799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

**Vizient Office of Public Policy and Government Relations**

# 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

**November 14, 2025**

## Background & Summary

On October 31, the Centers for Medicare & Medicaid Services (CMS) issued the annual final rule to update the Calendar Year (CY) 2026 Medicare payment and policies for the Physician Fee Schedule (PFS) (hereinafter, "Final Rule"). The Final Rule revises payment policies under the Medicare PFS, including a new efficiency adjustment which would reduce payments for most services and changes to the agency's approach to covering skin substitutes. Also, CMS finalized policy to implement the Medicare Inflation Rebate Program and changes related to manufacturers' reporting of Average Sales Price (ASP).

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

The final regulations are effective January 1, 2026, with some exceptions.

## Major Proposals Finalized and Key Changes from the Proposed Rule

### Conversion Factor and Payment Update

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 items and services furnished by a non-qualifying APM participant (referred to as the non-qualifying APM CF).

The final qualifying APM CF is 33.5675 (the proposed APM CF was 33.5875) and the final non-qualifying APM CF is 33.4009 (the proposed non-qualifying APM conversion factor was 33.4209), as shown in Table 1 and 2. The increase from CY 2025 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 final policies by specialty is shown in Table D-B7 of the Final Rule (pg. 1738-1741).

| Table 1: Calculation of the Final 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 | 0.49 percent (1.0049) | |
| CY 2026 2.50 Percent Increase | 2.50 percent (1.0250) | |
| **CY 2026 Conversion Factor** | | **33.5675** |

[1] Section 1848(d)(1)(A) of the Social Security Act
[2] https://www.congress.gov/bill/119th-congress/house-bill/1/text

| Table 2: Calculation of the Final 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 (1.0049) | |
| CY 2026 2.50 Percent Increase | 2.50 percent (1.0250) | |
| **CY 2026 Conversion Factor** | | **33.4009** |

## Efficiency Adjustment

CMS finalized a new "efficiency adjustment" to the work RVUs and corresponding updates to the intraservice portion of physician time for non-time-based services, with refinements. CMS will apply the efficiency adjustment to the intraservice portion of physician time and work RVUs every three years. In response to stakeholder concerns that efficiencies may not accrue indefinitely, CMS will monitor the impact of the efficiency adjustment over time. Also, CMS may revisit the frequency and consider establishing a sunset provision or other refinements in future rulemaking.

The methodology and other issues related to the efficiency adjustment is further detailed in the Final Rule (pg. 188-208). The CY 2026 efficiency adjustment is -2.5 percent and relies on the use of the Medicare Economic Index productivity adjustment over a five-year lookback period from CY 2022-2026.

CMS finalized exemptions to the efficiency adjustment, specifically time-based codes, services on the CMS telehealth list and new codes for CY 2026, as reflected in the Codes Subject to Efficiency Adjustment file (available for download on the CMS website).

## Practice Expense

### Indirect portion of the PE RVU

To establish practice expense (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. CMS finalized the proposal to stop using the American Medical Association's survey data to determine the PEs incurred per hour worked (PE/HR) data or cost shares.[3] Instead of updating the PE/HR data or cost shares, CMS finalized the proposal to maintain the current PE/HR data and cost shares for CY 2026 PFS ratesetting. CMS indicates that it remains interested in information that could help inform updates to the PE/HR data or cost shares through future rulemaking.

### Updates to the Practice Expense Methodology – Site of Service Payment Differential

Due to the agency's belief that allocating the same amount of indirect PE based on work RVUs for facility and non-facility settings may overstate the range of indirect costs incurred by facility-based physicians, CMS proposed and finalized updates to the PE methodology to address this differential. Specifically, for each service valued in the facility setting under the PFS, CMS proposed changing the PE RVU methodology by reducing the portion of the facility PE RVUs allocated based on work RVUs

[3] For the indirect portion of the PE RVU, CMS proposed policy to deviate from the agency's prior practice to consider survey data (e.g., AMA Physician Practice Information Survey (PPIS) and AMA Clinician Practice Information (CPI) survey) on indirect PEs incurred per hour worked (PE/HR) to determine how to allocate a service's direct and indirect costs.

to half the amount allocated to the non-facility PE RVUs, beginning in CY 2026. CMS finalized the policy largely as proposed with some variations. For example, CMS finalized policy to exclude codes with MMM global periods (maternity services) from the adjustment.

## 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 Malpractice (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 passed since the last update. In accordance with statutory requirements, CMS finalized the proposal to phase-in one half of the proposed GPCI adjustment in CY 2026 and the remaining half of the adjustment in CY 2027. The final GPCIs are displayed in Addenda D of the Final Rule.

## Medicare Telehealth Services

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

### Modifications to the Medicare Telehealth Services List and Review Process

CMS finalized policy to retain only steps 1-3 of the current 5-step review process for adding services to the Medicare telehealth services list. Specifically, CMS eliminated 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.

In addition, CMS finalized as proposed the removal of the “permanent” and “provisional” designations so that all services on the Medicare Telehealth Services List would be included on a permanent basis.

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 A-DI of the Final Rule (pg. 143). Consistent with the Proposed Rule, CMS finalized adding only the following categories of services to the Medicare Telehealth List for CY 2026: Multiple-Family Group Psychotherapy, Group Behavioral Counseling for Obesity, Infectious Disease Add-on and Auditory Osseointegrated Sound Processor, as outlined in Table A-D2 (Final Rule pg. 154). CMS found that Telemedicine E/M services do not meet Step 1 of the review process since the services are not separately payable when furnished in-person and, as a result, declined to add these services to the Telehealth Services List.

In the Final Rule, CMS also clarified the applicability of telehealth rules to Digital Mental Health Treatment (DMHT), Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) services. Specifically, CMS indicated that these services, which are inherently non-face-to-face, do not meet the statutory definition of Medicare telehealth service and do not meet Step 2 of the

agency's review process. CMS also clarified that a telehealth place of service would not be used for the services.[4]

Although CMS proposed deleting HCPCS code G0136 (Social Determinants of Health Risk Assessment) from the Medicare Telehealth Services List, based on public comment, the agency did not finalize this proposal and instead revised the code descriptor as related to an assessment of physical activity and nutrition.

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

For CY 2026 CMS finalized the proposal 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). In the Final Rule, CMS indicated that it may consider additional safeguards (e.g., enhanced claims monitoring or evidence-based utilization management) for future rulemaking.

## 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 finalized policy 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, except for services that have a global surgery indicator of 010 or 090.[5] In the Final Rule, CMS also clarifies that the definition of direct supervision does not mean that it is appropriate to allow for virtual presence for every service for every Medicare beneficiary in every clinical scenario and practitioner judgment should be used to determine the appropriate supervision modality on a case-by-case basis.

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[4] In the Final Rule, CMS indicates, "a telehealth place of service would not be used for services that are not subject to section 1834(m) of the Act" and, regarding Digital Mental Health Treatment (DMHT), Remote Physiologic Monitoring (RPM), and Remote Therapeutic Monitoring (RTM) services, "These services are not subject to section 1834(m) of the Act."

[5] 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.''

### Changes 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, though CMS did not propose to extend this policy and provided an alternative proposal, in the Final Rule, CMS changed course. Specifically, in response to stakeholder comments, CMS finalized policy to permanently allow teaching physicians to have a virtual presence in all teaching settings, only in certain clinical instances (e.g., the service is a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). CMS clarifies that this will continue to permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought, through audio/video real-time communications technology, for all residency training locations. CMS also reiterated that documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology.

### 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 Medicare Economic Index (MEI). The final MEI increase for CY 2026 is 2.7 percent and the payment amount for CY 2026 for the telehealth originating site facility fee (HCPCS code Q3014) is $31.85.

### Distant Site Requirements

In the Final Rule, CMS indicates that many stakeholders requested clarification regarding the perception of an expiring flexibility for telehealth practitioners to use their currently enrolled location instead of their home address when providing services from their home. In the Proposed Rule, CMS did not provide a proposal to extend this flexibility and in comments, stakeholders requested this flexibility be extended as done in CY 2024 and CY 2025 PFS Final Rules. In the Final Rule, CMS highlighted a recent FAQ which provides additional information on how providers furnishing telehealth-based medical care can prevent their home address and personal phone number from being published by CMS. Given this information from CMS, in the Final Rule, the agency indicated it does not believe that additional "extensions" of CY 2024 and CY 2025 policies are required via rulemaking. Also, CMS reminded stakeholders that that the agency defers to State law regarding licensure requirements for distant site Medicare telehealth practitioners. In addition, CMS noted that a separate Medicare enrollment is required for each State in which the practitioner furnishes and intends to bill for covered Medicare services. CMS also clarified that in the future any updates to this policy will be issued via subregulatory guidance.

### 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[6]) but provided limitations on its use. For CY 2026, CMS finalized as proposed policy 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). CMS also reminded stakeholders that the add-on code for inherent complexity (HCPCS code G2211) intends to address the lack of distinction between E/M codes used to describe visits that involve a longitudinal relationship between the practitioner and patient compared to visits that do not. Should additional changes be needed, these could be addressed through future rulemaking.

In addition, CMS responded to stakeholder comments expressing concern about prior budget neutrality adjustments that were excessive since CMS overestimated utilization of HCPCS code G2211. While CMS acknowledged that the CY 2024 utilization estimate exceeded actual reporting of HCPCS code G2211 in CY 2024, the agency reminded commenters that it does not make retrospective budget neutrality adjustments and would not compare actual claims reported for new coding against the utilization estimates made in the PFS final rule for the year in which such reporting began.

## 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 Final Rule, CMS restates its belief 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 finalized the creation of optional add-on codes for APCM services that would facilitate providing complementary BHI services by removing the time-based requirements of the existing BHI and CoCM codes. CMS indicates the additional add-on codes (HCPCS codes G0568, G0569 and G0570)[7] 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. Consistent with the Proposed Rule, CMS clarifies the new G-codes could be billed as an add-on service when the APCM base code is reported by the same practitioner in the same month.

## Policies to Improve Care for Chronic Illness and Behavioral Health Needs

### 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. In the Final Rule, consistent with commenters’ suggestions, CMS did not finalize the proposal to delete the code.

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[6] 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).

[7] HCPCS code G0568, an add-on code based on CPT code 99492 for an initial month of CoCM services delivered to patients also receiving APCM services, HCPCS code G0569, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and HCPCS code G0570, an add-on code for general behavioral health integration services based on CPT code 99484

Rather, CMS finalized policy to recharacterize the code to align with the administration's efforts to address the root causes of chronic illness. As such, CMS will retain HCPCS code G0136 and revised the code descriptor to read "Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5-15 minutes, not more often than every 6 months."

CMS further clarified that, beginning in CY 2026, the purpose of HCPCS code G0136 is to identify and value the work involved in administering a physical activity and/or nutrition risk assessment as part of a comprehensive medical history when medically reasonable and necessary in relation to the associated E/M or behavioral health visit. CMS expects that the practitioner furnishing HCPCS code G0136 would, at a minimum, refer the patient to relevant resources and consider the results of the assessment in their medical decision-making, or diagnosis and treatment plan for the visit.

## Payment for Skin Substitutes under the PFS and Outpatient Prospective Payment System (OPPS)

In the Final Rule, CMS finalized 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

Starting in CY 2026, CMS finalized the proposal to separately pay for the provision of certain groups of sheet skin substitute products (e.g., products coverable under Medicare rules) as incident-to supplies[8] when they are used during a covered application procedure paid under the PFS in the non-facility setting or under the Outpatient Prospective Payment System (OPPS). CMS reiterated that this final policy 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.[9]

CMS also clarified that the assigning of codes describing the provision of these products' PE RVUs does not have a direct, initial impact on the calculation of other PE RVUs. Instead, the future changes in rates for these services will be incorporated into PFS relativity and budget neutrality once data become available.[10]

After consideration of stakeholder comments, CMS finalized a policy to also consider skin substitutes that are not in sheet form (e.g., gels, powders, liquids, injectables, 3D-printed constructs, etc.) to be incident-to supplies under this policy but agreed with stakeholders that units for these products are difficult to standardize for payment purposes. To address the need to establish a payment mechanism for non-sheet form skin substitutes in the non-facility setting, CMS will maintain the current coding mechanism for these products and will direct Medicare Administrative Contractors (MACs) to continue to determine appropriate payment. In addition, for CY 2026, CMS revised HCPCS

[8] ''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

[9] FDA regulates products that CMS considers to be skin substitutes. The relevant categories of FDA regulation noted in the Final 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). CMS also finalized a definition of "biological" as ''a product licensed under section 351 of the Public Health Service Act'' at §§ 414.802 and 414.902.

[10] CMS indicated in the Final Rule, once data becomes available for CY 2027 and is incorporated into PFS ratesetting, overall reductions in payment amounts for skin substitutes could have a positive result on PFS relativity and budget neutrality for other services paid under the PFS by CY 2028.

code A4100 (Non-sheet form skin substitute, FDA cleared as a device, not otherwise specified (list in addition to primary procedure)) to allow billing for non-sheet form skin substitute products that do not yet have a more specific code. CMS will continue to evaluate payment for these products to determine if an alternative payment methodology may be better suited to non-sheet products.

### Establishing RVU and Initial Payment Rates

CMS finalized the proposal to group skin substitutes (other than those approved via BLA under section 351 of the PHS Act) into three FDA categories, PMA, 510(k) and 361 HCT/Ps, for purposes of developing payment rates in future notice and comment rulemaking. For CY 2026 only, CMS finalized the proposal to establish the same initial rate for each group of skin substitutes, including 510(k)-cleared devices, registered 361 HCT/Ps and PMA-approved devices. As a result, for CY 2026, the final payment rate is approximately $127.28 per $cm^3$, an increase from the Proposed Rule's rate of $125.38 per $cm^3$, which was due to FDA misclassifications that stakeholders had identified, rather than a change in methodology. Differential rates for each group are anticipated in future rulemaking.

CMS finalized policy to convert all skin substitute products to add-on codes with an indicator of ZZZ.[11] The RVUs and indicator statuses can be found in Addendum B in the Download files under the CY 2026 PFS Rule Addenda.

## Average Sales Price

For various reasons, including recommendations from a December Office of Inspector General (OIG) report, CMS proposed various changes and clarifications related to ASP calculations. In the Final Rule, the agency finalized some, but not all, of the proposed changes.

### Bundled Sale Price Concessions

While CMS proposed adding a definition for bundled arrangements and provides additional clarity in regulations to help manufacturers allocate discounts under bundled arrangements, the agency did not finalize the definition exactly as proposed.[12] Rather, CMS finalized a definition of bundled arrangements, but decided to exclude the terms "purchasing patterns" and "prior purchases", which were included in the proposed definition. CMS clarifies the final definition is effective for sales occurring on or after January 1, 2026, which is reflected in the Medicare Part B Drug Payment File beginning July 2026. The finalized definition is:

> "Bundled arrangement means 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

[11] Per CMS, ZZZ = Code related to another service. Medicare always includes it in the global period of the other service.
[12] As noted in the Final Rule, CMS "proposed to add a definition of the term bundled arrangement to § 414.802, similar to that which was proposed in the CY 2008 PFS proposed rule. Specifically, we proposed the definition to state "Bundled Arrangement means 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." "We also proposed adding paragraphs (iii) and (iv) at § 414.804(a)(2) to provide manufacturers with additional guidance on how to allocate discounts under bundled arrangements, which aligns with Medicaid's definition of bundled sale further described later in this section."

formulary), 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."[13]

In the Final Rule, CMS also finalized guidance regarding how to account for unbundling a bundled arrangement and allocating discounts for bundled sales.

### Bona Fide Service Fees

The term Bona Fide Service Fees (BFSF) includes four conditions that must be met to be considered a BFSF rather than a price concession to be deducted from ASP.[14] Although CMS proposed language regarding fair market value (FMV) methodology standards, FMV reassessments, and independent third-party valuator requirement, CMS did not finalize these proposals. In addition, CMS did not finalize the proposal that manufacturers reassess FMV upon contract renewal. However, CMS did finalize a portion of the initial proposal that manufacturers should provide summary information on FMV assessments as part of their reasonable assumptions. CMS will use "reasonable assumptions" to better understand the scope and frequency of FMV reassessments, and this information will aid with informing future policy developments.

In the Final Rule as related to the BFSF definition, CMS did not finalize the proposed list of fee examples and how they should be considered in the calculation of a manufacturer's ASP. In addition, CMS did not finalize a proposal which specified when fees are presumed to be price concessions.

CMS finalized changes related to the evidence associated with identifying a BFSF (e.g., manufacturers are to submit reasonable assumptions including documentation of the methodology used to determine FMV). CMS also finalized as proposed the policy to require certification letters from the recipient of a BFSF for prospective contracts that the fee is not passed on in whole or in part to a client or customer of the recipient of the fee, whether or not the entity takes title to the drug.

### Units Sold at Maximum Fair Price

In the Final Rule, CMS reiterated clarifications which were provided in Proposed Rule related to the Maximum Fair Price (MFP), which is negotiated as part of the Medicare Drug Price Negotiation Program. Specifically, CMS restated the following policy statement which clarifies that: (1) units of selected Part B or Part D drugs sold at the MFP are included in the manufacturer's ASP and (2) when the Medicare payment limit is based on MFP, the Medicare Part B Drug Payment Limit File will display the MFP-based payment limit. CMS received stakeholder feedback on these statements but did not provide any additional changes or clarifications.

### Autologous Cell-based Immunotherapy and Gene Therapy Payment

CMS finalized policy, similar to what was proposed, that the costs of patient-specific cell or tissue procurement and processing remain bundled into the payment for the product. CMS did not finalize

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[13] *See* pg. 1833-1834 of the Final Rule for regulatory text related to bundled payments, including information related to Basis of Payment.
[14] As noted the in the Final Rule, currently, the term "BFSFs" means fees paid by a manufacturer to an entity, that (1) represent FMV (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.

certain proposals to require the inclusion of certain procedures in the ASP calculation, as the agency agreed that manufacturer payments for preparatory procedures, such as cell collection and local processing, may meet the four-part regulatory criteria for BFSFs when they are itemized, represent FMV, are performed on behalf of the manufacturer and are not passed through to a purchaser. As noted by CMS, when these criteria are satisfied, such payments are excluded from price concessions; because ASP is calculated net of price concessions, these amounts are not deducted from ASP.

## Medicare Prescription Drug Inflation Rebate Program

Specific to Part D, CMS finalized, with some modifications from the Proposed Rule, use of 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 will use this methodology to exclude 340B units starting on January 1, 2026.

Also, CMS finalized the proposal to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims. This repository will allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. CMS will allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository. CMS intends to leverage existing processes and systems whenever possible. If CMS engages with a third-party to support the repository, protocols to address conflicts of interest will be followed.

In the Final Rule, CMS issued an Information Collection Request for the Medicare Prescription Drug Inflation Rebate Program related to the 340B repository which includes more details regarding how covered entities can submit data to the 340B repository, including format for data submission. While CMS declined to provide a timeline to move to a mandatory repository, CMS reiterated it is actively considering mandatory reporting to the 340B repository in the near future and encourages covered entities to take advantage of the testing period to prepare for future policy development related to 340B repository reporting.

## Ambulatory Specialty Model

Under the authority of the Center for Medicare and Medicaid Innovation (CMMI or Innovation Center), CMS finalized 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. The 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). In the Final Rule, CMS finalized numerous elements of the SSP, including

those related to eligibility and financial reconciliation requirements. CMS also finalized changes to the SSP quality program, among others. CMS provides a Fact Sheet regarding the SSP elements of the Final Rule.

## 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 Final Rule sets forth changes to the QPP starting January 1, 2026. Among several other highlights and proposals, CMS finalized adding six new MVPs and finalized the 75-point threshold to prevent a negative MIPS adjustment through the CY 2028 performance year/2030 payment year. CMS also provides several resources regarding the Final Rule on the Quality Payment Program website, including a Fact Sheet and Policy Comparison Table for download.

## What's Next?

The PFS tables for this CY 2026 Final Rule are available on the CMS website. Most provisions in the Final Rule go into effect January 1, 2026.

Vizient's Office of Public Policy and Government Relations are happy to answer any questions you may have about provisions in this Final Rule. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.