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Is Your System Ready for ASP Reform?

Why manufacturers must act now on Maximum Fair Price (MFP), bundling, and bona fide fees

The Centers for Medicare & Medicaid Services (CMS) continues its effort to tighten transparency and accountability in drug pricing, and the **CY 2026 Proposed Rule** (CMS-1832-P) introduces some of the most consequential changes to the **Average Sales Price** (ASP) calculation in nearly two decades. For pharmaceutical manufacturers, the rule marks a clear call to action: **review your internal systems, audit your pricing strategy, and prepare your operations now.**

The stakes are high. This is more than a technical and compliance update — it's a shift that will influence revenue, market access and pricing strategies across government and commercial channels.

Why a reduced ASP matters

ASP isn't just a reporting figure; it directly shapes revenue. Medicare reimburses most Part B drugs at: **ASP + 6%**
Every dollar decrease in ASP reduces reimbursement. Here's how that impacts manufacturers:

1. Lower Medicare reimbursement

- Smaller provider margins, especially if acquisition costs exceed payment
- Prescribers may avoid certain therapies if reimbursement doesn't cover costs
- Potential decline in product use as providers favor higher-margin alternatives

Result: Lower ASP can drive down physician-administered drug volume when provider economics no longer align.

2. Commercial market pressure

Even outside of Medicare, ASP serves as a pricing benchmark:

- Private payers may peg reimbursement or acquisition pricing to ASP-based rates
- Pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) track ASP trends to guide rebate or discount expectations
- 340B covered entities, though often purchasing at the ceiling price, monitor ASP to assess margin opportunities

A falling ASP can trigger pressure for lower prices, renegotiated terms or steeper rebates, especially for products with limited differentiation.

3. Pricing floor complications

ASP becomes the floor in value-based contracting or price transparency programs. A lower ASP can:

- Trigger price-matching clauses in commercial or government contracts
- Affect Medicaid rebate obligations, especially under best price/AMP crossover scenarios
- Create challenges in global pricing corridors, where U.S. public prices are used to benchmark or cap international prices

Reductions in ASP are rarely isolated and can cause a ripple effect across payer, channel and global strategies.

A deeper dive into the proposed rule and MFP, bundled arrangement & price concessions, and BFSFs

Following the examination of ASP fluctuation impacts on pharmaceutical manufacturers, this analysis focuses on 3 pivotal proposed provisions requiring immediate system and process evaluation. These provisions mandate potential operational adjustments before the proposed rule's implementation, with an anticipated effective date of January 1, 2026.

1. Inclusion of Maximum Fair Price (MFP) units in ASP calculations

For the first time, CMS will require manufacturers to include sales made at the Inflation Reduction Act (IRA) (MFP) in the ASP calculation. The MFP is a government-negotiated ceiling price for select high-expenditure Medicare drugs, introduced under the IRA of 2022 **(PL 117-169)**.

What this means:

MFP is a government-negotiated price for select high-expenditure Medicare Part B and D drugs. Previously, manufacturers faced ambiguity regarding the inclusion of these deeply discounted units in ASP calculations. CMS-1832-P provides clarity: **they must be included** — effective with **Q1 2026 ASP submissions (due April 30, 2026).**

Operational implications:

Manufacturers must now ensure they can:

- Identify MFP-eligible drugs across portfolios and systems
- Tag and segregate MFP sales by NDC and customer class within ERP and contract systems
- Include both MFP revenue and units in the ASP numerator and denominator, respectively
- Model the impact on ASP-based reimbursement to anticipate commercial and Medicare implications

Why It Matters:

MFP prices are significantly lower than traditional commercial prices. Their inclusion will depress ASP, potentially reducing Medicare reimbursement rates. Failing to account for them accurately could lead to CMS enforcement, audit risk and misaligned financial projections.

If you have a drug that competes on any indication with an MFP drug on or off-label, you may want to flag this drug for ongoing review, since it may be competing with a reduced-price competitor. This could impact your commercial and government program pricing and profit margins.

2. Bundled arrangements and price concessions: A redefined landscape

CMS proposes a stricter definition: all price concessions in a bundle must be allocated across all products in that bundle.

Key changes:

- Discounts offered conditionally or across multiple drugs/devices must now be spread across all included NDCs
- Incentives resembling discounts or rebates may not qualify as bona fide service fees (BFSFs) without documentation. A falling ASP can trigger pressure for lower prices, renegotiated terms or steeper rebates, especially for products with limited differentiation.

Operational implications:

Manufacturers must:

- Reassess discounting structures across access, hub, or portfolio contracting programs
- Model ASP implications of shifting formerly “BFSF-classified” payments into deductible price concessions
- Update contracting systems to allocate bundle-related discounts proportionally across all affected products

Why It Matters:

Manufacturers that previously structured agreements to optimize ASP via BFSFs may see those benefits reversed. If reclassified as price concessions, these funds will reduce ASP and potentially affect pricing across government channels.

3. Stricter BFSF requirements: End of the assumption era

Assumed BFSF status is no longer acceptable. Manufacturers must substantiate all BFSFs with auditable documentation.

New Requirements:

- Fixed fees benchmarked to market rates or supported by a cost-plus methodology
- Variable fees validated with third-party FMV analysis
- Certifications from service providers confirming fees are not passed through downstream entities
- All documentation must be maintained and submitted **quarterly**, beginning with the **April 30, 2026**, ASP report.

Operational implications:

- Implement BFSF validation workflows, including third-party FMV reviews and certifications
- Update vendor agreements to include certifications and audit rights
- Integrate documentation into ASP reporting systems

Why It Matters:

This rule represents a significant shift toward CMS enforcing pricing justification in ASP reporting. Manufacturers without robust valuation protocols or auditable trails may find themselves out of compliance or forced to reclassify key fees as ASP-reducing concessions.

It’s time to evaluate and update for a compliant ASP engine

CMS-1832-P represents a structural shift in how manufacturers must approach ASP reporting. No longer is it simply a finance-led quarterly task — it now touches contracting, systems, legal, and compliance in fundamental ways.

By Q4 2025, manufacturers should:

- Identify MFP-eligible drugs and tag transactions accordingly
- Audit bundled discount arrangements for proportionality
- Establish a BFSF FMV documentation process and secure vendor certifications
- Enhance ASP reporting systems to incorporate new tracking and support requirements
- Update internal SOPs to reflect these new CMS expectations

ASP isn’t just a compliance number; it’s a financial lever that influences Medicare revenue, market access and long-term pricing strategy. CMS-1832-P represents a paradigm shift in how manufacturers must calculate, document and defend their ASP submissions.

Proactive manufacturers will preserve market access and pricing integrity. Reactive ones will face reduced revenue, increased risk and potential CMS scrutiny.

Pharmaceutical companies that act now will be better positioned to:

- Avoid compliance pitfalls
- Minimize pricing surprises
- Align contracting strategy with new regulatory expectations

CMS isn’t just refining the ASP calculation — it’s redefining how manufacturers must justify their pricing practices. ASP is no longer a snapshot of pricing — it’s a compliance obligation demanding real-time visibility, operational discipline and cross-functional coordination.

We would like to hear your thoughts on how you're preparing and how we can assist you with navigating your ASP compliance and strategy needs, as well as other complex challenges. Vistex helps many Life Sciences manufacturers with government pricing and commercial solutions. Let's work on your proactive solution...together.

Bob Steller

Industry Principal, Life Sciences at Visex North America

Bob Steller is an expert in Life Sciences revenue management, operational improvement, and information systems. With 28 years of experience, including 21 years with pharmaceutical companies, Bob leverages his deep knowledge of the industry's unique requirements to help clients streamline financial processes and boost overall performance.

Erica Petersohn

Business Advisor Solution Delivery, Government Pricing & Compliance

Erica is a business advisor for Vistex, specializing in the Life Sciences sector. She brings over 25 years of experience in US government pricing, FSS contracting, and Medicaid programs, with experience in both consulting and working at pharma companies throughout her career. In recent years, she has also focused on state price transparency reporting, helping pharmaceutical companies navigate these evolving requirements. She plays a key role in aligning business needs with system requirements, providing strategic guidance to both clients and internal teams.

Melisa Sepe

Business Advisor Solution Delivery, Managed Care

Melisa is a business advisor for Vistex, specializing in the Life Sciences sector. She has 20 years of experience in Managed Care, with a specific focus on rebate operations and analytics: from contact negotiations, through rebate processing, to contract performance analytics, Gross-to-Net consolidations and accrual forecasting. Melisa leverages her experience in these areas to help teams identify and implement process improvements.

How Vistex Adds Value in Life Sciences

Today's Life Sciences market is impacted by scrutiny over rising costs, tighter innovation funding, proving therapy and product value, and complying with shifting regulatory mandates. Vistex helps Life Sciences companies manage the complexities of pricing, commissions, chargebacks, rebates, royalties, contract authoring, loyalty programs, and regulatory compliance. Vistex provides value to Life Sciences through revenue management, utilizing real-world evidence and outcomes by dismantling silos, validating and exploiting data, and identifying the most profitable plans for satisfying stakeholders.

About Vistex

Vistex solutions help businesses take control of their mission critical processes. With a multitude of programs covering pricing, trade, royalties and incentives, it can be complicated to see where all the money is flowing, let alone how much difference it makes to the topline and the bottomline. With Vistex, business stakeholders can see the numbers, see what really works, and see what to do next – so they can make sure every dollar spent or earned is really driving growth, and not just additional costs. The world's leading enterprises across a spectrum of industries rely on Vistex every day to propel their businesses.

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