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Employee Benefit Plan Review

CMS Finalizes Changes to Bona Fide Service Fee Requirements, Alongside Other Adjustments to Medicare Part B Drug Reimbursement Methodology

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The Centers for Medicare & Medicaid Services (CMS) has released its Final Rule for the Calendar Year (CY) 2026 Physician Fee Schedule (PFS), detailing significant updates to Medicare Part B payment policies. These changes will directly affect drug manufacturers' government price reporting obligations and the calculation of Average Sales Price (ASP). The Final Rule took effect on January 1, 2026.[1]

Drug manufacturers should prepare for more stringent requirements around the classification of Bona Fide Service Fees (BFSFs), expanded documentation obligations, and a heightened risk that certain fees may be reclassified as price concessions. The changes may negatively impact ASP and trigger downstream effects in the Medicaid Drug Rebate Program (MDRP), which often benchmarks reimbursement methodology against ASP.

Additionally, manufacturers should be aware of CMS's clarifications regarding the incorporation of the Maximum Fair Price (MFP) into ASP calculations and should plan to account for CMS's finalized inflation rebate methodology into future forecasts of Part B and Part D rebate liability. Cell and gene therapy stakeholders should take specific note of CMS's decision to maintain bundled payment policies for autologous products. Additionally, skin substitute manufacturers must prepare for a significant reimbursement change, as CMS will no longer treat these products (unless approved under a BLA Section 351 of the Public Health Services Act) as drugs or biologics for reimbursement purposes.

Key Provisions Impacting Manufacturer Obligations and ASP Calculations

Bona Fide Service Fee Classification

CMS finalized new requirements that seek to tighten drug manufacturers' classification of BFSFs for purposes of calculating ASP. These changes introduce new administrative obligations on manufacturers, including enhanced documentation and formal certification processes.

- *ASP Reasonable Assumption Documentation Requirement*: Manufacturers will be required to produce documentation of the reasonable assumptions used for calculating ASP, specifically their methodology for classifying BFSFs and determining Fair Market Value (FMV) for all current, new, and renewed contracts. CMS expects FMV documentation to be well-detailed and descriptive of the data sources, assumptions and rationales used. Reasonable assumption information for current contracts must be submitted to CMS by April 30, 2026, and then with each future ASP submission. CMS will provide a standardized FMV reasonable assumption template. The agency has assured that it will protect the privacy of reasonable assumptions information to the extent required by the law. To comply with the new requirement, manufacturers should ensure their internal BFSF/FMV analyses are current and well-supported.

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- *Pass Through Certification Requirement*: Manufacturers must obtain formal certification or warranty from contracting service providers (e.g., distributors, GPOs, pharmacies) to confirm that fees paid to providers are properly classified as BFSFs and will not be passed through to clients, customers, affiliates or any other entity. Certification is required only for new contracts, not existing ones. CMS will supply a certification template, and submissions are due beginning April 30, 2026. Manufacturers should carefully evaluate how this requirement may affect service provider relationships and the classification of fees as BFSFs versus price concessions, which directly impacts ASP.
- *Notable BFSFs Changes Not Finalized*: CMS chose not to finalize its proposed revised definition for BFSFs, which sought to outline an explicit list of services that should be classified as price concessions rather than BFSFs. Under this abandoned approach, percentage-based fees and certain third-party payments – such as credit card fees, tissue procurement fees, data sharing fees, and distribution service fees – would generally not have qualified as BFSFs. Relatedly, CMS scrapped its proposal to require that FMV methodology be tailored based on whether or not fee arrangements are directly tied to drug quantity and price. The Final Rule also withdrew CMS's plan to explicitly define "affiliates" as entities to which BFSFs may not be passed. While the decision to abandon these proposals represents a favorable outcome for manufacturers, CMS has indicated that it may revisit them in future rulemaking.

ASP Bundled-Sale Arrangements

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- *Adopted Definition*: CMS adopted the definition detailed in the proposed rule that defined a "bundled arrangement" as 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." Notably, CMS removed references to "purchase patterns" and "prior purchases" in the Final Rule due to concerns about ambiguity and misalignment with the MDRP.
- *Proportional Discount Allocation*: Under the Final Rule, consistent with the MDRP, discounts for bundled arrangements must be allocated proportionally based on the dollar value of the units of all drugs or

products sold under the arrangement. In cases where bundled sales include a combination of contingent and non-contingent discounts, manufacturers are expected to allocate the total discount proportionally across the included products.

- *VBA Exclusion*: CMS clarified that – unlike in the MDRP – value-based arrangements (VBAs) are excluded from the bundled arrangement definition for ASP purposes.

Additional Provisions Finalized By CMS

Maximum Fair Price Clarification

The Final Rule adopts CMS's clarifications regarding the treatment of the MFP under ASP methodology for drugs subject to the Medicare Drug Price Negotiation Program, as established by the Inflation Reduction Act. CMS specified that units sold at the MFP must be included in each manufacturer's ASP calculation, consistent with how MFP is treated in the calculation of Medicaid Best Price. Additionally, CMS announced that it will begin publishing an MFP-based payment limit for drugs selected for negotiation, replacing the quarterly publication of ASP values for selected Part B drugs.

Part B and Part D Inflation Rebate Methodology

CMS finalized several provisions related to the implementation of the inflation rebate requirements enacted in the Inflation Reduction Act of 2022, which requires drug manufacturers to pay rebates when drug prices increase at a rate faster than inflation.

- *Calculation of Benchmark Quarter Payment Amount for Part B Drugs*: CMS confirmed that in situations where sufficient pricing data for a new drug is unavailable to calculate a rebate amount, the benchmark quarter payment amount will be calculated as the "third full calendar quarter after a drug is assigned a billing and payment code as the payment amount benchmark quarter, no earlier than the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later." If no published payment limit is available for the relevant benchmark quarter, the calculation will rely on the positive ASP or positive Wholesale Acquisition Cost (WAC) reported by manufacturers. If neither is available, CMS may use publicly available pricing information as the basis for the calculation.
- *Part D Claims-Based Methodology*: CMS will implement a claims-based methodology to exclude 340B units from Part D rebate calculations beginning January 1, 2026. The claims-based methodology seeks to identify 340B-eligible units by evaluating prescriber and pharmacy affiliations using data from PDE records, Medicare claims, and the 340B OPAIS database. In the Final Rule, CMS added several minor refinements aimed at minimizing the undercounting of 340B units. CMS also finalized the creation of a Medicare Part D Claims Data Repository to allow for covered entities to voluntarily submit Part D claims to assist CMS in its rollout of feasibility testing for its 340B repository.

Skin Substitute Payment Reform

CMS finalized substantial changes to how skin substitute products are categorized and reimbursed by Medicare Part B. Previously treated as biologics and reimbursed under the ASP methodology, CMS has expressed concern regarding rising expenditures for skin substitute products in recent years. Starting January 1, 2026, CMS will separately reimburse skin substitute products as "incident-to supplies" when provided in non-facility or hospital outpatient settings such as private physician offices and patient's homes as part of a covered application procedure. Manufacturers of these products will not be required to continue submitting ASP data to CMS. These changes will not apply to products approved under a Biologics License Application (BLA) per Section 351 of the Public Health Service Act.

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Acknowledging the wide variety of skin substitute products, CMS will also reclassify them to better align with FDA categorization. These products will now be grouped under one of three categories: PMA, 510(k), or HCT/P. CMS finalized a single payment rate of approximately $127.28 per square centimeter across the three categories for CY 2026, though CMS indicates it may set differentiated payment rates based on claims data across the categories in the future. CMS expects the changes to reduce Medicare Part B expenditures for skin substitutes by nearly 90 percent.

The changes to the reimbursement methodology for skin substitute products will not affect the Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers local coverage determination (LCD). That LCD, which addresses the circumstances when skin

substitutes will be covered for the treatment of diabetic foot ulcers and venous leg ulcers and the products that will be covered for such indications. The LCD will take effect on January 1, 2026.

Autologous Cell-Based Immunotherapy and Gene Therapy Payment

CMS finalized the continuation of its existing policy to pay for Chimeric Antigen Receptor (CAR) T-cell therapies as a bundled payment, rather than separately reimbursing for the preparatory procedures used to manufacture autologous cell-based immunotherapy and gene therapies. CMS chose to implement this policy despite concerns from commenters that bundling may undervalue physicians' work in producing these therapies and create inconsistencies with CMS's payment approach for stem cell treatments. Notably, CMS did not finalize its separate proposal to classify payments made by cell and gene therapy manufacturers for tissue procurement as price concessions that impact ASP.

Changes Impacting Physician Payment for Non-Drug Services

The finalized PFS Rule implements many broader changes to physician payment, including those that will:

- Increase physician reimbursement by 3.77% for providers enrolled in advanced alternative payment models (APMs) and by 3.26% for non-APM providers;
- Establish an efficiency adjustment of -2.5% to work RVUs and physician time for non-time-based services, with periodic applicability to all codes except time-based codes and HCPCS codes specifically exempted by CMS (CMS is in the process of finalizing the exemption list); and
- Update indirect practice expense (PE) methodology to decrease payment to facility-based doctors for each RVU to 50% of the reimbursement required for non-facility services.

Note

1. Find the Final Rule at https://www.federalregister.gov/documents/2025/11/05/2025-19787/medicare-and-medicaid-programs-cy-2026-payment-policies-under-the-physician-fee-schedule-and-other; and the CMS Fact Sheet at https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-medicare-physician-fee-schedule-final-rule-cms-1832-f.

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