American Hospital Association™
Advancing Health in America

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August 17, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4215-P, Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule

Dear Administrator Oz:

On behalf of our nearly 5,000 member hospitals, health systems and other healthcare organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 healthcare leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule implementing and codifying the Medicare Drug Price Negotiation Program (MDPNP) and Medicare Prescription Drug Benefit Program under the Inflation Reduction Act (IRA) of 2022.

The AHA strongly supports CMS' efforts to implement the IRA's drug pricing provisions in a manner that lowers costs for Medicare beneficiaries and preserves access to needed therapies. As CMS continues to operationalize the MDPNP, it is critically important that the agency codify policies that are administratively feasible for hospitals and health systems most likely to be furnishing negotiation-eligible drugs to Medicare beneficiaries. In particular, the agency's implementation of the MDPNP should avoid unintended consequences for the 340B Drug Pricing Program and the communities that benefit from the program.

Our principal recommendation is that CMS use its authority to require drug manufacturers to make the Maximum Fair Price (MFP) available through a prospective, point-of-sale mechanism and eliminate any option that would permit manufacturers to satisfy their obligations through retrospective rebates or post-sale reconciliations. Allowing drug manufacturers to choose between prospective and

retrospective approaches would add significant operational costs and challenges for hospitals, threatening broader health system affordability aims, and stymie efforts to coordinate with the 340B program to avoid duplicate discounts.

PROSPECTIVE MFP AVAILABILITY BEST SUPPORTS EFFICIENCY, TRANSPARENCY AND ALIGNMENT WITH OTHER DRUG PROGRAMS

The success of the MDPNP depends on a clear and consistent mechanism for providing access to the MFP. The IRA affords the secretary broad discretion to implement access to the MFP in a manner that effectuates the statute and coordinates appropriately with other federal drug pricing programs.[1] Allowing manufacturers the option to satisfy MFP obligations through retrospective rebates creates substantial complexity across the pharmaceutical supply chain. Hospitals, pharmacies, manufacturers, wholesalers and vendors would be required to track, reconcile and adjudicate transactions after the fact. Such an approach would increase administrative costs and the likelihood of disputes regarding eligibility and claim matching, as well as hinder policymakers and other stakeholders' ability to have transparency into the final acquisition cost of drugs.[2]

These concerns are not merely theoretical, but reflect the realities faced by hospitals currently receiving retrospective reimbursement under the system the agency has established through prior guidance. Prospective discounted prices, on the other hand, avoid these problems and provide a transparent and auditable mechanism for ensuring beneficiaries receive the negotiated price. Moreover, the IRA directs the secretary to establish procedures to ensure the MFP of a drug is applied before " … any coverage or financial assistance under other health benefit plans or programs that provide coverage or other financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals … and any other discounts."[3] These administrative requirements are best satisfied through a process that ensures prospective access to the MFP.

Therefore, the AHA urges CMS to exercise the discretion afforded by the IRA to establish a single national standard requiring manufacturers to provide the MFP prospectively at the point of sale for all transactions involving negotiation-eligible drugs that ensures proper coordination with other federal drug programs, such as the 340B program.

HOSPITALS' EXPERIENCE WITH THE CURRENT MFP EFFECTUATION PROCESS DEMONSTRATES WHY PROSPECTIVE PRICING IS NECESSARY

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[1] See Inflation Reduction Act §§ 11001(c), 11002(c).

[2] https://www.aha.org/lettercomment/2025-05-01-aha-comments-medicare-transaction-facilitator-under-medicare-drug-price-negotiation-program

[3] Section 1196(a)(1) of the Social Security Act (42 U.S.C. 1320f-5(a)(1)).

The implementation of MFP effectuation beginning in 2026 has already demonstrated the significant operational challenges associated with retrospective payment mechanisms. Hospitals, health systems and their pharmacy partners have reported substantial administrative burdens associated with identifying eligible claims, tracking MFP transactions, reconciling payment amounts, monitoring manufacturer refund activity, and resolving discrepancies across multiple dispensing and purchasing systems.[4] Many hospitals have expressed concerns that the current refund-based structure requires extensive manual processes and investments in new information technology capabilities to ensure that eligible transactions are properly identified and that manufacturers have met their obligations. Unlike traditional upfront discounts, retrospective payment models have introduced uncertainty regarding the timing and amount of reimbursement, requiring providers to maintain additional oversight and auditing functions. These concerns are particularly acute for safety-net, rural and other resource-constrained hospitals that lack dedicated personnel and systems to manage increasingly complex manufacturer reimbursement arrangements.

We believe these practical implementation challenges provide a compelling rationale for requiring a prospective, point-of-sale MFP program. Prospective pricing eliminates the need for extensive after-the-fact reconciliation, provides immediate pricing certainty throughout the supply chain, and reduces administrative costs and burden on hospitals, pharmacies, manufacturers and vendors. Most importantly, it creates a transparent mechanism for coordinating the MDPNP with the 340B program while minimizing the risk of duplicate discounts.

RETROSPECTIVE MFP MODELS HAVE CREATED UNINTENDED CONSEQUENCES FOR 340B HOSPITALS

The AHA is especially concerned that permitting retrospective MFP effectuation could establish the operational foundation for broader manufacturer efforts to move the 340B program away from upfront discounts and toward a rebate-based model. As AHA has communicated to Health and Human Services, a 340B rebate program would fundamentally alter the program and impose substantial costs and burdens on covered entities.[5] In fact, the agency's own estimate puts the cost of its proposed rebate program for 340B covered entities at over half a billion dollars annually.[6] We believe this amount actually underestimates the true cost of the program to hospitals.

Unlike manufacturers, many hospitals, particularly rural, critical access, sole community and safety-net facilities, do not have the resources or infrastructure necessary to finance large volumes of drug purchases while awaiting rebate payments. Delayed

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[4] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/

[5] https://www.aha.org/lettercomment/2026-07-15-aha-responds-hrsa-340b-rebate-model-pilot-program-information-request

[6] https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001

reimbursement adversely affects hospital cash flow, increases administrative overhead and diverts scarce resources away from patient care. In addition, a rebate model requires hospitals to develop new systems to identify eligible claims, submit rebate requests, resolve manufacturer disputes, audit transactions and manage payment delays. Such requirements create significant compliance costs while increasing the likelihood of payment discrepancies and disagreements over eligibility determinations.

Importantly, while Section 1193(d) of the IRA requires manufacturers to provide access to the MFP and directs that 340B covered entities receive access to the lower of the MFP or the 340B ceiling price, Congress did not prescribe a specific operational mechanism through which that access must be provided.[7] Instead, Congress assigned the secretary with responsibility for administering the MDPNP and establishing the procedures necessary to implement it. The statute further recognizes the continued operation of the 340B program by requiring access to the lower of the MFP or the 340B ceiling price and directing the secretary to establish procedures to ensure nonduplication. These provisions demonstrate that Congress intended the MDPNP to be coordinated with, rather than disrupt or undermine, the 340B program. Nothing in the statute suggests that the duplicate discount safeguards were intended to serve as a vehicle for fundamentally restructuring the 340B program, replacing its longstanding prospective discount framework with a retrospective rebate model, or shifting significant new administrative burdens onto covered entities. Rather, the nonduplication provisions are best understood as safeguards to ensure appropriate coordination between the two federal programs while preserving the benefits of both. **Accordingly, CMS has ample authority to require a prospective, point-of-sale approach to MFP effectuation, which is the most effective means of preventing duplicate discounts, minimizing administrative burden and ensuring that implementation of the MDPNP does not inadvertently erode access to 340B pricing or undermine the safety-net providers that rely on the program to serve their patients and communities.**

ADDITIONAL CONCERNS

The AHA also encourages CMS to carefully evaluate any future implementation requirements that shift administrative responsibilities to providers, hospitals or pharmacies. As CMS continues to develop policies related to MFP effectuation, reporting, eligibility verification and compliance monitoring, the agency should minimize provider reporting obligations and avoid creating duplicative tracking systems that require hospitals to maintain separate operational processes for Medicare-negotiated drugs. In addition, CMS should ensure that any future guidance or rulemaking regarding MFP availability maintains clear national standards and avoids permitting manufacturer-specific approaches that could create inconsistency across products and markets. Uniform processes are essential to reducing compliance burden and ensuring predictable access to negotiated prices.

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[7] Section 1193(d) of the Social Security Act (42 U.S.C. 1320f-5(a)(1)).

In conclusion, the AHA appreciates CMS' work to implement the Medicare Drug Price Negotiation Program and its efforts to lower prescription drug costs for Medicare beneficiaries. **However, to ensure successful implementation and avoid significant unintended consequences for hospitals and the 340B program, we urge CMS to use its authority to require that manufacturers make the MFP available through a prospective, point-of-sale mechanism and should not permit retrospective rebate-based alternatives.** Such a policy would reduce administrative burden, facilitate compliance with duplicate discount requirements, promote operational certainty across the supply chain and avoid creating a precedent that could pave the way for a costly and burdensome 340B rebate model.

We appreciate your consideration of these comments. If you have any questions, please contact me or have a member of your team contact AHA Director of Pharmaceutical Policy Bharath Krishnamurthy at bkrishnamurthy@aha.org. We look forward to continued engagement with CMS on these important issues.

Sincerely,

/s/

Stacey Hughes
Executive Vice President
Government Affairs and Public Policy