Submitted via email to IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Dr. Meena Seshamani, M.D., Ph.D.
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Drug Price Negotiation Program (MDPNP) Draft Guidance

Dear Dr. Seshamani:

We, the undersigned organizations, represent the broad range of health care providers and programs that participate in the federal 340B Drug Pricing Program. We are writing to share our concerns regarding the Centers for Medicare & Medicaid Services' (CMS) May 3, 2024, draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) provisions. As 340B covered entities, we rely upon our 340B financial benefit to provide vital care and services to our patients and communities, consistent with Congress' intent for the program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Therefore, we are greatly concerned that the guidance, if implemented as proposed, would impermissibly interfere with covered entities' (CEs) ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on CEs, would recommend that CEs share their claims data directly with manufacturers, and would force CEs to pay higher prices higher than 340B until they receive a refund from a manufacturer in instances where a drug's MFP is lower than its 340B ceiling price. By hindering CEs' ability to receive upfront 340B discounts, CMS' proposed approach would ultimately harm the patients and communities that benefit from CEs' use of the savings realized through these discounts. In issuing the guidance, CMS has failed to meet its statutory obligation to ensure that CEs receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP.

CMS proposes a process for implementing the MFP provisions for non-340B claims that essentially excludes CEs from accessing the lower of 340B or MFP, as they are required to be able to do under section 1193(d) of the Social Security Act (SSA). In recognition of this reality, CMS urges CEs and manufacturers to independently develop a solution that implements section 1193(d) for 340B claims. The proposed guidance directly conflicts with CMS's statutory responsibility to set standards that implement section 1193(d).

Therefore, we urge CMS to abandon the provisions in the guidance pertaining to 340B and develop a workable means for CEs to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP, or alternatively, require manufacturers to sell drugs at MFP. In addition, CMS should develop a methodology that would enable CEs to choose to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF) and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer. CMS should also develop a clear process whereby manufacturers make hospitals whole by promptly providing the difference when a drug's MFP is lower than its 340B ceiling price or, as requested above, require manufacturers to sell drugs at MFP.

[1] H.R. Rep. No. 102-384, pt. 2 (1992).

For non-340B claims, the proposal would have the provider purchase drugs at prices significantly higher than MFP, which CMS believes will usually be at or around wholesale acquisition cost (WAC), and wait weeks to receive a payment from the manufacturer to net the purchase cost to MFP ("default payment"), unless the provider and manufacturer enter into an alternative agreement. Recognizing that a default payment should not be made for 340B claims because those drugs are priced below MFP, CMS proposes that manufacturers develop "deduplication" policies that would be subject to approval by CMS. CMS fails to delineate clear standards that CMS would use to support approval or denial. It appears that so long as manufacturers abide by their CMS-approved deduplication polices, those policies would apply to 340B claims regardless of whether they truly effectuated access to the lower of MFP or 340B and even if they included CE compliance with broad data-sharing requirements established by manufacturers. The only option for redress by CEs would be to complain to CMS and hope the agency would take action in some manner and timeframe that has not been clearly defined in the guidance.

Though CMS does not require that manufacturers follow any specific process for 340B claims, as it does for non-340B claims, it makes several suggestions:

1. Manufacturers could, but would not be required to, decline to pay a default payment on claims identified as 340B at the point of sale with a 340B modifier.[2] CMS acknowledges that 340B eligibility of most claims is determined after the point of sale.[3]

2. CEs could share 340B claims data with manufacturers. This would be a private arrangement between each CE and each manufacturer of drugs subject to the MFP and would take place completely outside of the process CMS is proposing for non-340B claims.[4] CMS proposes no standards or guidelines for how this process would work.

3. CEs could buy drugs at WAC, instead of the 340B price, receive the default payment and then, again under some undefined process, request that the manufacturer pay the difference between MFP and 340B.[5]

This suggested framework is problematic, unworkable, and inconsistent with CMS's statutory obligation under the IRA. First, a point-of-sale modifier for 340B claims is completely incompatible with the virtual inventory system used by the overwhelming majority of 340B pharmacies, in which 340B claims cannot be tagged until after the claim is submitted. The virtual inventory model has been in use since 340B was enacted more than 30 years ago. It would be unworkable to expect these pharmacies to use a separate physical inventory of 340B drugs.

We would strongly oppose CMS allowing manufacturers to mandate 340B claims data submission through their own deduplication policies and believe that outcome is well outside CMS' statutory authority. It also directly conflicts with CMS' explicit authority in section 1193(d)(1) of the SSA to develop a process in which manufacturers do not provide the MFP for drugs sold at the 340B price

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[2] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 –1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 49, 109 (May 3, 2024).
[3] *Id*. at 50. The National Council for Prescription Drug Programs (NCPDP), which developed the standard for point-of-sale identification of 340B claims, has stated it is impossible for the overwhelming majority of CEs to use point-of-sale modifier. National Council for Prescription Drug Programs, 340B Information Exchange Reference Guide 24 (June 2019), https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.
[4] *Id.* at 46, 50, 109.
[5] *Id*. at 49.

and, per sections 1193(a)(5) and 1196(b)**,** and that the process be one that CMS can "administer" and for which CMS can ensure compliance. CMS can neither administer nor ensure compliance with unclear and vague statements about what the parties should agree to outside of and separate from the government's stated process, especially when there could be thousands of different policies. Furthermore, there is no language in the IRA's 340B provisions suggesting that manufacturers have any authority to create their own nonduplication methodologies.

Permitting each manufacturer to have its own methodology for nonduplication of 340B and MFP could also create significant barriers to CEs accessing the lower of the 340B ceiling price or MFP and could be tremendously burdensome for CEs to manage. We are especially concerned because the lack of guidelines suggests that there is no limit to the conditions a manufacturer could conceivably impose.

For example, a manufacturer might use a CE's National Provider Identifier to treat all outpatient claims as 340B, even if they are not. Alternatively, a manufacturer might require CEs to submit large volumes of data to the manufacturer or its vendor in order to receive the 340B price or MFP as a refund. This would be at odds with the longstanding practice of CEs accessing the 340B discount as a purchase price and would be highly disruptive to how CEs manage their 340B inventory and impose an impermissible financial burden on CEs, which would be required to purchase at a price significantly above 340B and wait to get paid at some undetermined point in the future by a manufacturer, essentially requiring public and nonprofit safety-net providers to float revenue to the manufacturer. Outside of a very narrow exception for AIDS Drug Assistance Programs, HRSA has never authorized manufacturers to offer 340B discounts as refunds instead of purchase prices. The IRA does not give CMS the authority to permit or encourage manufacturers to do so.

Additional concerns about manufacturers requiring covered entities to submit claims data directly to the company or its vendor include:

- It could be challenging for CEs, particularly small ones, to navigate and manage a wide variety of manufacturer methodologies, especially as more drugs are selected in future years.
- It would be impossible for CMS to effectively monitor and ensure manufacturer compliance because the agency would have to understand, monitor, and enforce multiple nonduplication methodologies.
- Manufacturers could ask for a large amount of unnecessary claims data.
- The reporting methodology that a manufacturer requires CEs to use could be extremely burdensome.
- Manufacturers might place unreasonable restrictions on the availability of the MFP or the 340B ceiling price (e.g., assurance of 340B compliance).

Moreover, our CEs have extensive negative experience with sharing 340B claims data through a vendor backed by manufacturers, 340B ESP, in connection with restrictions manufacturers are already putting in place limiting access to the use of contract pharmacies in 340B. Even though CEs submit data to a single vendor representing multiple manufacturers, drug companies impose different standards regarding whether and how they will use the data, resulting in significant and unpredictable variation around reinstatement of 340B pricing for contract pharmacies. CEs have reported that 340B pricing is made available for only some NDCs, but not all, and only at some contract pharmacy locations, but not all. CEs are forced to devote time and staff resources to follow up on notifications in 340B ESP's portal that claims submissions are incomplete to ensure they do not lose 340B pricing, imposing a significant burden on CEs. Many of these notifications are baseless and do not represent an actual issue with claims submissions.

For these reasons, CMS should abandon its current proposal for the IRA's 340B provisions and develop a workable means for CEs to continue purchasing at the 340B price without identifying a

claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP or, alternatively, require manufacturers to sell drugs at MFP. In addition, CMS should develop a methodology that would enable CEs to retrospectively submit 340B claims data to CMS' MTF and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer. This process has been used successfully for Oregon Medicaid for more than a decade.

We also oppose the guidance's proposed implementation of MFP when it is lower than the 340B price. The guidance effectively prohibits use of 340B in those instances, expecting that CEs would purchase drugs for 340B-eligible patients at a non-340B price. This would substantially disrupt CEs' longstanding practice of purchasing and using 340B drugs for their patients, including their 340B-eliglble Medicare patients, and could have significant implications for their virtual inventory systems. It would also require CEs to pay a price higher than 340B until the manufacturer issues the refund at some undefined later point in time. CEs are entitled under the 340B statute to purchase and use 340B priced drugs for all of their 340B-eliglible patients and nothing in the IRA changes that obligation. *Instead, CMS should develop a clear process whereby manufacturers make CEs whole by providing the difference when the MFP is lower than the 340B ceiling price or, as already requested above, require manufacturers to sell drugs at MFP.*

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Thank you for considering our comments. Please feel free to reach out to any of the contacts below if you have any questions or if we can provide any additional information.

Sincerely,

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National Alliance of State & Territorial AIDS Directors
HIV Medicine Association
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