PhRMA Says 340B Rebate Pilot Helps With PFS Data Repository; CMS Advances ASP Changes

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Starting Jan. 1, 2026, CMS is establishing a repository where covered entities participating in the 340B drug discount program can voluntarily submit Medicare Part D claims data related to 340B drugs -- a policy brand drug industry representatives say could be populated with the help of the upcoming pilot program permitting drug companies to issue rebate payments for 340B drugs instead traditional upfront discounts.

The data in the repository will be used by CMS to remove 340B units from the Part D inflation rebates.

The voluntary repository is one of several policies CMS finalized Friday (Oct. 31) and intends to implement under the physician fee schedule rule for 2026, along with policies to:

Set up a claims-based methodology to remove 340B drug units from Part D rebate calculations. Include the drug units of selected drugs sold at a new maximum fair price (MFP) post-price negotiations the calculation of the drug manufacturer’s average sales price. Define the term “bundled arrangement” and clarify to manufacturers how to account for bundled price concessions when calculating a drug’s ASP. Require reasonable assumptions for ASP calculations as a part of quarterly ASP data submissions to CMS, including documentation of the methodology used to determine fair market value for current, new, and renewed contracts for bona fide service fees (BFBS). Require verification from manufacturers that a BFSF is not passed on to a client, or customer of an entity for new and renewed BFSF contracts.

After reviewing public comments, CMS chose not to finalize revisions to the definition of BFSF or to the standards and methodology that manufacturers should use to determine fair market value.

CMS will also continue to carry out the existing bundled payment policy for CAR T-cell therapies and extending it to autologous cell-based immunotherapy and gene therapy, but after consideration of public comments, the agency will not finalize its proposal to prevent these payments from qualifying as BFSFs or to require their inclusion in ASP beginning Jan. 1, 2026.

“Instead, manufacturer-paid preparatory services may be treated as BFSFs when the four-part test in 42 CFR 414.802 is satisfied and thus excluded from ASP,” CMS says.

The final physician fee rule was released just as the Health Resources and Services Administration announced the eight drug companies it approved to participate in the controversial 340B rebate pilot program, also starting in January.

In comments submitted ahead of final rule's Oct. 31 release, the Pharmaceutical Research and Manufacturers of America (PhRMA) had suggested that CMS utilize claims-level data reported by 340B covered entities to manufacturer rebate platforms, which would allow CMS to use the claims repository to exclude 340B units from Part D inflation rebate calculations for drugs participating in the 340B rebate pilot prior to the start of mandatory covered entity reporting. Broadening the pilot program in this manner would provide a clear and simple path to accurately remove 340B units from the Part D inflation rebate, PhRMA says.

The brand drug lobby also recommended that CMS align the data fields for the claims repository with the data fields utilized under the 340B rebate pilot to allow for more seamless reporting across programs.

PhRMA did express disappointment CMS has yet to mandate reporting from covered entities to a 340B claims data repository given the statutory requirement for CMS to exclude all 340B drug units from Part D inflation rebate calculations, but it does believe the "Prescriber-Pharmacy" claims-based estimation approach offers a better approach to identifying 340B units than a previous estimation proposal CMS pitched for calendar year 2025 that was never finalized. To garner more voluntary and meaningful participation with the repository, the lobby said CMS must set a clear date in the future for when it intends to issue a regulation making reporting to the repository a requirement for all 340B covered entities.

The Biotechnology Innovation Organization also urged CMS to mandate claims-data reporting from 340B covered entities to a repository, and the biotech lobby also says the proposed repository would meaningfully complement CMS' efforts to establish the pilot program for 340B rebate payments and improve the integrity and efficiency of the 340B program.

But while BIO says the proposed claims-based estimation approach is a notable improvement from the estimation approach proposed last year for 2025 that was not finalized, the lobby maintains any estimation approach that does not require the use of 340B and non-340B claims modifiers will not provide an accurate representation of 340B claims.

"CMS has a statutory obligation to enforce the prohibition on inflationary rebates on 340B units, as well as the requirement that manufacturers offer eligible entities the lower of the 340B ceiling price or the 'maximum fair price,' but not both. To uphold all applicable statutory obligations, CMS cannot simply rely on estimates, but rather, CMS

must guarantee manufacturer access to claims data to validate that inflation rebate invoices reflect adherence to the statutory prohibition on duplicate discounts. Therefore, we continue to believe that any solution must involve 340B and non-340B modifiers and a comprehensive and mandatory 340B claims data repository," BIO said in its comments on the proposed rule.

In addition to concerns about CMS' approach to ensuring 340B drug units are kept out of inflation rebate calculations for Part D drugs, both lobbies were at odds with the agency's proposed policy adjustments to how it would calculate the ASP of drugs payable under Part B in relation to price concessions and bona fide service fees, as well as in relation to certain cell and gene therapies and when selling select drugs with a new maximum fair price following drug price negotiations.

PhRMA, BIO and the Association for Accessible Medicines, the generic drug lobby, did not want CMS to move forward with its various policies for adjusting calculations to ASP, and each said in their separate comments to the agency these policies could have myriad unintended consequences for brand treatments, generic drugs and biosimilars.

PhRMA said including negotiated prices in calculations for the ASP of selected Part B drugs would drastically reduce reimbursement across Medicare, Medicaid, the commercial market and other public health programs, and it would especially harm specialty providers as well as small and rural providers, eventually leading to reduced patient access to treatments and an increase in closures and market consolidation.

The brand drug lobby also said the move would go against what's in the Inflation Reduction Act and the original intent of Congress. Because the MFP of a selected drug is excluded from the average manufacturer price (AMP) under the IRA, PhRMA said it should also be excluded from ASP to ensure pricing benchmarks remain comparable and the pricing metrics for both Part B and Part D inflation rebates are treated consistently. It also noted Congress did not authorize including the MFP in ASP calculations because CMS does not have the legal authority to make such a change.

PhRMA also did not want CMS to define the term "bundled arrangement" to clarify how drug companies should account for bundled price concessions when calculating ASP or to revise the definition of bona fide service fees.

PhRMA raised concerns that CMS hadn't fully considered the operational burden and cost these proposals would impose, noting that many of the proposed requirements would introduce extensive procedural obligations without any clear added value.

"By proposing rigid mandates, CMS risks diverting manufacturer and other stakeholder resources towards costly compliance activities that do little to improve data accuracy or program integrity and do not account for certain realities of pharmaceutical contracting. We urge CMS to consider whether these proposals may inadvertently hinder, rather

than advance, the Trump Administration's goals of promoting economy and efficiency while reducing administrative bloat. As the President has cautioned, federal regulations have become an "ever-expanding morass" that often 'further increas[e] compliance costs and the risk of non-compliance,'" PhRMA said in its Sept. 12 comments to CMS.

AAM was also worried the policy changes would contribute to decreasing the calculation of ASP altogether, which it said could erode Medicare payment rates for generic drugs and biosimilars and cause providers to struggle with payment rates below acquisition costs.

"A decline in ASP is generally a desirable trend, as it reduces costs for the Medicare program, taxpayers, and beneficiaries. However, declines in ASP must be balanced against the need to create a stable marketplace that encourages continued investment by generic and biosimilar manufacturers. If generic and biosimilar manufacturers lose confidence that the market will support a return on their investment to develop a product, the generic and biosimilar pipeline will decline, leading to fewer options for providers and patients and less overall price competition," AAM said in its comment letter.

PhRMA also did not want CMS to cement its proposed policy for autologous cell-based immunotherapies or gene therapies -- which the agency ultimately decided to shelve. PhRMA said CMS had not provided rationale for its ASP proposals related to tissue collection for these cell and gene-based treatments including an explanation for why the agency would exclude tissue collection fees from bona fide service fee status even when those payments meet the definition to be considered bona fide service fees.