American Hospital Association™
Advancing Health in America

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July 2, 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, Maryland 21244

Re: Medicare Drug Price Negotiation Program Draft Guidance

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(AHA) appreciates the opportunity to share our feedback on the Centers for Medicare & Medicaid Services' (CMS) draft guidance on the Medicare drug price negotiation program. The AHA supports the intended goals of the Inflation Reduction Act (IRA) to lower the exorbitant costs of drugs in the U.S. However, the agency's proposal to effectuate this policy in a retrospective manner is problematic and may undermine the very goals Congress and the agency have of lowering drug prices for patients and providers.

The agency's proposed retrospective refund process is complex, burdensome and would be operationally unworkable, particularly with respect to the critical 340B Drug Pricing Program. We are deeply concerned that such an elaborate process would put providers in the position of chasing rebates and 340B discounts from drug manufacturers instead of requiring manufacturers to make the lower negotiated prices available upfront, just as the 340B program currently works. In addition, given the implications for the 340B statute, which the Health Resources and Services Administration (HRSA) has interpreted through agency guidance as a prospective discount program, there are significant questions about the draft guidance's retrospective approach. **Therefore, we urge the agency to finalize a process that ensures *prospective* access to the maximum fair price (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 manufacturers are complying with the law.**

OPERATIONAL CONCERNS WITH CMS' PROPOSAL

The agency's retrospective approach is unnecessarily complex and operationally challenging, which will add substantial costs to providers as they would need to build the infrastructure necessary to chase rebates from drug manufacturers. The imposition of new costs on drug purchases directly undermines the intent of the IRA. In addition, the retrospective approach could fundamentally change the 340B program, which would strip vital resources from providers caring for the most vulnerable communities.

Transmission of data and other sensitive information. In section 40.4.1 of the draft guidance, CMS discusses the role of the Medicare Transaction Facilitator (MTF) in transmitting data between covered entities and manufacturers. The AHA appreciates CMS' commitment to limiting the type and amount of data and other sensitive information that would be made available to manufacturers for purposes of carrying out the program. However, we do not believe the proposed retrospective processes provide adequate safeguards to ensure the protection of private or otherwise sensitive information shared by eligible Medicare patients and dispensing entities. Instead, we urge CMS to consider a prospective approach with a more robust role for the MTF such that sensitive information, like a patient's personally identifiable information, or a dispensing entity's banking information, is not made available to the manufacturer or any other entity. The MTF could act as a clearinghouse to facilitate both pricing verification and payment between dispensing entities and manufacturers, which would better protect against the sharing of sensitive data across multiple stakeholders. Recent data breaches of third-party vendors in the health care industry, such as the Change Healthcare cyberattack, underscore the importance of limiting any unnecessary transfer of sensitive data. **We believe the MTF would be best positioned to evaluate data submitted by covered entities, plans and manufacturers and share only that information which is absolutely necessary for purposes of effectuating the program.**

Implications for 340B program operations. 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. The program relies on the ability of participating entities to purchase covered outpatient drugs at an *upfront* discounted price which enables the entity to generate price savings that is used to support a range of patient programs and services such as behavioral health, medication-assisted treatment and diabetes education. Simply put, any retrospective model to accessing the 340B discounted pricing would jeopardize the ability of 340B covered entities to support access to these important patient programs. This is for two reasons. First, as noted above, drug manufacturers have a history of avoiding payment of 340B discounts. A retrospective approach would give them a new, complex administrative process through which to avoid paying such discounts. Our concerns are not unfounded given that drug companies and their vendors have explored such efforts in the past, and Congress, in a bipartisan manner, has written to

the Health and Human Services (HHS) Secretary to disallow such an approach.[1] Second, the costs of administering such a program would effectively deplete a portion of the savings — shifting dollars meant for patient programs to third party technology companies and other administrative actors.

A retrospective 340B rebate model would mean covered entities would not be able to purchase covered outpatient drugs at the 340B price at the point of sale. Instead covered entities would be required to purchase these drugs at a much higher price and wait for a refund. This would require hospitals and their 340B third-party administrators (TPAs) to completely change their 340B operations and would create devastating cash flow issues, including for many hospitals that continue to operate under substantial financial strain. Further, this would require the 340B covered entity or its TPA to transmit sensitive claims data to each drug manufacturer (of which there are many) creating unnecessary burden and cost to the covered entity, and which can be used by the drug manufacturer for their own financial advantage. Finally, we believe a retrospective process would create an administrative nightmare for covered entities and for HRSA. 340B covered entities that have not received refunds from manufacturers could choose to seek relief through the 340B administrative dispute resolution (ADR) process as an instance of a manufacturer overcharge. As a result, the 340B ADR process could be inundated with such requests for administrative review, creating uncertainty for covered entities, manufacturers and the government.

STATUTORY CONCERNS WITH CMS' PROPOSAL

The IRA includes several provisions authorizing the HHS Secretary 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. The agency's draft guidance seeks to effectuate the program through a series of complex processes with which we have concerns. Chief among these is that the two processes the agency proposes to effectuate the MFP are retrospective and unfairly disadvantage providers and other entities who care for Medicare patients in favor of drug manufacturers who are the entities responsible for setting high drug prices.

CMS makes clear that the statute directs the manufacturer, not the agency or the HHS Secretary, to make the MFP available to all dispensing entities for selected drugs. We agree. However, the statute does recognize the HHS Secretary's administrative responsibilities for the purposes of administering the program.[2] These responsibilities include entering into agreements with manufacturers, selecting negotiation-eligible drugs, publishing the MFP for selected drugs, and engaging in other administrative duties, including conducting oversight and enforcement requirements under the

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[1] https://calhospital.org/wp-content/uploads/2020/11/201113_final_340b_hhs_letter.pdf
[2] See section 1196 of the Social Security Act (42 U.S.C. 1320f-5).

program.[3] In addition, the statute 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."[4] We believe these administrative requirements are best satisfied through a process that ensures prospective access to the MFP. At the very least, the statute does not prohibit the HHS Secretary from establishing a prospective approach. In fact, CMS acknowledges in this draft guidance that manufacturers may meet their statutory responsibilities either prospectively, by ensuring the acquisition cost paid by a dispensing entity is no more than the MFP, or retrospectively, by reimbursing a covered entity for the difference between such entity's acquisition cost and the MFP. Yet, in this draft guidance, the agency only proposes a retrospective process.

The agency's retrospective process also appears to conflict with the 340B program. 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.[5] However, the 340B statute authorizes 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 ceiling price.[6] HRSA's long-standing 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.[7]

We cannot conceive of a process where there could be retrospective access to the MFP but prospective access to the 340B price while still complying with the statutory requirements under both the IRA and 340B statutes. It appears that the agency cannot either since it does not provide for such a process in its draft guidance. We believe the only way to protect upfront access to the 340B price while also ensuring that 340B covered entities have access to the lower of the 340B price or the MFP is to effectuate a prospective process. **Therefore, we urge CMS to finalize a prospective process that aligns with HRSA's historic interpretation of the 340B statutory requirements and balances the interests of Medicare patients, dispensing entities and manufacturers under the program.**

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[3] See section 1191(a) of the Social Security Act (42 U.S.C. 1320f).
[4] Section 1196(a)(1) of the Social Security Act (42 U.S.C. 1320f-5(a)(1)).
[5] See section 1193(d) of the Social Security Act (42 U.S.C. 1320f-2(d))
[6] See section 340B(a)(1) of the Public Health Service Act (42 U.S.C. 256b(a)(1)).
[7] 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).

PROPOSED APPROACH 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. We propose one such process the agency could implement 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 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 TPA. Since the statute requires the HHS Secretary to publish the list of selected drugs far in advance of the applicability period, we presume that it would not be too burdensome for dispensing entities to establish a separate physical or virtual inventory for these drugs and could be facilitated by their TPAs, if necessary.

MTF facilitates data verification. Upon purchase of the drug, the dispensing entity would submit the claim to the plan sponsor via the same process the agency lays out in the draft guidance. If a selected drug is purchased at the MFP and it is approved by the plan sponsor, no further action is needed by the MTF or the manufacturer. For a selected drug purchased at the 340B price, the 340B covered entity or its TPA would submit to the MTF a batch datafile that contains only necessary data elements for each 340B-eligible drug claim.[1] The necessary data elements would include whether a selected drug was purchased at the prospective 340B price or MFP and an indicator noting whether the MFP is higher or lower than the 340B price for that drug. Since current regulations allow only the 340B covered entities, drug manufacturers, and HRSA to have access to proprietary 340B pricing data, the MTF would need one of these parties to notify them as to which price, 340B or MFP, is lower. We propose that the covered entity or its TPA could accommodate this with the ability of the manufacturer to verify the information later. Once the batch datafile is received by the MTF, it could reconcile the data elements against the prescription drug event (PDE)

[1] This process is similar to the "Oregon model" employed by the State of Oregon to protect against the 340B statutory prohibition of a drug being subject to both 340B discounted pricing and a Medicaid rebate. www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx

data submitted by the plan sponsor to verify that the claim was approved by the plan, is an eligible 340B claim, and flag claims where the MFP for the selected drug Is lower than the 340B price. For any claim where the 340B price is lower than the MFP, the MTF could notify the dispensing entity that no further action is needed. This would allow the dispensing entity or its TPA to ensure proper inventory management.

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 that 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. In order 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.[8] 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 ensures both 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.

ACCOUNTABILITY MEASURES TO ENSURE COMPLIANCE

In addition to the concerns outlined above, we believe that the proposed mechanisms to oversee and enforce the requirements of the program are insufficient and fail to conform with the specific penalties for noncompliance.[9] For example, in section 100.1 of the proposed guidance, CMS states that it may impose a civil monetary penalty in the event that a primary manufacturer does not make the MFP for a selected drug available to an MFP-eligible individual (or a covered entity providing such a selected drug to such an individual). However, the statutory language does not provide the HHS Secretary with discretion in applying a civil monetary penalty. Rather, the language expressly requires

[8] https://www.cms.gov/files/document/2021-05-27-medicare-shared-savings-program.pdf
[9] See section 1197 of the Social Security Act (42 U.S.C. 1320f-6).

the HHS Secretary to apply a very specific civil monetary penalty in such a situation. We believe that statutory compliance and the integrity of the program can only be protected with clear and consistent enforcement of such rules. As written, the proposed guidance unnecessarily increases the risk of noncompliance and diminishes both the value and impact of both the drug negotiation and 340B programs. We urge CMS to establish a more robust oversight and enforcement mechanism that conforms with the requirements set forth in the statute.

In conclusion, 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 dispensing entities, manufacturers, the government, and most importantly, the Medicare patients who stand to benefit from access to lower cost drugs. We believe that the only way these interests can be achieved is through a process that ensures prospective access to the MFP and 340B price for a selected drug. We welcome the opportunity to discuss our comments or any other aspects of this important program in more detail.

Sincerely,

/s/

Ashley Thompson
Senior Vice President, Public Policy Analysis and Development