Healthcare Distribution Alliance

HEALTH DELIVERED

September 12, 2025
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201
Filed by electronic submission

Re: 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 ("2026 Physician Fee Schedule Proposed Rule"); CMS–1832–P

Dear Administrator Oz:

On behalf of the Healthcare Distribution Alliance ("HDA"), we appreciate the opportunity to comment on the Calendar Year 2026 Physician Fee Schedule Proposed Rule,[1] (the "Proposed Rule") and, more specifically, proposed changes by the Centers for Medicare & Medicaid Services ("CMS") to the definition, implementation and documentation of Bona Fide Service Fees ("BFSFs") excluded from the Average Sales Price ("ASP") calculation for Medicare Part B drugs (collectively referred to as the "BFSF Proposed Changes"). HDA represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.

For the reasons set forth more fully in these comments, HDA strongly urges CMS not to finalize the BFSF Proposed Changes as they are unlawful and exceed CMS' regulatory authority. These proposed changes also risk significantly disrupting established supply chain models without delivering meaningful reductions in drug costs, which is a concern highlighted in the Healthcare Distribution Alliance's 2024 document *The Unintended Consequences of Narrowing Bona Fide Service Fees*.[2] The BFSF Proposed Changes, most notably requiring Fair Market Value ("FMV") to be assessed by a third party using a specific methodology and requiring recipients of these fees to certify that they will not pass through these fees, add unlawful requirements and unnecessary complexity to a

[1] 90 Fed. Reg. 32352 (July 16, 2025), *available at* https://www.govinfo.gov/content/pkg/FR-2025-07-16/pdf/2025-13271.pdf.

[2] The Unintended Consequences of Narrowing Bona Fide Service Fees, *available at* https://www.hda.org/getmedia/ec2fdfbb-1770-4fee-abb7-1dad3c223f89/2024The-Unintended-Consequences-of-Narrowing-Bona-Fide-Service-Fees.pdf.

longstanding and consistently applied framework, and will result in pharmaceutical manufacturers, distributors, and ultimately others incurring significant financial and administrative burdens on an ongoing and consistent basis without improving program integrity.

1. The BFSF Proposed Changes are Contrary to the Trump Administration's Commitment to Alleviating Administrative Burdens Through Deregulation

HDA respectfully submits that the BFSF Proposed Changes run directly counter to the Administration's efforts to reduce the administrative and compliance burdens associated with overregulation. Executive Order 14192, "Unleashing Prosperity through Deregulation," states that "[i]t is the policy of my Administration to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen."[3] HHS took great steps towards advancing these efforts through the Department's Deregulation Request for Information.[4] In the Proposed Rule, CMS reiterates these principles, stating that the agency seeks "input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other stakeholders in the Medicare program."[5]

The BFSF Proposed Changes involve precisely the type of unnecessary administrative complexity and burden that President Trump and his Administration have repeatedly disavowed. As described in greater detail below, the existing BFSF definition is more than sufficient to address the concerns that CMS has articulated. The existing BFSF 4-part test is well-settled and generally functions well, and stakeholders have already established processes and infrastructure to manage their compliance obligations. CMS's proposal to revise the definition of BFSF and impose additional requirements at this juncture serves only to increase administrative burden and compliance expense, which has the effect of discouraging innovation, creating barriers to entry, decreasing competition, and disadvantaging smaller companies. It does so without any countervailing benefit that justifies this regulatory burden.

2. The Established Four-Part BFSF Test Provides Stakeholders with a Known, Workable Framework for Assessing Whether Customer Fees Are Bona Fide, and It Does Not Need Refinement or Interpretation

For over 18 years, CMS has had a clear regulatory framework in place for determining what fees qualify as BFSFs that are excluded from pricing calculations for ASP-based reimbursement. This framework is well-known, applied and documented by pharmaceutical manufacturers in calculating and reporting ASP. The identical regulatory BFSF definition and 4-part test are used by manufacturers in calculating Average

[3] "Unleashing Prosperity Through Deregulation," The White House, Jan. 31, 2025 (https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/).
[4] Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make America Healthy Again, 2025-08384.pdf (90 Fed. Reg. 20,478 (May 14, 2025).
[5] 90 Fed. Reg. at 32353.

Manufacturer Price (AMP) and determining Best Price for purposes of the Medicaid program.

CMS cites to a 2022 report by the Office of Inspector General ("OIG") as the basis for the BFSF Proposed Changes, but this report actually found only a "small number of … variations" in how manufacturers classify BFSFs for ASP purposes.[6] A closer review of OIG's findings confirms that the current framework is, in fact, working well. The report reflects that OIG surveyed 20 manufacturers and only *one* expressed an interest in greater guidance from CMS regarding BFSFs.[7] A request for guidance from one manufacturer is hardly adequate to support a dramatic regulatory change. In the absence of evidence that suggests abuse or industry-wide requests for guidance, the OIG report is an inadequate basis for the BFSF Proposed Changes.

Furthermore, the proposed changes will result in additional financial and administrative burdens for pharmaceutical manufacturers and other stakeholders, without any countervailing justifiable benefit.

3. CMS Lacks Statutory Authority To Impose A BFSF Standard For ASP That Conflicts With The BFSF Standard That Congress Adopted for AMP

The BFSF Proposed Changes would exceed CMS' authority under the ASP statute and contradict Congress's intent that ASP remain aligned with AMP, as explained below.

First, the proposal would treat percentage-based service fees as presumptive "price concessions," which conflicts with the ASP statute. That statute expressly identifies the price concessions that manufacturers must include in ASP. By reclassifying them based solely on a fee's percentage structure, the proposal disregards the ASP statutory framework and contravenes Congress's intent.

In addition, the BFSF Proposed Changes would disrupt the alignment between ASP and AMP that Congress has sought to create. Under section 1847A(d)(2)(B) of the Social Security Act (SSA), OIG is required to compare ASP to AMP and, if the ASP for a drug exceeds the AMP by a set percentage, the Secretary of Health and Human Services is required to substitute the ASP-based payment amount with a lower calculated rate. CMS' Proposed Rule would introduce inconsistencies and confusion regarding ASP calculations as compared to AMP, distorting the comparison required by Congress under section 1847A(d)(2)(B) of the SSA without authorization under the ASP statute.

Importantly, the Medicaid Drug Rebate Program ("MDRP") statute explicitly excludes from the definition of AMP "bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees…" and other identified categories of fees. Congress was well

[6] *See* 90 Fed. Reg., 32,541; HHS OIG, *Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices*, at 2, 10-11 (Dec. 2022), https://oig.hhs.gov/documents/evaluation/3215/OEI-BL-21-00330-Complete%20Report.pdf (hereafter, "OIG Report").
[7] *Id.* at 13.

aware that such fees are frequently variable or percentage-based, reflecting that a distributor's costs and risks (for example, inventory carrying costs, spoilage risk, and credit risk) scale with product value and volume. By carving these categories out of AMP regardless of how those BFSFs are structured, Congress confirmed that variability in fee structure does not presumptively convert a BFSF into a price concession.

Creating an ASP presumption against percentage-based or other variable fees would therefore conflict with Medicaid's definition of bona fide service fees and break the statutory alignment between ASP and AMP. Because the ASP framework relies on AMP as a statutory comparator, CMS should not adopt an ASP-specific rule that reclassifies fees Congress treated as bona fide service fees for AMP. Doing so would distort the ASP-AMP comparison, frustrate OIG oversight, and introduce inconsistency that the governing statutes do not authorize.

It would also be inappropriate and inconsistent with the major questions doctrine for CMS to make such a consequential change to ASP without first receiving clear direction from Congress. As the Supreme Court explained in striking down the prior Administration's unwarranted attempt to "effect a fundamental revision of the statute, changing it from one sort of scheme of regulation into an entirely different kind,"[8] an agency may not make regulatory changes carrying enormous "economic and political significance" unless it has received "clear congressional authorization."[9] This principle squarely applies here.

CMS would be abandoning the traditional (and Congressionally-required) comparison of market prices for one that treats certain market arrangements with suspicion. It would also trigger measurable systemwide consequences, including forced revaluation and re-contracting across thousands of distribution agreements, substantial new third-party valuation and certification costs, and distortions to the ASP-AMP comparison that Congress mandated for oversight. Under the major questions framework, CMS would need much clearer statutory authority than the ASP statute's residual reference to "other price concessions"[10] to make a change of that magnitude. The correct reading of the "other price concessions" language *excludes* BFSFs like distribution fees and inventory management fees, which are business expenses, not price concessions. In any event, that language plainly does not supply the "clear congressional authorization" that would be necessary to so dramatically rework the traditional approach to ASP.

4. <u>CMS Has Failed To Take Account Of The Financial, Operational, and Practical Costs Of Imposing Inconsistent BFSF Rules Across ASP And AMP</u>

CMS has also failed to consider the potentially significant costs that could be incurred by stakeholders and other federal programs as a result of the proposed changes, contrary

[8] *Biden v. Nebraska*, 143 S. Ct. 2355, 2373 (2023) (cleaned up).
[9] *Id.* at 2373, 2375.
[10] 42 U.S.C. § 1395w-3a(c)(3).

to the Administrative Procedure Act principle that an agency must consider all significant aspects of the rule it proposes to adopt.[11]

With respect to FMV methodology, the proposal to require cost-based approaches to assess FMV for percentage-based fees risks introducing inconsistency with Medicaid AMP calculations.[12] The Medicare statute expressly cross-references the Medicaid statute,[13] and, in prior rulemaking, CMS explicitly sought to align the Medicare and Medicaid approaches with respect to FMV to facilitate compliance.[14] In the same rulemaking, CMS reinforced the presumption that a fee is not passed on for purposes of AMP if there is no evidence or knowledge to the contrary – in order to "more fully align" BFSF in AMP with ASP policy.[15]

In addition to being contrary to statute (as discussed in Section 3), the introduction of an inconsistent BFSF standard between Medicaid and Medicare would raise considerable questions about potential costs to industry actors and the government. An agency may not impose different requirements for calculating AMP and ASP "based on two fundamentally contradictory readings of th[e] [same] definition."[16] Relatedly, CMS has failed to address the inconsistency between the proposal and the Department of Justice's historic concerns around reporting distributor and other service fees as discounts, rather than BFSFs, where that decision lowers AMP and therefore lowers Medicaid rebates.[17]

In light of the ASP and AMP statutorily-mandated comparisons, and CMS' longstanding position that there should be alignment between these two programs, it is imperative that

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[11] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency… entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."); *Michigan v. EPA*, 576 U.S. 743, 759 (2015) (agency must consider costs, including compliance costs, as part of reasoned decisionmaking).

[12] *See* 81 Fed. Reg. 5170.

[13] SSA § 1847A(c)(2)(A).

[14] In the CY 2016 Medicaid Outpatient Drug Final Rule, the agency reiterated that it was aligning its position with the discussion in the CY 2007 PFS Final Rule that "the appropriate method for determining whether a fee represents fair market value may depend upon specific contracting terms and the services involved." *See* 81 Fed. Reg. at 5179-80.

[15] 81 Fed. Reg. 5170, 5178.

[16] *See HIV & Hepatitis Pol'y Inst. v. HHS*, 728 F. Supp. 3d 1, 13 (D.D.C. 2023) (agency's competing interpretations of "cost sharing" under Affordable Care Act were arbitrary and capricious); *see Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 798–99 (D.C. Cir. 1984) (noting that "[i]t would be arbitrary and capricious for HHS to bring varying interpretations of the statute to bear" based "on mere expedience"); *see also Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 ("Unexplained inconsistency is . . . a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.").

[17] *See e.g.*, Dept. of Justice, Press Release; "AstraZeneca and Cephalon to Pay $46.5 Million and $7.5 Million, Respectively, for Allegedly Underpaying Rebates Owed Under Medicaid Drug Rebate Program," July 6, 2015, *available at* https://www.justice.gov/archives/opa/pr/astrazeneca-and-cephalon-pay-465-million-and-75-million-respectively-allegedly-underpaying (AstraZeneca settled allegations that it knowingly underpaid rebates owed under the Medicaid Drug Rebate Program for $46.5 million, and Cephalon settled for the same alleged behaviors for $7.5 million).

CMS not finalize any proposal that threatens to upset the alignment between the two programs and/or result in significant, unintended fiscal consequences for the federal government.

5. <u>There Are Legal and Practical Barriers to the Proposed Requirement that FMV Be Assessed Using a Cost-Based Approach for Variable Fees</u>

HDA disagrees with CMS's proposal to require that, where a fee is percentage-based or designed in a way to approximate a percentage-based fee (collectively, "variable fees"), manufacturers must determine fair market value using a cost-based approach, unless a material portion of cost data is not available, in which case a market-based approach may be used. Rather, pharmaceutical manufacturers and other stakeholders should continue to have flexibility in how FMV is assessed as CMS has recognized in prior rulemaking. This existing framework functions well – it supports extremely competitive arm's-length fair market value arrangements. With wholesaler gross margins at 1.7% and net profits at .4%[18], meaningful changes to the manner in which BFSFs are treated will be overly burdensome, harmful to the supply chain, and will stretch already thin resources and margins.

a. <u>CMS has failed to articulate a rationale for its proposal to require a cost-based approach for variable fees.</u>

As a preliminary matter, CMS fails to articulate any credible rationale for requiring the use of a cost-based methodology instead of a market-based methodology to assess the fair market value of variable fees. Market-based and cost-based methodologies are both widely used throughout the valuation industry, and valuation experts exercise their professional judgment to determine the most appropriate methodology for any particular arrangement. CMS asserts that it is making these proposals in response to recommendations from OIG that it issue more guidance regarding fair market value, but the agency offers no rationale to support the specific requirements that it proposes to impose, nor does the agency demonstrate any expertise to make such assessments. Specifically, CMS does not offer any explanation as to why a cost-based methodology is preferable or superior to a market-based approach for ascertaining the fair market value of variable fees. CMS also fails to articulate any basis for proposing different fair market value standards for fixed fees versus variable fees. The failure to articulate a rationale for this disparate treatment is particularly striking, given that both fixed fees and variable fees are subject to the same core requirement of being consistent with fair market value.

Moreover, it is arbitrary and capricious for CMS to attempt to adopt a burdensome fair market value standard here where it cannot do so for AMP, as explained in Section 3, and where it has not done so in other legal contexts overseen by the agency.

b. <u>Cost-based methodologies may not be sufficient to address the complexities of distribution services.</u>

[18] 95th Edition HDA Factbook (2024-2025). https://www.hda.org/publications/95th-edition-hda-factbook-the-facts-figures-and-trends/

CMS's proposal would introduce unnecessary complexities and undermine efforts at transparency and consistency. Specifically, pharmaceutical distribution involves a highly complex suite of services that are provided within a highly dynamic environment, and distributors are subject to a wide array of state and federal regulations, including the Drug Supply Chain Security Act ("DSCSA"), which requires an electronic, interoperable system to trace prescription drugs at the package level throughout the distribution chain. Pharmaceutical distributors make substantial, ongoing investments in infrastructure to support appropriate tracing of prescription drugs and optimize their systems to protect against the threat of counterfeit, stolen, contaminated, or otherwise harmful drugs entering the U.S. supply chain and maintain, and continuously improve, programs designed to detect and prevent diversion within the pharmaceutical supply chain. As a practical matter, independent FMV appraisers will be unable to remain apace of these types of investments – many of which are confidential, proprietary, and reflective of business judgment regarding infrastructure investment – or even know that these investments exist, and this in turn threatens artificially reduced assessments of fees.

Within the above regulatory framework, distributors provide sophisticated services, including thermally controlled packaging and transport, electronic data reporting, advanced analytics, administrative third-party contract management, exception management systems, quality controls and inventory logistics, for most pharmaceutical products available on the market. The cost of many of those services is inextricably tied to the cost of the drug. We also note that distribution service fees do not impact patient access, formulary placement, patient cost sharing, or drug preference. Rather, they address the costs and risks of the management of daily delivery of drugs, factoring in the long-term risk of nonpayment. Each of these endeavors can vary for different types of drugs – e.g., specialty and rare disease drugs often have additional and complex storage, handling, packaging, and other services to support their distribution to patients. Since products have widely varying characteristics and requirements, it is not practically feasible to determine fixed, cost-based service fees on a per-SKU basis. Instead, the wholesale industry has functioned well through the existing approach, which understands costs as generally scaled based on pricing of drugs, given that higher priced drugs generally have more complexity in handling, storage, and distribution. In addition, because distributors take title to the products, higher priced products increase financial risk and costs, including insurance. As such, it is reasonable that fees would vary with the cost of drug products.

Distributors carry thousands of products and product configurations, all in service of ensuring an effective, stable pharmaceutical supply chain. By way of example, in the case of generic pharmaceuticals, full line wholesalers do not just carry one product from one manufacturer; they typically carry the same product from most or all of the generic manufacturers that have supply for that product. If a single generic drug configuration is manufactured by 5 manufacturers, full line distributors frequently carry that same drug from all 5 manufacturers.

Simply put, pharmaceutical distribution entails far more than simply storing products and shipping them to their destination. Distributors take title to drug products and assume responsibility for compliant storage, security, safety, insurance, and transportation, among other things. Discerning and allocating the cost inputs within the distribution ecosystem that would be necessary to rely solely on a cost-based valuation methodology is challenging, and, even where feasible, necessarily introduces significant subjectivity.

Market-based valuation approaches allow valuators to determine the appropriate fair market value range for distribution service fees based on market data derived from arm's length negotiation. In the context of complex service offerings such as pharmaceutical distribution, allowing valuators to rely on market-based valuation methodologies ensures that service fees are aligned with actual economic value.

While a cost-plus approach might be reasonable for certain service arrangements, it does not work with all service arrangements. Implicit in CMS's proposal to impose stricter methodological and documentation requirements to establish the FMV of variable fees is a suggestion that a variable fee is somehow more suspect than a fixed fee. We respectfully submit that this perspective is deeply flawed. Percentage-based fees are entirely appropriate for distribution services due to the nature of distribution services, which necessarily scale with the cost of drugs, as recognized by Congress in the context of Medicare Part B reimbursement itself.

Distribution fees reflect competitive pressures, scale efficiencies, and significant technology investments. These are factors that may not be captured by cost inputs alone. For example, fees for highly specialized services and services like data reporting have no readily available cost-based value because they reflect substantial, aggregated information and system-based investments. Moreover, the cost-plus approach might not appropriately value or allocate fixed costs that are paramount to safe and efficient distribution of prescription drugs in the United States. For instance, wholesalers have made significant investments in systems to ensure unit level traceability as mandated by the DSCSA as well as to monitor for suspicious orders of controlled substances. The sophisticated systems required to maintain these obligations keep our supply chain safe and secure but also make it highly efficient.

6. <u>Requiring Recipients of BFSFs to Certify That Fees Are Not Passed Through Would Be Contrary to Statute and Financially and Administratively Burdensome for Pharmaceutical Manufacturers and Downstream Entities in the Supply Chain, With Little Benefit to CMS's Goal of Increased Consistency in ASP Reporting (Proposed 42 C.F.R. § 414.804(a)(5))</u>

We respectfully disagree with CMS's proposal to change its over 18-year policy that, in the absence of evidence or knowledge to the contrary, pharmaceutical manufacturers may presume that fees are not passed on to a client or customer of an entity receiving the service fee, and to require that manufacturers obtain certification letters from BFSF

recipients "as evidence" that the fee is not passed on.[19] As noted, CMS would require manufacturers to "submit [to CMS a] certification letter from the recipient of a bona fide service fee (as defined under § 414.802) as evidence that the fee is not passed on in whole or in part to an affiliate, client or customer of the recipient of the fee, whether or not the entity takes title to the drug."[20] This proposal exceeds CMS's statutory authority under the Social Security Act, and, furthermore, is practically impossible due to significant, long-understood feasibility and other issues.

We see no support for such a certification in the Medicare statute, which simply looks to the "price" that a manufacturer offers to a purchaser in the market – not the independent downstream decisions of purchasers in terms of how they treat a FMV service fee or their decision regarding whether to provide a certification that discloses information about their independent downstream financial relationships. In addition, we submit that the proposal to require recipients of BFSFs to affirmatively warrant or certify that they do not pass through such fees is simply untenable.

There is no express or implicit support for such a certification requirement in the statute. The time and administrative logistics that will be needed to develop, send, and collect such certifications from BFSF recipients will be significant. CMS's regulatory impact analysis underestimates the burden of the change in the pass-through prong of the BFSF test and fails to grapple with the reality that obtaining a certification may not only take considerable time but, in many instances, may be impossible. It is not clear how the failure to obtain a certification of any sort constitutes clear evidence of pass-through. For these reasons, we urge CMS to keep the current presumption that, in the absence of evidence or knowledge to the contrary, a manufacturer may presume the fee is not passed through. This longstanding standard has worked reasonably well to allow parties to evaluate BFSF arrangements in a principled, feasible manner.

If CMS does finalize the change to the pass-through prong of the 4-part BFSF test, we urge CMS to clarify the timing and form of such certifications – ensuring market actors have sufficient and reasonable time to adjust to any such changes – and to recognize that a representation and warranty in a contract is a sufficient certification as to the non-pass through of fees.

7. CMS Should Not Finalize Its Proposal to Add a Vague Reference to "Affiliate" in the Pass-Through Prong of the BFSF Four-Part Test (Proposed 42 C.F.R. § 414.802)

CMS also proposes to expand the definition of the pass-through requirement to specify that the fee may not be passed on to "a client or customer of entity, or to an *affiliate*."[21] CMS states that the addition of the word "affiliate" is meant to more "comprehensively address the type of arrangements that may exist between certain corporate entities."[22]

[19] 90 Fed. Reg. 32352, 32849.
[20] *Id*.
[21] *Id*. (emphasis added).
[22] *Id*.

However, CMS lacks statutory authority to extend the definition of a purchaser to include an affiliate of a purchaser, or to relatedly presume that an exchange of remuneration within a corporate family changes the nature of an upstream bona fide service fee and turns it into a price concession. A "price" is negotiated between the seller and the purchaser in privity of contract. The affiliate is not a party to that negotiation or price determination. CMS offers no statutory authority to support a position that an intra-company financial transaction alters the nature of a manufacturer's service fee arrangement with a given purchaser.

Additionally, CMS's purported justification for any such change fails to acknowledge that corporate structures often include multiple entities, leading to various intra-family arrangements. It is unclear how or why a purchaser's sharing of remuneration within its corporate family – an activity that could take place for a number of legitimate business reasons – converts a service fee into a discount. HDA sees no legal authority for such a position and strongly recommends that CMS remove "affiliate" from the definition of BFSF and otherwise ensure that pass-through considerations focus on the intent of the manufacturer to offer downstream price concessions.

8. <u>If CMS Finalizes the BFSF Proposed Changes, Delayed Implementation is Imperative</u>

If, despite the concerns we have expressed here, CMS elects to adopt some or all of its BFSF Proposed Changes, we strongly urge CMS to delay the effective date of any such changes by at least 12-18 months after issuance of the final rule in order to allow the industry to adapt in an orderly manner, conduct necessary valuations, and put new procedures in place.

If the BFSF Proposed Changes are finalized, manufacturers may seek to re-negotiate existing distribution service fee arrangements, undermining supply chain efficiency and security. Restructuring and re-contracting are time-consuming and financially burdensome for both upstream and downstream stakeholders. The current timeline does not provide the industry with sufficient time to ensure compliance and establish appropriate contracting. Phased implementation or a future effective date would greatly mitigate the risk of supply chain disruption and ensure that compliance is achievable.

Distributors provide administrative, logistical, and operational support to more than 750 manufacturers nationwide. To recontract, off-cycle, with this volume of manufacturers will require most contracts to be re-negotiated within a compressed timeline, significantly shorter than the typical year-long contract cycle. Ensuring compliance will necessitate additional staff, leading to unnecessary administrative and operational burdens. All of these steps take time and deliberation, and CMS's failure to allow for sufficient time risks enormous disruption to the market and the availability of prescription drugs.

To avoid disruption and confusion, CMS must recognize the practical needs of industry stakeholders and provide adequate time for transition if it moves forward with changes.

9. There Is No Regulatory Impact Analysis Assessing the Costs Associated with the BFSF Proposed Changes

CMS has also failed to undertake a detailed regulatory impact analysis of the changes. ASP is the basis for actual reimbursement to physicians, hospitals and others that administer drugs to Medicare beneficiaries. These same providers will already be facing reduced reimbursement under Medicare for select drugs subject to Maximum Fair Prices under the Inflation Reduction Act beginning in 2028. Decreases in reimbursement can lead to decreased patient access to certain drug therapies, possibly exacerbating drug shortages for therapeutic alternatives, especially in rural communities, and would force providers to face difficult choices when it comes to access.

Furthermore, CMS's regulatory impact assessment does not account for spill-over impact on the Medicaid program, or additional investments that could be required to determine the appropriate approach across the two programs. As set forth above, CMS has not explained how it possesses legal authority to interpret an identical regulatory definition in inconsistent manners across two programs.

10. Maximum Fair Price (MFP) Should be Excluded from the Calculation of ASP

CMS should not require the Inflation Reduction Act's (IRA) Maximum Fair Price (MFP) benchmark to impact manufacturer ASP calculations starting in 2026. Doing so would change ASP from a current market-based benchmark – as Congress intended in the Medicare Modernization Act – to a metric largely dominated by a single CMS-set price. This will cause major repercussions for providers and patients who rely on physician-administered drugs. In addition, the IRA specifically excludes Part B drugs for the Program's first two program years. Inclusion of MFP on selected Part D drugs in manufacturer ASP calculations for 2026 and 2027 would run counter to the intent of the IRA to delay impact on the Part B program until 2028.

Conclusion

For the foregoing reasons, HDA urges CMS not to finalize the BFSF Proposed Changes.

We welcome the opportunity to provide further data or participate in stakeholder discussions on these proposals. Please do not hesitate to contact Patrick Kelly, Chief Advocacy Officer (pkelly@hda.org), should you have any additional questions.

Sincerely,

Patrick Kelly

Patrick Kelly
Chief Advocacy Officer