CMS proposes to broaden use of the add-on code by extending use to the home or residence E/M visits code family (CPT codes 99341, 99342, 99344, 99345, and 99347-99350).

Enhanced Care Management

Integrating Behavioral Health into Advanced Primary Care Management (APCM)

In the CY 2025 PFS Final Rule, CMS finalized coding and payment for APCM services (HCPCS codes G0556-G0558). However, stakeholders urged CMS to consider including behavioral health related care into APCM. In the Proposed Rule, CMS notes that it believes that physicians and practitioners who provide APCM services should be able to provide Behavioral Health Integration (BHI) services and Collaborative Care Model (CoCM) services, without needing to document their time spent performing the service, to reduce burden and support team-based care. Therefore, for CY 2026, CMS proposes to create optional add-on codes for APCM services that would facilitate providing complementary BHI services by

[9] *See* 42 CFR 410.32

[10] The full descriptor for the O/O E/M visit complexity add-on code, HCPCS code G2211, is (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).

removing the time-based requirements of the existing BHI and CoCM codes.[11] CMS indicates the proposed additional add-on codes (GPCM1-GPCM3) would be considered a "designated care management service" and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

In addition, CMS provides a Request for Information (RFI) related to APCM and prevention. **CMS is interested in comments on how it should consider the application of cost-sharing for APCM services and other coding changes to further recognize the work of advanced primary care practices in preventing and managing chronic disease.** Additional questions related to this RFI are available in the Proposed Rule (pg. 151).

Policies to Improve Care for Chronic Illness and Behavioral Health Needs

Updates to Payment for Digital Mental Health Treatment (DMHT)

In the CY 2025 PFS Final Rule, CMS finalized Medicare payment for DMHT devices beginning January 1, 2025, recognizing these devices as supplies furnished incident to professional behavioral health services under a treatment plan. CMS established three HCPCS codes (G0552–G0554) to support billing for device supply and monthly treatment management. Also, CMS established conditions of payment for the codes, such as a requirement that the device meet certain FDA-related criteria and that the billing practitioner must diagnose the patient with a mental health condition and prescribe or order the DMHT device.

In the Proposed Rule, CMS acknowledges that the technologies and platforms for digital therapeutics are rapidly evolving and that it is at an early stage of covering DMHT devices. For CY 2026, CMS proposes to expand payment for DMHT devices for Attention Deficit Hyperactivity Disorder (ADHD), which must meet FDA clearance or De Novo authorization and comply with validated effectiveness measures. Under this proposal, all the existing conditions of payment for HCPCS codes G0552–G0554 would apply. CMS does note that it does not believe it can appropriately price all the DMHT devices for which payment may be made under current policies and proposals. As a result, CMS is not proposing changes to the existing contractor-priced status for HCPCS code G0552. CMS continues to welcome information and may consider national pricing through future rulemaking.

In addition, CMS seeks comments on the possibility of establishing for CY 2026 additional separate coding and payment for a broader based set of services describing digital tools used by practitioners intended for maintaining or encouraging a healthy lifestyle, as part of a mental health treatment plan of care.

Comment Solicitation on Payment Policy for Software as a Service (SaaS)

CMS identifies several challenges in evaluating SaaS for clinical use and payment (e.g., wide and unverifiable cost variations among similar products, limited comparability to existing medical services due to their novelty, and a lack of sufficient Medicare claims data to assess utilization and value). CMS acknowledges that the absence of a consistent payment policy for

[11] CMS proposes to establish three new G-codes to be billed as add-on services when the APCM base code is reported by the same practitioner in the same month. Code descriptors for the proposed HCPCS codes (GPCM1-GPCM3) is available in the Proposed Rule (pg. 150-151)

SaaS and Artificial Intelligence (AI) devices may hinder patient access. **CMS seeks input on how SaaS and AI tools impact chronic disease management and primary care, and how their associated costs should be integrated into evolving payment models like Advanced Primary Care and risk-based arrangements under the PFS.**

CMS also indicates that its current PE methodology does not adequately account for the growing use of SaaS and artificial intelligence (AI) technologies in clinical care, particularly in outpatient and physician office settings. These technologies often involve licensing and analysis fees rather than traditional equipment costs, and outdated data sources do not capture their direct cost impact. **CMS requests suggestions on how to enhance the agency's ability to provide accurate and consistent payment for procedures incorporating SaaS.** Additionally, CMS notes that there is a comment solicitation in the CY 2026 Hospital Outpatient Prospective Payment (OPPS) Proposed Rule regarding SaaS furnished in hospital outpatient departments and ASCs.

RFI: Prevention and Management of Chronic Disease

In the Proposed Rule, CMS also poses various questions regarding how it can enhance support for prevention and management of chronic disease. These questions are available in the Proposed Rule (pg. 156-158).

Technical Refinements to Revise Terminology for Services Related to Upstream Drivers of Health

In the CY 2024 PFS Final Rule, CMS finalized coding and payment for HCPCS Code G0136, which relates to administration of a social determinants of health risk assessment tool. CMS believes the resource costs described by the code are already accounted for in existing codes. As such, CMS proposes to remove this code from the Medicare Telehealth List and make other conforming changes to the regulatory text related to annual wellness visits.

In addition, related to Community Health Integration Services (HCPCS code G0019), CMS proposes to replace the term "social determinants of health (SDOH)" with the term "upstream driver(s)" as the agency believes this term is more comprehensive and includes a variety of health factors that can impact the health of Medicare beneficiaries.

Payment for Skin Substitutes

In the Proposed Rule, CMS proposes significant changes regarding payment for skin substitute supplies to provide a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings.

Separate Payment for Skin Substitute Products as Incident-to Supplies

Generally, skin substitutes are paid separately in the non-facility setting as biologicals (i.e., ASP plus 6%), instead of as supplies, when used during a covered application procedure. In addition, each skin substitute product receives a unique billing code, typically a level II HCPCS code, and payment limit. In the CY 2022 PFS Final Rule, CMS finalized a payment approach for synthetic skins substitutes provided in the physician office settings.
Since CY 2014, under the OPPS, CMS unconditionally packaged skin substitute products furnished in the hospital outpatient setting (OPD) into their associated application procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, CMS also

finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group. In the CY 2021 OPPS Final Rule, CMS revised the description of skin substitutes to include both biological and synthetic products.

Starting CY 2026, CMS proposes to separately pay for the provision of certain groups of skin substitute products (e.g., products coverable under Medicare rules) as incident-to supplies[12] when they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. CMS clarifies that this proposal does not apply to biological products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology.[13]

CMS notes that it may consider packaging skin substitute products with the related application procedures in both the OPD setting and non-facility setting in future rulemaking. **CMS seeks comments on the proposal to separately pay for the provision of certain groups of skin substitute products, as well as the proposal to implement this policy in both the non-facility and hospital outpatient settings.** Additional information regarding the OPPS proposal for skin substitutes is available in the CY 2026 OPPS Proposed Rule.

Establishing RVU and Initial Payment Rates

In the Proposed Rule, CMS indicates that it developed initial payment rates for each group of skin substitute products (grouping is based on three FDA regulatory categories) based on the weighted, per-unit average of ASPs for the fourth quarter of calendar year 2024. These initial payment rates are listed in the file titled ''Skin Substitute Products by FDA Regulatory Category'' on the CMS website under downloads for the CY 2026 PFS proposed rule. Notably, in establishing payment rates when ASP data was not available, CMS used hospital cost report data, which has not historically been used to establish or adjust practice expense RVUs.

CMS also proposes to use hospital utilization patterns to inform payment rates for skin substitutes under the PFS. In future rulemaking, CMS intends to use claims data to inform payment rates which would likely result in payment valuations that diverge based on the updated data.

CMS indicates that the proposed PE and MP RVUs would result in an initial payment rate of approximately $125.38/cm^2 for skin substitute products in all three FDA regulatory categories (including PMA approved devices, 361 HCT/Ps, and 510(k) cleared devices) prior to the application of the geographic adjustments, for CY 2026. Additional information regarding how CMS determines this rate is available in the Proposed Rule (pg. 169-170).

CMS seeks comments on the proposal to establish PE RVUs and initial payment rates for skin substitute products in each of the three FDA regulatory categories using ASP,

[12] ''Incident-to supplies'' refers to supplies that are furnished as an integral, although incidental, part of the physician's professional services in the course of diagnosis or treatment of an injury or illness

[13] FDA regulates products that CMS considers to be skin substitutes. The relevant categories of FDA regulation noted in the Proposed Rule are: Self-determination Under Section 361 of the PHS Act and the Regulations in 21 CFR 1271 (361 Human Cells, Tissues, and Cellular Tissue-Based Products (HCT/Ps)); 510(k) Premarket Notification Submissions, Premarket Approval Applications, and De Novo Requests; and Biologics License Application (BLA). Additional information regarding these categories is available in the Proposed Rule (pg. 167). CMS also proposes to codify the definition of "biological" as ''a product licensed under section 351 of the Public Health Service Act'' at §§ 414.802 and 414.902.

or Mean Unit Cost (MUC) when ASP is not available, using per-unit averaged pricing data from the fourth quarter of 2024. CMS also seek comments on whether these calculations, if finalized, should be updated with the most recently available data at the time the final rule is drafted.

Strategies for Improving Global Surgery Payment Accuracy

As noted in the Proposed Rule, there are thousands of physicians' services that are coded and valued under the PFS as global surgical packages ("globals"). Globals are single codes that are valued to include all services provided during a specified period of days (0-day, 10-day, or 90-day global packages) by a physician (or another practitioner in the same group practice for a specific surgical procedure). In the Proposed Rule, CMS indicates that it is considering steps to improve the accuracy of global surgical service valuation and payment for these services, particularly related to setting the procedure shares.[14] CMS outlines different potential approaches to set procedure shares and seeks comments related to each approach in the Proposed Rule (pg. 173).

Drugs and Biological Products Paid Under Medicare Part B

Average Sales Price Calculation

In many cases, payment for separately payable Part B drugs is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. If CMS determines a payment limit for a drug, it is published in the ASP pricing file or Not Otherwise Classified (NOC) pricing file, which are both updated quarterly. Manufacturers are required to report ASP and part of the ASP calculation requires manufacturers to deduct price concessions (e.g., volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under the Medicaid Drug Rebate Program and the Medicare Prescription Drug Inflation Rebate Program)). Bona Fide Service Fees (BFSF) are not considered price concessions and therefore are not deducted when calculating the ASP.

While there are existing regulations and guidance related to the ASP calculation, CMS highlights a December 2022 Office of Inspector General (OIG)-published report entitled "Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices"[15], which recommended that CMS consider whether additional guidance would ensure more consistent ASP calculations. As a result, CMS proposes various clarifications and policy regarding price concessions, including treatment of bundled arrangements and fees presumed to be price concessions. In addition, CMS proposes to update the definition of BFSF and to provide further guidance to demonstrate how different types of fees should be considered in the ASP calculation.

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[14] Currently, Medicare pays surgeons a fixed share of a global procedure's valuation when billed with specified modifiers, specifically, modifier -54. These "procedure shares" are based on long-standing assumption and are clustered at certain values, for example, 79 percent, 80 percent, or 81 percent for roughly half of procedures with 90-day global periods and 90 percent for most procedures with 10-day global periods (the remaining approximately 20 percent and 10 percent for 90-day and 10-day procedures, respectively, account for post-operative care).

[15] https://oig.hhs.gov/reports/all/2022/manufacturers-may-need-additional-guidance-to-ensure-consistent-average-sales-price-calculations/

Also, CMS proposes to modify the approach for ASP reporting related to autologous cell-based immunotherapy or gene therapy. Specifically, CMS proposes that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself and that, beginning January 1, 2026, any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that were paid for by the manufacturer be included in the calculation of the manufacturer's ASP.

Lastly, CMS clarifies that the Maximum Fair Price (MFP), which is negotiated as part of the Medicare Drug Price Negotiation Program, is to be included in manufacturers' ASP calculations. CMS indicates this policy is effective January 1, 2026.

Medicare Prescription Drug Inflation Rebate Program

The Inflation Reduction Act (IRA) established new requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. For Part B drugs, CMS considers the rate of inflation for a calendar quarter, starting with the first quarter of 2023. For Part D drugs, CMS considers the rate of inflation over a 12-month period, beginning with October 1, 2022. Related to Parts B and D, CMS proposes different approaches to calculating the payment amount in the payment amount benchmark quarter, depending on specific circumstances (e.g., no ASP or WAC data available, quarters with monthly units but no Average Manufacturer Price).

In addition, specific to Part D, CMS proposes to use a claims-based methodology to exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program. CMS proposes to use this methodology to exclude 340B units starting on January 1, 2026. Under the methodology, CMS would evaluate whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered 340B covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE as a 340B contract pharmacy (hereinafter ''Prescriber-Pharmacy Methodology''). CMS acknowledges that this proposal, which relies on the 340B OPAIS database[16], may not list covered entities that have an "in house" pharmacy that are not registered in the OPAIS database. **CMS seeks comments on whether and how to account for this limitation in the identification of 340B dispenses in the Prescriber-Pharmacy Methodology.** Also, CMS acknowledges that the proposed methodology may overestimate the number of units that are 340B-eligible. Additional information regarding this methodology is available in the Proposed Rule (pg. 289-290).

Also, CMS proposes to establish a 340B repository, which would launch in Fall 2026, to receive voluntary submissions from 340B covered entities of certain data elements from Part D 340B claims.[17] CMS indicates that it intends to allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B

[16] https://340bopais.hrsa.gov/

[17] For those covered entities voluntarily reporting, CMS proposes to collect identifying information and the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy NPI; and (5) NDC–11.

Program beginning in 2026 to begin testing the usability of the 340B repository. CMS would require covered entities to certify the completeness and accuracy of the data submitted, and attest that the submitter is authorized to submit on behalf of the entity. Also, CMS indicates it is exploring approaches to confirming completeness and accuracy of data submissions to the 340B repository and is soliciting comments on methods to review and ensure the accuracy of reported data. CMS would match the stored data elements in the 340B repository to Prescription Drug Event (PDE) transactions for each Part D rebatable drug dispensed during the applicable period. If CMS determines that the data reported to the repository is usable and reliable, then in the future, CMS may propose policy to use such data to exclude 340B units from rebate calculations. CMS also indicates that data submitted to the repository would not be made available to external parties (e.g., manufacturers, Part D plan sponsors). CMS strongly encourages all covered entities to submit data elements to the 340B repository during the 2026 testing period and indicates it will address the possibility of mandatory reporting in future years in rulemaking.

Ambulatory Services Model

Under the authority of the Center for Medicare and Medicaid Innovation (CMMI or Innovation Center), CMS proposes a new mandatory alternative payment model, the Ambulatory Specialty Model (ASM), which focuses on heart failure and low back pain. The ASM's duration is 5 performance years and would begin January 1, 2027. ASM would test whether adjusting payment for specialists based on their performance on targeted measures of quality, cost, care coordination and meaningful use of certified electronic health record (EHR) technology (CEHRT) results in enhanced quality of care and reduced costs through more effective upstream chronic condition management. Vizient is in the process of developing a summary of the ASM, which will be available here once released. Additional information about the ASM is also available from CMS here.

Shared Savings Program

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program (SSP) by forming or joining an accountable care organization (ACO). Under the SSP, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances, may be required to share in losses if it increases health care spending. Under the SSP, there are different participation tracks (i.e., BASIC[18] or ENHANCED[19]) that allow ACOs to assume various levels of risk. As of January 1, 2025, the SSP has 477 ACOs with over 650,000 healthcare providers and organizations providing care to over 11.2 million assigned beneficiaries.

Considerations for Timing of ACOs' Progression to Performance-Based Risk in the Shared Savings Program

[18] Currently, the BASIC track offers a glide path for eligible ACOs to transition from a one-sided shared savings-only model to progressively higher increments of financial risk and potential reward under two-sided shared savings (otherwise referred to as performance-based risk) and shared losses models within a single 5-year agreement period.
[19] Currently, the ENHANCED track offers ACOs the opportunity to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards.

CMS continues to believe that financial models under which ACOs bear a degree of financial risk have potential to induce more meaningful systematic change in providers' and suppliers' behavior towards meeting the SSP's goals, compared to one-sided models. As a result, CMS is revisiting various SSP policies on the amount of time an ACO can remain under a one-sided model and the progression to performance-based risk, including the current policy that allows ACOs to participate for up to 7 performance years under a one-sided model. Specifically, CMS proposes that for agreement periods beginning on or after January 1, 2027, an ACO that is inexperienced with performance-based risk Medicare ACO initiatives entering the BASIC track's glide path at Level A may continue to elect to remain under a one-sided model for all subsequent performance years of its first 5-year agreement period. However, CMS proposes that such an ACO must enter its second or subsequent agreement period under Level E of the BASIC track or the ENHANCED track, with limited exceptions.

In the Proposed Rule, CMS clarifies that if the proposed approach is finalized, ACOs currently participating in a first agreement period under the BASIC track's glide path (with 2022, 2023, 2024 and 2025 start dates) and ACOs entering a first agreement period in the BASIC track's glide path with the January 1, 2026 start date, would be ineligible to enter a subsequent agreement period under the BASIC track's glide path, with a start date on or after January 1, 2027. Instead, such ACOs, should they continue their participation in the SSP for a second or subsequent agreement period, would be limited to participation in Level E of the BASIC track or the ENHANCED track (subject to the exception prohibiting ACOs with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, from participating in the ENHANCED track). **CMS seeks comment on this proposal.**

Eligibility Requirements

In the Proposed Rule, CMS addresses various circumstances that could impact eligibility for SSP, including ACO Participant Change of Ownership (CHOW) Scenarios (pg. 308-311) and skilled nursing facility (SNF) affiliate CHOW scenarios (pg. 311-312).

In addition, under the SSP regulations, CMS ''deems'' an ACO to have initially satisfied the statutory requirement to have at least 5,000 assigned Medicare FFS beneficiaries, if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the three historical benchmark years. CMS proposes changes to the SSP to allow for participation by ACOs with a minimum of 5,000 assigned beneficiaries in their third benchmark year, even if the ACO has fewer than 5,000 assigned beneficiaries in benchmark year (BY) 1, BY2, or both. In addition, CMS proposes safeguards to limit ACOs entering a new agreement period with fewer than 5,000 assigned beneficiaries in BY1, BY2, or both, at the time of application, to participation in the BASIC track.

CMS also proposes to apply an alternative performance payment limit and loss recoupment for ACOs with fewer than 5,000 assigned beneficiaries in any of their benchmark years. Tables 49 and 50 of the Proposed Rule (pg. 318-319) provide examples of the alternative payment limit and alternative calculations that would apply for an ACO with fewer than 5,000 assigned beneficiaries in at least one benchmark year under the proposal. Also, for these ACOs, CMS proposes to limit their use of policies that provide certain low revenue ACOs participating in the BASIC track with additional opportunities to share in savings.

Revisions to the Definition of Primacy Care Services Used in SSP Beneficiary Assignment

To implement a statutory requirement, CMS determines an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of certain primary care services for performance years beginning on or after January 1, 2019. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment. In prior rulemaking, CMS identified the types of primary care services that are relevant for purposes of assigning beneficiaries to ACOs.

Based on feedback from ACOs and the agency's review of HCPCS and CPT codes used for reimbursement under the PFS, CMS proposes a revised definition of primacy care services used for assignment for the performance year starting on January 1, 2026, and subsequent performance years. CMS proposes adding the Enhanced Care Model Management Services (HCPCS Codes GPCM1, GPCM2 and GPCM3) to the definition of primary care services. Also, CMS proposes to remove HCPCS code G0136 (Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5–15 minutes) from the definition of primary care services. **CMS seeks comments on any other existing or new HCPCS or CPT codes proposed elsewhere in the Proposed Rule that the agency should consider adding to the definition of primary care services for purposes of ACO assignment in future rulemaking.**

Quality Performance Standard & Other Quality Reporting Requirements

CMS uses quality performance standards to assess ACOs for the quality of care furnished. Over time, these performance standards may change, including specifying higher standards, new measures, or both for purposes of assessing such quality of care.

In the Proposed Rule, CMS offers various changes related to quality, including proposing a revised definition of a beneficiary eligible for Medicare Clinical Quality Measures for ACOs Participating in the Medicare SSP (Medicare CQMs). Due to concerns raised by ACOs, CMS proposes to apply a revised definition of Medicare CQMs effective January 1, 2025 and for subsequent performance years. For example, CMS proposes to revise the definition to require "at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included at § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.'' A complete list of the changes are noted in the Proposed Rule (pg. 325). CMS anticipates that the proposed changes would reduce ACOs' burden in patient matching necessary to report Medicare CQMs as there would be greater overlap with the list of beneficiaries that are assignable to an ACO.

In the CY 2025 PFS Final Rule CMS finalized a phase-in schedule for incorporating measures into the APP Plus quality measure set.[20] In the Proposed Rule, Table 51 (pg. 330) outlines the proposed APP Plus quality measure set for SSP ACOs for performance year 2028 or the performance year that is one year after the eCQM specification becomes available for Quality ID: 493 Adult Immunization Status, whichever is later. CMS also proposes revisions impacting performance years 2025 and 2026, which are outlined in Table 52 and 53 (pg. 332-334) of the Proposed Rule.

[20] The APP Plus Quality Measure Set was created in the CY 2025 PFS Final Rule and aims to align with the Adult Universal Foundation measures.

Also, CMS proposes changes to the SSP quality reporting monitoring provisions, including that the agency may take additional actions prior to termination if an ACO fails to meet both the quality performance standard and the alternative quality performance standard.

In addition, CMS proposes to remove the health equity adjustment applied to an ACO's quality score beginning in performance year 2025, and to revise the terminology in the SSP regulation used to describe the health equity adjustment and other related terms. For example, instead of using the phrase "health equity adjusted quality performance score", CMS proposes the phrase "quality score" and instead of "health equity adjustment bonus points", CMS proposes the phrase "population and income adjustment bonus points". In the Proposed Rule (pg. 328-329) CMS proposes other, similar changes to existing regulations. Also, CMS proposes to rename the Health Equity Benchmark Adjustment, which was finalized in the CY 2025 PFS Final Rule, to the "Population Adjustment". CMS makes clear it is proposing to revise only the terminology in the regulations and that the calculations in the regulations would be unchanged if the proposal is finalized.

The agency also proposes expanding the application of the quality and finance Extreme and Uncontrollable Circumstances (EUC) policies to ACOs and APM Entities that are affected by an EUC due to a cyberattack, among other EUC-related proposals.

Lastly, CMS emphasizes its interest in transition to digital quality measurement (dQM) in CMS quality reporting and value-based purchasing programs. The agency provides a related RFI in the Proposed Rule (pg. 334) specific to the SSP.

Updates to the Quality Payment Program (QPP)

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the QPP for eligible clinicians. Under the QPP, MIPS eligible clinicians can participate via one of two tracks – the MIPS (reporting via traditional MIPS or MIPS Value Pathways (MVPs)) and APMs. Generally, the Proposed Rule sets forth changes to the QPP starting January 1, 2026 and highlights that CMS remains interested in sunsetting traditional MIPS in the future. Among several other highlights and proposals, CMS proposes six new MVPs and issued several RFI related to MVPs, a timeline for implementing Fast Healthcare Interoperability Resources (FHIR) and the Promoting Interoperability performance category. CMS also provides several resources regarding the Proposed Rule on the Quality Payment Program website and a Fact Sheet and Policy Comparison Table for download.

What's Next?

CMS typically publishes the PFS final rule by early November, with effective dates of most policies being January 1, 2026. The comment period closes on September 12, 2025.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued client feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.