Stay Current

PAUL HASTINGS

August 2025

Follow us on LinkedIn

Regulatory Update

CMS Proposes ASP Reporting Overhaul — Implications for Fair Market Value and Bona Fide Service Fees

By Wendy Goldstein, BJ D'Avella, Laura A. Skinner and Ravneet Talwar

The Centers for Medicare & Medicaid Services (CMS) recently published its Proposed 2026 Physician Fee Schedule Rule (Proposed Rule), with extensive implications for drug pricing, Average Sales Price (ASP) calculations, and Fair Market Value (FMV) calculations.

Background

Manufacturers must calculate and submit ASP on a quarterly basis to CMS, which then uses ASP to determine the applicable reimbursement rates under the Medicare Part B program. ASP is calculated as the weighted average price provided to commercial customers, with certain exceptions. Among other requirements, price concessions (i.e., volume discounts, prompt pay discounts, chargebacks, rebates or other reductions in price that a manufacturer provides to purchasers) must be deducted from the ASP calculation (thereby lowering the ASP), while Bona Fide Service Fees (BFSFs) need not be deducted from ASP.

Companies that inaccurately classify a price concession as a BFSF may face allegations that they artificially inflated the ASP — which in turn may have several negative results, including:

- Medicare overpayments and subsequent costly ASP restatements;
- higher coinsurance amounts for Medicare beneficiaries; and
- "false claim" allegations and government investigations.

CMS has historically provided a four-part test (defined in 42 C.F.R. § 414.802) to help guide companies in correctly classifying both price concessions and BFSFs. To be considered a BFSF that is not deducted from ASP rather than a price concession, a fee must meet all four criteria defined below.

Under the four-part test, BFSFs are defined as fees, paid by a manufacturer to an entity, that:

1. represent FMV;
2. are itemized services actually performed on behalf of the manufacturer;
3. the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and
4. 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.

The Proposed Rule includes guidance that can have significant implications with regard to two of the four components of the four-part test: Criteria #1 and #4 in the list above. According to CMS, the updated guidance is intended to help avoid inaccurate ASP calculations and their effects on the Medicare Part B program and its beneficiaries.

Criteria 1: Fair Market Value

CMS has historically taken a hands-off approach to manufacturers' determinations of FMV, consistently declining to define the term. For example, in 2016, CMS explained that, "[g]iven the continually changing pharmaceutical marketplace, we will continue to allow manufacturers the flexibility to determine the FMV of a service when evaluating whether the service fee is bona fide or not." *81 Fed. Reg. 5170, 5179 (Feb. 1, 2016)*. In what would be a significant shift intended to help ensure that companies identify BFSFs (and hence calculate ASP) accurately, the Proposed Rule introduces criteria governing how FMV would be calculated as part of BFSF determination:

- For those services fees that *do not* vary directly with the amount of drug sold or the price of a manufacturer's drug, CMS would require that FMV be determined either based on market comparables or the cost-plus markup method.

- For those service fees that *do* vary directly with the amount of drug sold or the price of a manufacturer's drug, CMS would require that:

    - FMV be determined by cost-plus markup method (or if any material portion of cost data is unavailable, by using a market-based approach based on verifiable market data until sufficient cost data become available); and

    - the FMV assessment be conducted by an independent third party and documented with a description of the methodology used. The FMV methodology documentation would have to be submitted, along with other reasonable assumptions, to CMS as part of each quarter's ASP reporting process.

CMS has also proposed revisions to clarify when certain fees are presumed to be price concessions. If fees paid by a manufacturer to an entity vary directly with the amount or price of a manufacturer's drugs (i.e., the fees paid are (i) percentage-based fees, or (ii) flat or fixed fees structured to approximate percentage-based fees), such fees will be presumed to be price concessions and must be deducted from the calculation of the manufacturer's ASP. Manufacturers may rebut this presumption, however, if they demonstrate that any such fees are consistent with FMV based upon a cost-plus markup approach that may be supported by relevant market data.

To emphasize the importance of such FMV analyses with respect to service fees, CMS has proposed a requirement that manufacturers conduct periodic FMV assessments of ongoing third-party service arrangements no less often than the renewal frequency of the arrangement.

Criteria 4: Service Fees Are Not Passed on to a Client or Customer

Recognizing that manufacturers may not know whether fees they pay to a service provider are passed on to another entity, CMS has permitted manufacturers to assume that service fees are not passed on (absent evidence to the contrary) since 2007. Under the Proposed Rule, however, that assumption would no longer be permitted; manufacturers would instead be required to obtain a certification or warranty from each service provider whose fees are treated as a BFSF that the fees are not passed on in whole or in part to an affiliate, client, or customer of the service provider, whether or not the entity takes title to the drug. Note that CMS has added the term "affiliate" to the BFSF definition and has defined an affiliate as an "affiliate of an entity that is receiving the fee… [in exchange for] the service" — which represents a departure from past guidance that limited the pass-through requirements to clients or customers of the service provider without including affiliates as defined here.

The Proposed Rule would require that beginning with the 1Q 2026 ASP reports, these certification letters be a component of each quarterly ASP submission to CMS, along with the FMV and other reasonable assumptions documentation described above.

Additional Guidance on the Proposed Rule Changes

In an apparent effort to provide directional guidance and clarify its stance that manufacturers must determine the FMV of services such as data and distribution services, CMS provides the following four (non-exhaustive) examples of fees that would not necessarily meet the revised four-part test requirements:

- Credit card processing fees
- Tissue procurement fees
- Any portion of the data fees in excess of FMV
- Any portion of the distribution services fees in excess of FMV

Potential Implications for Manufacturers

These proposed changes create a complex compliance and legal landscape for manufacturers, especially those whose contracts span both Medicare and Medicaid programs. In the Proposed Rule, CMS has proposed the stricter, more prescriptive framework for BFSFs described above under Medicare Part B; barring additional guidance or rulemaking from CMS, however, Medicaid would retain the original four-part BFSF test from the 2007 Average Manufacturer's Price (AMP) Final Rule.

This divergence in BFSF methodologies, based on the Proposed Rule, fosters risk, especially when a manufacturer utilizes the same service fee arrangement (e.g., with a wholesaler or data vendor) for both Medicare and Medicaid reporting. Specifically, these risks include the following:

- **Conflicting FMV Standards:** Medicare would now require cost-plus or market-based FMV with third-party validation, while Medicaid would continue to allow companies to perform internal FMV determinations. This risk will be compounded by the fact that BFSF determinations for ASP will now require manufacturers to conduct an analysis every time a third-party arrangement is up for renewal, while Medicare has no such requirements. If CMS audits the same contract under both programs, the agency may reach different conclusions about whether a given service fee is within FMV.

- **Price Concession Reclassification:** A fee deemed to be a BFSF under Medicaid could be reclassified as a price concession under Medicare, which could in turn trigger ASP recalculation and potential overpayment liability.

- **Documentation Gaps:** Medicare would require submission of FMV documentation and vendor certifications under the Proposed Rule; Medicaid would continue to have a less restrictive standard. If a manufacturer fails to meet Medicare's higher standard, it could face enforcement even if Medicaid compliance is intact.

- **False Claims Act Exposure:** Misclassification of BFSFs across programs can affect AMP, ASP, Best Price, and 340B price reporting — all of which are tied to government reimbursement. This could open the door to qui tam actions, investigations, litigation, and monetary penalties.

The table below summarizes ASP reporting changes that manufacturers will need to consider if the Proposed Rule is finalized and indicates how those changes relate to current AMP reporting requirements.

Element	Medicare (ASP Reporting)	Medicaid (AMP Reporting)
BFSF Framework	Proposed CMS guidance (2025 ASP rule updates)	2007 AMP Final Rule
FMV Requirement	Mandatory third-party FMV validation on a detailed cost/market basis	FMV required, but manufacturer discretion allowed; no set formula
Type of Fees Presumed BFSF	Limited: percent-of-sales or volume-based fees are presumed price concessions unless rebutted	Broader: service fees assessed under AMP's 4-part test
Documentation Required	Quarterly submission of FMV documentation & pass-through vendor certifications to CMS	Documentation retention only (for audit purposes)
Timing	Must be submitted each quarter along with the ASP	Retained but not submitted regularly
Reclassification Risk	High: CMS may reclassify fees as price concessions, triggering ASP recalculation	Lower: Medicaid permits flexibility if 4-part test is met
Compliance Burden	High: Requires audit-grade validation and frequent submissions	Moderate: Manufacturer-led FMV determination suffices

Strategic Implications

The proposed changes for ASP reporting signal a shift from greater manufacturer discretion toward more CMS-driven methodology and documentation requirements. There are myriad implications of this shift, including the following:

- Manufacturers may need to renegotiate fee structures (especially percentage-based models).
- ASP reductions (and past quarter restatements) may follow if service fees are reclassified as price concessions.
- Regulatory divergence between Medicare and Medicaid BFSF definitions increases legal and compliance risk, as companies may have to classify the same fee in a given contract as a BFSF under Medicaid, for example, but as a price concession under Medicare — which may lead to:
  - potentially inaccurate ASP and/or AMP calculations;
  - breach of contract provisions related to accurate fee disclosure consistent with applicable laws, regulations and federal program requirements; and
  - exposure to government audits and/or enforcement.

Manufacturers should consider preparing now for Q1 2026 ASP reporting (due April 30, 2026) by taking the steps described in the checklists below. We have provided two lists of action items below: one that companies would be well-advised to take immediately, and one that is contingent upon the content of the eventual final rule.

Recommended Compliance Checklist for Manufacturers

Category	Action Items
Immediate Steps	
Stakeholder Coordination	• Engage Legal, Compliance, Market Access, and Finance teams and alert them to the potential implications of the Proposed Rule • Communicate with vendor relationship owners to alert them to the potential changes and consequent potential need to amend agreements so they can begin to socialize the additional service level requirement with relevant vendors • Prepare and submit comments on the Proposed Rule by September 12, 2025
Contract Review	• Review service fee agreements to identify potential service fees as well as relevant government reimbursement regimes (i.e., to identify which are Medicare only, which may be under Medicare and Medicaid, etc.) • Flag percentage-based or volume-linked fees • Prepare draft contract amendment language that would require relevant vendors to certify of BFSF eligibility, i.e., that fees are not passed through
FMV Documentation	• Engage third-party valuation experts as needed • Conduct BFSF/FMV assessments in parallel with annual needs assessment and contracting processes • Document assumptions, methodology, valuations, and bona fide business need for the services • Prepare for quarterly documentation submission alongside ASP
Steps Contingent Upon Passage of the Final Rule	
ASP Protocols	• Train internal teams on new CMS expectations • Review and revise FMV, BFSF, ASP methodology and SOPs as needed • Ensure FMV data is tied to active contract terms • Ensure FMV and pass-through vendor certification letters are submitted to CMS with the ASP • Amend contract provisions to reflect updated CMS guidance
Risk Mitigation	• Establish escalation paths for non-compliant contracts • Monitor for OIG audit trends • Address dual Medicare/Medicaid BFSF frameworks

As the regulatory landscape evolves, manufacturers face a pivotal moment to safeguard pricing integrity and compliance across federal reimbursement regimes. While the proposed rule introduces complex implications for FMV, BFSF, and ASP, those companies that act today can position themselves not only to respond but to take the lead in risk mitigation within a shifting policy environment.

✧ ✧ ✧

If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York professionals:

Wendy Goldstein
+1-212-318-6411
wendygoldstein@paulhastings.com

Laura A. Skinner
+1-212-318-6516
lauraskinner@paulhastings.com