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Advancing Health in America

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May 1, 2025

Kim Brandt
Chief Operation Officer and Deputy Administrator of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request under the Paperwork Reduction Act (PRA) (CMS-10912)

Dear Ms. Brandt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care 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) information collection request regarding the Medicare Transaction Facilitator (MTF) under the Medicare drug negotiation program.

The AHA strongly supports the goal of reining in the exorbitant costs of prescription drugs in the U.S. However, **we remain concerned that the retrospective process established by the prior administration to effectuate the maximum fair price (MFP) for selected drugs undermines congressional intent and impedes the agency's goals of lowering drug prices for patients and providers. We believe that a prospective approach requiring all parties to participate in one standardized process overseen by CMS is the most efficient and effective way to advance the goals of the Inflation Reduction Act (IRA) and the 340B program.**

The MTF is intended to support the exchange of data among dispensing entities, plan sponsors and drug companies to implement drug discounts. Under guidance adopted by the prior administration, the MTF also serves as an optional mechanism to facilitate payment between drug manufacturers and dispensing entities. Although dispensing entities are required to participate in the MTF payment module, drug manufacturers are not.

The retrospective process is complex, overly burdensome and operationally unworkable, particularly with respect to the critical 340B Drug Pricing Program. By allowing drug manufacturers to deny upfront access to the MFP or the 340B price and forcing dispensing entities to participate in a retrospective process designed by the manufacturers themselves, this process unfairly disadvantages patients and the providers who serve them in favor of the drug manufacturers whose pricing practices necessitated legislative intervention in the first place. Requiring providers to pursue rebates and 340B discounts after the fact, rather than mandating that manufacturers offer the lower negotiated prices upfront, runs counter to the established structure and intent of the 340B program. This needlessly complicated framework has already triggered a wave of avoidable litigation by creating a direct and unnecessary conflict between the drug price negotiation and 340B programs — an outcome not required, nor contemplated, by the statute.

Fortunately, CMS can now course correct the previous administration's misguided approach and help ensure the Medicare drug discount program fully achieves its goals of delivering lower prices to the patients and providers who count on these critical drugs. We appreciate the Trump administration's efforts to reduce unnecessary administrative burden and promote efficiency across the federal government and private sector. Building on that intent, CMS can simplify the complex retrospective process by requiring all parties to participate in a single, standardized payment system administered by the MTF. This approach would promote strong oversight while ensuring both efficiency and accountability. **We strongly urge CMS to finalize a process that ensures efficient and prospective access to the MFP and 340B price for all dispensing entities furnishing selected drugs to eligible Medicare patients. In addition, we urge the agency to impose strict accountability measures to ensure drug manufacturer compliance with applicable laws.**

CONCERNS WITH THE IMPLEMENTATION OF THE DRUG PRICE NEGOTIATION PROGRAM

The Inflation Reduction Act of 2022 (IRA) included several provisions authorizing the secretary of Health and Human Services (HHS) to establish a drug price negotiation program (the program) under which the secretary enters into agreements with manufacturers to negotiate lower prices for certain prescription drugs on behalf of individuals enrolled in the Medicare program. While the AHA supports CMS' efforts to negotiate lower prices for certain high expenditure drugs on behalf of Medicare beneficiaries, we believe a prospective, standardized approach administered under the oversight of the MTF is the most effective way to meet the program's goals and ensure timely patient access to needed medications.

The IRA directs the HHS 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."[1] These administrative requirements are best satisfied through a process that ensures prospective access to the MFP. Unfortunately, the guidance issued by CMS focused on two retrospective processes, with little mention of a prospective process. The retrospective process finalized by the agency to effectuate the MFP is counter to the intent and goals of the program and unfairly disadvantages providers and other entities that care for Medicare patients in favor of drug manufacturers, which are the entities responsible for setting high drug prices. In short, this approach amounts to a "pay and chase" model in which providers serving the most vulnerable populations will be forces to pay excess amounts to multi-billion dollar drug companies only to have to attempt to recoup their statutorily-owed discount later.

We appreciate the agency's efforts to balance the interests of a diverse set of stakeholders by devising a mechanism that would enable dispensing entities to access the MFP. We also appreciate the agency addressing hospitals' concerns about sharing data directly with drug companies by establishing a neutral third-party MTF to facilitate the exchange of data and payment between dispensing entities, plan sponsors and drug companies. We remain concerned, however, that this elaborate process will put providers in the position of chasing rebates from drug manufacturers instead of requiring manufacturers to make the lower negotiated prices available upfront.

We are further concerned that CMS' current approach will allow each drug company to establish a unique payment arrangement — and unilaterally change the scope of any such arrangement, so long as 90-day notice is given — creating excessive burden and uncertainty for hospitals and other dispensing entities. While the agency requires drug companies to participate in the MTF data module (DM), it does not require them to participate in the MTF payment module (PM). As a result, each drug company can set up its own unique payment process and then change the process on a whim, leaving hospitals and other dispensing entities with the administrative burden of managing each unique process to access discounts. This approach could prove especially untenable for hospitals and other dispensing entities that may have established annual or longer-term contracts with vendors and third-party administrators to assist with claims processing.

In addition to massive operational costs and related burdens, having so many different processes and also frequently changing processes will complicate hospitals' ability to track whether they were actually paid within the 14-day payment window and paid the full amount owed. Hospitals report that tracking this information across multiple different systems would be costly technologically and extremely burdensome on staff, as in many cases it would need to be done manually. If these barriers left hospitals unable to identify and act on delayed payments, they could face cash flow and budgetary constraints**.**

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

To avoid these issues, we urge CMS to require drug companies to participate in the MTF PM to standardize the payment process across drug companies, and enable dispensing entities to track refund receipts using a less burdensome and more timely process. Alternatively, we urge the agency to disallow drug companies from unilaterally changing alternative payment arrangements once established and approved by CMS.

In addition to the unnecessary complications created by the process finalized earlier by CMS, the agency's retrospective approach increases the risk of noncompliance on the part of drug manufacturers and diminishes the value and impact of the drug negotiation process. By not requiring drug manufacturers to participate in the MTF PM, we are concerned there will not be sufficient oversight to ensure drug manufacturers are complying with the law. We urge CMS to establish a more robust oversight and enforcement mechanism that conforms with specific penalties for noncompliance.[2]

RETROSPECTIVE MPF PROCESS ENABLES DRUG COMPANY MISUSE OF THE 340B PROGRAM

The retrospective process fundamentally changes the 340B program, stripping vital resources from providers caring for the most vulnerable communities. The 340B program is a critical resource for participating hospitals and other covered entities to stretch their resources to maintain, improve and expand access to care for the patients and communities they serve. From the start of the 340B program, participating entities purchased covered outpatient drugs at an *upfront* discounted price, which enables the entity to generate price savings that are used to support a range of patient programs and services, such as behavioral health, medication-assisted treatment and diabetes education. However, any retrospective model to access 340B discounted pricing would jeopardize the ability of 340B covered entities to support access to these important patient programs. **We remain deeply concerned that the prior administration's final guidance on the Medicare drug negotiation program has allowed drug companies to wrongly justify fundamental changes to the 340B program, changing it from an upfront discount to a retrospective rebate.[3]**

The IRA requires that drug manufacturers allow dispensing entities that participate in the 340B program access to the lower of the 340B price or the MFP for selected drugs.[4] However, the federal government has long interpreted 340B statute as a prospective discount program, authorizing the secretary to enter into pharmaceutical pricing agreements (PPA) with manufacturers where the amount paid by 340B covered entities to the manufacturer to acquire a covered outpatient drug does not exceed the 340B

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[2] See section 1197 of the Social Security Act (42 U.S.C. 1320f-6).

[3] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[4] See section 1193(d) of the Social Security Act (42 U.S.C. 1320f-2(d))

ceiling price.[5] Long-standing federal guidance interpreting its responsibilities under the 340B statute sets up a process that allows 340B covered entities to purchase covered outpatient drugs at an *upfront* discounted price.[6]

In its final guidance, CMS acknowledged potential implications for access to 340B pricing given that drug companies can choose to make access to the MFP available prospectively or retrospectively; however, the agency does not address this issue any further. CMS' silence on this issue appears to have been perceived by drug companies as a "green light" to pursue a 340B rebate model whereby drug companies will make the 340B price available in a retrospective manner similar to the agency's process for making the negotiated MFP available through the MTF DM and PM. To date, we have seen five drug companies (Johnson & Johnson, Novartis, Eli Lilly, Bristol Meyers Squibb and Sanofi) announce they will no longer provide the upfront 340B discounted price and instead will unilaterally implement a retrospective rebate model. We anticipate more drug companies will pursue a similar approach.[7]

The 340B statute authorizes only the secretary of HHS to approve any model that alters access to 340B pricing for covered entities. Though the secretary has not approved any of these rebate models and HRSA has notified these companies that their efforts violate the 340B statute, all five companies have sued the federal government to pursue their rebate model. In those lawsuits, all five companies cited the prior administration's final guidance as a reason necessitating the establishment of a 340B rebate model.

We do not see a viable path under the statutory requirements of both the IRA and 340B programs that allow for retrospective access to the MFP but prospective access to the 340B price. It appears that CMS does not either since it does not provide such a process in its guidance. We believe that implementing a **prospective process** is the only viable way to protect upfront access to the 340B price while also ensuring that 340B covered entities receive the lower of the 340B price or the MFP. **We urge CMS to implement a process for prospective access to the MFP, aligning with the federal government's historic interpretation of the 340B statutory requirements and balancing the interests of Medicare patients, dispensing entities and manufacturers under the program.**

IMPACT ON THE 340B PROGRAM

We cannot underscore enough the damage a retrospective 340B rebate would have on 340B hospitals and the patients they serve, including undermining the

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[5] See section 340B(a)(1) of the Public Health Service Act (42 U.S.C. 256b(a)(1)).
[6] Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).
[7] For example, see Sanofi's proposed model: https://www.statnews.com/wp-content/uploads/2024/11/Sanofi_Credit_Model_Policy_Letter_11.22.2024_.pdf

purpose of the program and the benefits it affords to patients and communities across the country.

The AHA conducted a survey in March 2025 to better understand the impact of a retrospective 340B rebate model on its members. The findings from this survey include:

1) Ninety-nine percent of hospitals indicated that a retrospective rebate model would limit their ability to fund critical patient programs and services. The rebate models would create access issues for patients who are unable to access certain 340B drugs because the hospital would be unable to stock them. Many hospitals reported that the requirement to purchase drugs at a higher price could lead to an inability to purchase certain drugs in the quantities required to meet patient demand.
2) The rebate model would require 340B hospitals to subsidize millions of dollars to drug companies by purchasing certain outpatient drugs at a higher price (e.g. wholesale acquisition cost). Some hospitals have indicated this alone could result in more than $10 million in added costs. Shifting this kind of financial liability to organizations operating on thin or negative margins and on the front lines of serving our most vulnerable populations, including millions of Medicare beneficiaries, could directly impact their ability to meet patient needs. This could harm patient access to care while also directly undermining the purpose of the 340B program.
3) More than 200 hospitals reported that floating millions of dollars to drug companies would reduce their cash on hand enough to risk violating their bond covenants. 340B hospitals rely on bond financing to raise money for new projects that enhance patient care. Those bonds typically include covenants requiring hospitals to maintain a certain amount of days of cash on hand. Violating those covenants would have calamitous effects on 340B hospitals, including downgrades in credit ratings, increased borrowing costs, lack of access to state-of-the-art medical equipment, and more.
4) One hundred percent of hospitals reported increased costs due to operational impacts of the rebate model. The model would create an enormous administrative burden for 340B covered entities, which would bear the responsibility of providing claims-level data elements to drug companies or risk not getting paid. Some hospitals have indicated that establishing the infrastructure for sharing these data is not only costly to establish, but some of the data being required by drug companies may be impossible to provide in their required timeframes. It effectively floats millions of dollars to drug companies without any assurance of being paid the discounts that are owed under the law. In addition, the 340B rebate models proposed so far are each markedly different, requiring different data elements and creating different timelines for 340B covered entities. If implemented, this will create an additional layer of burden and uncertainty for 340B hospitals.

An unapproved 340B retrospective rebate model wrests oversight of the program away from HHS and places it in the hands of self-interested drug companies in ways neither Congress nor the department intended. The model is also in direct opposition to the administration's goals of reducing burdensome administrative requirements that prevent Americans from accessing the care they need to live their healthiest lives. **We strongly urge CMS to revisit its guidance and make clear that drug companies cannot misuse their obligations under the IRA to create an unlawful rebate model in the 340B program.**

PROPOSED APPROACH TO ENSURING PROSPECTIVE ACCESS TO MFP AND 340B PRICING

Given the concerns outlined above, we urge the agency to adopt an approach that ensures *prospective* access to the MFP for any dispensing entity furnishing drugs to an eligible Medicare patient. In the case of a dispensing entity that is eligible and participating in the 340B program, we ask the agency to ensure that the 340B entity retains its ability to access the upfront 340B discounted price. Below, we propose one such process that would achieve these goals, is operationally feasible, and adheres to the statutory requirements, including the need to protect against the 340B nonduplication provision in section 1193(d)(1) of the Act.

Purchasing at the prospective MFP or 340B price. Under our proposed approach, any dispensing entity would have prospective access to the MFP price when purchasing a selected drug for any eligible Medicare patient. Any dispensing entity participating in the 340B program would retain its ability to purchase a selected drug at the 340B price for all eligible Medicare patients. This likely would likely require dispensing entities to maintain separate inventories for these selected drugs. Dispensing entities, particularly those that participate in 340B, already operate separate 340B and non-340B inventories for their drugs either through separate physical inventories or through a virtual replenishment model facilitated by a third-party administrator (TPA). Since the statute requires the HHS secretary to publish the list of selected drugs far in advance of the applicability period, it would be feasible for dispensing entities to establish a separate physical or virtual inventory for these drugs, which could be facilitated by their TPAs if necessary.

MTF facilitates refund payments from manufacturers to dispensing entities. If the MFP is lower than the 340B price for the selected drug, the MTF should then transmit to the manufacturer only the data required to verify the pricing. It is important that the MTF limits the ability of the manufacturer to receive data that is beyond the scope of effectuating the MFP and could be used by the manufacturer for its own financial advantage. Upon receipt of the data elements from the MTF, the manufacturer would have a 14-day timeframe, as proposed in section 40.4 of the agency's draft guidance, to verify the pricing data and direct the MTF to facilitate payment to the dispensing entity. For the MTF to facilitate *timely* payment, we propose that dispensing entities share banking information only with the MTF. At the same time, we propose the MTF require

each drug manufacturer to submit funds necessary to process any required refunds for the difference between the 340B price and MFP in a non-interest-bearing escrow account to be held by the MTF. The concept of CMS facilitating an escrow account is not without precedent as the agency uses escrow accounts in managing refunds under the Medicare shared savings program. Upon manufacturer verification of pricing or the 14-day timeframe, whichever occurs sooner, the MTF should be automatically authorized to deduct the appropriate amount from the manufacturers escrow account and issue payment to the dispensing entity. We believe this both ensures timely payment and minimizes burden for dispensing entities by not requiring them to share banking information with multiple manufacturers. As a final step, the MTF would notify the dispensing entity that the MFP price of the drug has been verified by the manufacturer and a refund has been issued so that the covered entity and/or TPA can ensure proper inventory management under a physical or virtual replenishment model.

In conclusion, we appreciate the opportunity to provide feedback on this critically important program. We urge this administration to reconsider the approach previously developed, and simplify the payment process to better align with current law and congressional intent. It is of the utmost importance that the program is implemented in a way that carefully balances the interests of patients, providers, the government and manufacturers. We believe that a prospective approach requiring all parties to participate in one standardized process overseen by CMS is the most efficient and effective way to ensure patients will benefit from access to lower cost drugs.

We welcome the opportunity to discuss our comments or any other aspects of this program in greater detail. If you have any further questions, please feel free to contact Megha Parikh, AHA associate director of policy and analytics, at mparikh@aha.org.

Sincerely,

/s/

Ashley Thompson
AHA Senior Vice President, Public Policy Analysis and Development