AMERICA'S ESSENTIAL HOSPITALS

March 5, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: Improving Implementation of Federal Programs to Reduce Drug Costs: Feedback on Progress in Effectuating the Maximum Fair Price and Protecting 340B Discounts

Dear Administrator Oz:

On behalf of our nearly 400 member hospitals, we appreciate the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS) on achieving the intent of the Medicare Drug Price Negotiation Program (MDPNP) while protecting appropriate access to 340B Drug Pricing Program discounts. We have identified initial challenges and propose ways to better understand and address them. We look forward to continuing to work with CMS and the Health Resources and Services Administration (HRSA) to ensure the MDPNP program works as intended.

America's Essential Hospitals has advanced policies and programs that promote health and access to health care. We support our members with advocacy, policy development, research, education, and leadership development. Communities depend on essential hospitals for care across the continuum, health care workforce training, research, public health, and other services. Supported by Essential Hospitals Institute, the association's research and education arm, essential hospitals innovate and adapt to lead all of health care toward better outcomes and value.

The mission of essential hospitals closely aligns with President Trump's vision to make all Americans healthy. Essential hospitals are committed to serving people in all communities that need access to quality care. Although essential hospitals account for only 6% of acute-care hospitals nationwide, they provided 29% of the nation's charity care in 2023. About three-quarters of the patients our members serve are uninsured or enrolled in Medicaid or Medicare.[1] In addition, nearly two-thirds of essential hospitals provide services to rural patients and

[1] Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. https://essentialdata.info. Accessed March 2, 2026.

AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: contact@essentialhospitals.org

communities.[2] To meet the needs of all patients, essential hospitals constantly engage in robust quality improvement initiatives and have created programs that improve quality and access, including efforts to combat chronic health conditions, all while lowering health care costs and health care spending. The 340B program is a critical tool in these efforts, with 97% of our member systems relying on 340B to serve their patients.[3]

Congress required that manufacturers provide the lower of the 340B ceiling price or the established maximum fair price (MFP), protecting manufacturers from duplicate discounts and providers from paying higher prices for these drugs. As implementation has begun, our member hospitals have reported instances when existing mechanisms do not work appropriately. **Some manufacturers are failing to provide a timely MFP to covered entities as required under the MDPNP. Thus, cash-strapped 340B hospitals are forced to expend additional administrative and financial resources to contest the improper determinations and receive the refunds to which they are entitled**. In addition, CMS has opportunities to streamline and expedite the dispute resolution and refund processes.

We believe CMS can use oversight tools within its existing guidance as well as additional steps recommended below to improve program operations. **We urge CMS action to preserve the MDPNP's intent, preferably before the MDPNP expands to include additional products in 2027**.

Below, we provide additional detail on the feedback we have received from members as well as our proposals to better understand the problems and reduce errors moving forward.

Reported Challenges in Ensuring Timely Access to the Mandated MFP or 340B Price

1. Some manufacturers are using faulty assumptions, contrary to CMS guidance, that improperly identify claims as 340B-eligible and refuse to provide an MFP refund for such claims within the required 14-day window.

Reports from our members indicate that, since the implementation of the MDPNP on Jan. 1, some manufacturers are using deduplication approaches that CMS' prior guidance has identified as problematic. As a result, claims are improperly identified as 340B-eligible, leading to a wrongful denial of an MFP refund. Due to manufacturer policies, 340B hospitals are not receiving MFP refunds to which they are entitled within CMS' required 14-day prompt MFP payment window.[4]

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[2] America's Essential Hospitals. Policy Brief: Essential Hospitals Ensure Access to Care in Rural Areas. March 2025. https://essentialhospitals.org/wp-content/uploads/2025/03/2025-Access-to-Care-inRural-Areas-Brief.pdf. Accessed Feb. 10, 2026.

[3] Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. https://essentialdata.info. Accessed March 2, 2026.

[4] CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of Maximum Fair Price in 2026 and 2027. Oct. 2, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. Accessed March 4, 2026.

Some manufacturers are identifying a claim as 340B-eligible based on limited proxy information, rather than confirmed claim-level 340B status. For example, we understand some manufacturers are identifying claims as 340B-eligible if they are associated with a 340B covered entity. **CMS explicitly prohibited this practice in its MDPNP final guidance**. The guidance states that a National Provider Identifier (NPI) "alone (whether a prescriber NPI or a hospital/provider NPI) generally will not constitute sufficient evidence that a claim was 340B-eligible as not all individuals served by covered entities are necessarily eligible to receive a drug purchased at the 340B ceiling price."[5]

Inappropriate denials are particularly impactful when 340B providers have "carved out" certain pharmacy operations from purchasing 340B discounted drugs due to compliance issues (e.g., state Medicaid rules or patient definition issues). In those instances, even though a certain pharmacy must exclusively purchase at the group purchasing organization (GPO) price and can never receive a 340B discount, it is denied the MFP simply because the pharmacy is associated with a 340B covered entity. In addition, one member hospital reported MFP denials for *inpatient* purchases, which are ineligible for outpatient-only 340B discounts.

When our members raised this concern to Beacon MFP platform support, the platform responded that covered entities "should apply 340B modifiers to 340B claims to support program integrity." Yet, in its final MDPNP guidance, CMS explicitly declined to require the use of a claim modifier for 340B claims and reiterated that submission of "340B Claim Indicator" data is optional for covered entities.[6] In consideration of the issue in annual rulemaking, CMS acknowledged that the 340B status of a Medicare Part D drug is usually not known by the dispenser at the point of sale but rather retrospectively.[7]

Erroneous denials due to improper assumptions cause meaningful harm to our member hospitals. 340B hospitals are facing a new and unforeseen administrative burden as they now must challenge a significant number of improper denials and provide additional information to receive their entitled refund.

a. The MFP rebate process has created a prompt payment loophole that creates new risks for provider access to MFP.

CMS' 14-day prompt pay window for MFP refunds is critical to protecting timely access to lower-cost drugs. However, the erroneous denials have revealed a loophole—**CMS has not set a deadline for providers to receive access to the MFP when a claim is inappropriately denied as 340B-eligible.**

The situation creates unanticipated financial burden for providers. When an MFP refund is improperly denied, 340B hospitals do not receive their entitled refund within the 14-day required payment window. 340B hospitals then must wait for an indefinite period to receive such refunds, since **there is currently no mandatory process or timeline for manufacturers to determine that the MFP was inappropriately denied and provide the required refund**. As the refund process is functioning now, cash-strapped 340B hospitals cannot appropriately budget and operate.

[5] Ibid.
[6] Ibid, at 60, 203.
[7] 90 Fed. Reg. 32352 (July 14, 2025).

Additionally, 340B hospitals must pay the wholesale acquisition cost (WAC) to purchase the negotiated drugs since the use of GPOs for covered outpatient drugs is prohibited for such entities. Hospitals serving a substantial percentage of low-income and uninsured patients are thus forced to cover the exponentially higher purchase cost for an unknown amount of time.

b. Improvements are needed to ensure prompt resolution of MFP disputes.

The association has heard reports that dispute resolution is being routed through 340B ESP, even for non–contract pharmacy entities. This process creates a significant implementation problem for covered entities that do not operate contract pharmacies and/or do not currently submit data to 340B ESP. **340B hospitals are forced to navigate a new system to rectify issues caused by manufacturers, even in states with prohibitions on manufacturers requiring 340B ESP use in the contract pharmacy context**.

Proposals for CMS Action to Understand and Mitigate Reporting Challenges

a. CMS should use the mechanisms it outlined in its MDPNP final guidance to ensure that manufacturers are effectuating the MFP.

In CMS' MDPNP final guidance, the agency outlined how it will monitor access to the MFP, particularly when the agency receives reports of noncompliance from dispensing entities/other market participants. Given the reports from our members that some manufacturers are failing to provide MFP refunds within the 14-day prompt payment window, **we encourage CMS to use these mechanisms to encourage manufacturer compliance.**

First, CMS stated that it "will monitor the status of unpaid claims and claims paid at a refund amount other than the standard default refund amount (SDRA)."[8] Specifically, manufacturers are required to maintain documentation when they deny an MFP refund or provide a refund other than the SDRA, and CMS may request such documentation to ensure compliance with the MDPNP. We encourage CMS to collect such records to understand the discrepancies occurring in the program.

Second, CMS indicated the actions it will take if it receives complaints from dispensing entities/other market participants that a manufacturer has not consistently made the MFP available by providing a refund within the 14-day prompt payment window. The agency will (1) issue a Notice of Potential Noncompliance to the manufacturer and (2) encourage the manufacturer to address the discrepancies as soon as possible.[9] CMS should further investigate the instances of noncompliance identified in this letter, issue notices of potential noncompliance, and encourage the noncompliant manufacturers to fix their deficient procedures as soon as possible.

Third, the agency committed to identifying manufacturer plans that have a greater risk of noncompliance and to subject such manufacturers to a heightened level of monitoring and oversight to ensure they are consistently providing the MFP.[10] CMS should publicly share which

[8] CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of Maximum Fair Price in 2026 and 2027. at 284-85. Oct. 2, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. Accessed March 4, 2026.,
[9] Ibid. at 282.
[10] Ibid. at 136, 286.

manufacturers are subject to such heightened scrutiny and what steps it has or will take to ensure that such manufacturers comply with the statute.

Fourth, CMS' guidance notes that if a manufacturer fails to provide access to the MFP for eligible drugs, the agency may impose a Civil Monetary Penalty (CMP).[11] **We encourage CMS to consider levying CMPs if manufacturers continuously engage in improperly denying MFP refunds.**

2. CMS should close the loophole in refunding erroneously denied MFP rebates, limit inaccurate deduplication methodologies, and streamline dispute resolution.

Manufacturers should be subject to time limits and CMS oversight for repayment of erroneously denied MFP refunds. Otherwise, only affected providers will have an interest in timely resolution. In addition, CMS should streamline the process for providers to effectively dispute claims. For example, CMS should limit the amount of documentation a manufacturer can require, permit disputing of multiple claims, and allow other means of reducing provider burden. A streamlined process is particularly appropriate when denied claims are obviously 340B-ineligible due to carved-out service locations or provision in inpatient settings.

As the association has highlighted previously, allowing each manufacturer to have its own methodology for providing the lower of the MFP and 340B ceiling price forces covered entities to take on a tremendous financial and administrative burden to receive the price to which they are entitled under federal law.[12] **CMS should apply our members' feedback and the details from the oversight measures outlined in the prior section to limit inappropriate deduplication practices and encourage practices that support both the MDPNP and 340B programs**.

Our members' experiences show that only some manufacturers' deduplication processes are problematic. Other manufacturers appear to be complying with CMS guidance and providing the proper price and/or refund to 340B hospitals. CMS should first take the necessary steps to understand which manufacturers' practices are and are not working. Then, based on that assessment, the agency should modify its guidance to require all manufacturers to use the most effective deduplication practices moving forward.

CMS has also indicated that it is launching a voluntary 340B claims repository this year, which it might use in the future to exclude 340B drugs when determining Medicare Part D inflation rebates.[13] We applaud CMS for testing the repository and implementing user and industry feedback before making further decisions on the repository's future. Investing in the repository is a helpful alternative to individual manufacturer requirements when addressing MFP/340B

[11] Ibid. at 285, 295.
[12] Advocates for Community Health, Ryan White Clinics for 340B Access, National Alliance of State & Territorial AIDS Directors, et al. Joint Letter to Meena Seshamani on July 2, 2024. https://essentialhospitals.org/wp-content/uploads/2024/07/Joint-Comments-on-5.3.24-IRA-Draft-Guidance-7.2.24.pdf. Accessed March 4, 2026.
[13] 90 Fed. Reg. 49741. (Nov. 5, 2025).

deduplication issues while protecting access to 340B discounts and limiting provider burden.[14]

Request for Manufacturers' Plans

CMS has indicated that stakeholders may request copies of manufacturers' plans for effectuating the MFP.[15] At this time, America's Essential Hospitals is requesting copies of all manufacturers' plans to understand the various deduplication processes being used and seek feedback from our members on promising and problematic practices.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Robert Nelb, MPH, at 202-585-0127 or rnelb@essentialhospitals.org.

Sincerely,

Jennifer DeCubellis
President and CEO

[14] See Siegel B. Letter to Mehmet Oz on Sept. 12, 2025. https://essentialhospitals.org/wp-content/uploads/2025/09/CY2026-PFS-9.12.25.pdf. Accessed March 4, 2026.
[15] MDPNP Final Guidance, at 286.