American Hospital Association™
Advancing Health in America

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December 26, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director 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 Dr. Seshamani:

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 share our comments on the Centers for Medicare & Medicaid Services (CMS) information collection request (ICR) regarding the Medicare Transaction Facilitator (MTF) and the Medicare drug negotiation program. **We remain concerned that the process established by CMS may undermine congressional and agency goals of lowering drug prices for patients and providers.**

ROLE OF THE MEDICARE TRANSACTION FACILITATOR

We appreciate the agency's effort to balance the interests of a diverse set of stakeholders by devising a mechanism that would enable dispensing entities to access the negotiated maximum fair prices (MFP). We also appreciate the agency addressing hospitals' concerns about sharing data directly with drug companies by establishing a third-party, neutral MTF to facilitate the exchange of data and payment between dispensing entities, plan sponsors and drug companies. We remain concerned, however, that CMS' approach will allow each drug company to establish a unique process thus creating significant 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, requiring hospitals and other dispensing entities to manage innumerable different arrangements. This not only creates massive operational costs and burdens, but it also 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 led hospitals to be unable to identify and act on delayed payments, they could face cash flow and budgetary constraints. **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 in a less burdensome and more timely process.**

Further, CMS appears to allow drug companies to unilaterally change the scope of any alternative payment arrangements as long as 90-day notice is given. This could create challenges for hospitals and other dispensing entities that may have established annual or longer-term contracts with vendors and third-party administrators that assist in claims processing. Therefore, not only could hospitals and other dispensing entities not be able to accommodate certain changes, but also the ability of drug companies to make changes introduces further uncertainty into the process. **We urge the agency to disallow drug companies from unilaterally changing alternative payment arrangements once established and approved by CMS.**

IMPLICATIONS FOR THE 340B PROGRAM

From the start of the 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. **We are deeply concerned that the agency's Oct. 2 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.**[1]

In its final guidance, CMS acknowledges 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. **Given the concerns outlined below, we urge the agency to ensure that prospective access to 340B pricing is maintained to prevent unintended harm to 340B hospitals and their patients.**

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

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 four drug companies (Johnson & Johnson, Eli Lilly, Bristol Meyers Squibb, and Sanofi) attempt to establish a 340B rebate model, and we anticipate more drug companies will pursue a similar approach.[2]

The 340B statute authorizes only the secretary the ability 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 the Health Resources and Services Administration has notified these companies that their efforts violate the 340B statute, all four companies have sued the federal government in an effort to pursue their rebate model. Each of the four companies has cited CMS' Oct. 2 final guidance as a reason necessitating the establishment of a 340B rebate model.

We cannot underscore enough the damage a 340B rebate model would have on 340B hospitals and the patients they serve. A 340B rebate model would:

1) Create access issues for patients who may be unable to access certain 340B drugs because the hospital is unable to stock it. By requiring hospitals to purchase the drug at a higher price, many hospitals have reported that it could lead to an inability to purchase certain drugs at the quantities required to meet patient demand.
2) 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 – something that is not only dangerous for patient access to care but also directly undermines the purpose of the 340B program.
3) Create an enormous administrative burden for 340B covered entities that would have to establish the programs necessary to provide claims data elements to drug companies or risk not getting paid. Some hospitals have indicated this 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, which would only exacerbate the problems of floating 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

[2] 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

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 rebate model not only violates the law but undermines the purpose of the 340B program and the benefits it affords to patients across the country. It wrests oversight of the program away from the Department of Health and Human Services and places it in the hands of self-interested drug companies in ways neither Congress nor the department intended. **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.**

We appreciate the opportunity to provide feedback to the agency on this critically important program. It is of utmost importance to us that the agency effectuates a policy that balances the interests of Medicare patients who stand to benefit from access to lower-cost drugs, and also the dispensing entities, manufacturers, taxpayers and government. We believe the only way these interests can be achieved is in a manner that does not unintentionally add burden to providers and undermine the vitally important 340B program. We welcome the opportunity to discuss our comments or any other aspects of this important program in more detail. Please contact me if you have any questions, or feel free to have a member of your team contact Bharath Krishnamurthy, AHA's director of policy and analytics, at bkrishnamurthy@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development