Submitted electronically via IRARebateandNegotiation@cms.hhs.gov

March 10, 2023

Dr. Meena Seshamani, M.D. Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Part D Inflation Rebate Comments

Dr. Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

CMS is soliciting comment on whether submission of the 340B identifier on the pharmacy claim is the preferred mechanism to identify 340B units dispensed in Part D, or if there is a better alternative. CMS is interested in determining the most reliable way to identify Part D claims filled with 340B units so these associated units can be excluded from the determination of units of Part D rebatable drugs beginning in 2026 in accordance with the statute.

Pharmacies submitting a 340B identifier involves high administrative burden and financial risk and should be considered a last resort. 340B Covered Entities may contract with retail pharmacies (e.g., national chains, regional chains, independents) to provide certain pharmacy services such as dispensing medications to patients who may be eligible to receive drugs covered under the 340B program. This "contract pharmacy" agreement is often administered by a Third-Party Administrator which coordinates data and financial obligations between the Covered Entity, contract pharmacy, and manufacturers.

Proactive Identification

As CMS stated in its solicitation of comments, the current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does not require a pharmacy to identify which prescription claims were dispensed using drugs purchased at a discount under the 340B program. Although the standard does include a field where a 340B indicator could be provided, it is optional for pharmacies to use, based on trading partner agreements.

To proactively include a 340B identifier on a prescription claim, a pharmacy needs to know at the point of sale that the patient, their prescription and the parameters of their arrangement with the covered entity, qualify for the 340B program drug pricing. The indicator exists but there is a significant operational challenge to identifying when pharmacies should use it. Due to the multiple factors that go into determining that a drug dispensed is eligible for 340B pricing, it is not common for a pharmacy to know at the point of sale that a prescription could be dispensed with a 340B-priced drug. The model is also susceptible to pharmacy benefit managers reimbursing 340B claims at a lower rate, due to lower acquisition, thus capturing funds that are intended for the Covered Entity to provide care to un- or underinsured individuals. **For those reasons, NCPA opposes proactive identification of 340B units by pharmacies, and instead offers alternative proposals below.**

Retroactive Identification

NCPA opposes retroactive identification of 340B units by pharmacies, as it is unduly burdensome for pharmacies to be able to comprehensively make these identifications. NCPA instead offers alternative proposals below. This would be the case both for claims adjusted to 340B units, as well as claims that are adjusted from 340B identification. Pharmacies that use virtual inventory rely on third-party administrators to determine, after replenishment and potentially significant lag time, if a specific prescription was fulfilled using 340B inventory. Pharmacies using a virtual inventory are traditionally not determining 340B claim eligibility as they are wholly reliant on external entities, using completely separate, non-interfaced information systems, to determine missing data elements.

CMS recognizes that the NCPDP does allow use of an "N1" transaction to retrospectively identify drugs purchased under the 340B pricing, but CMS understands that few pharmacies use this transaction. **NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems**. Even if pharmacies did use the N1 transaction, they would still need to revisit every claim multiple times. NCPDP's guidance on N1s is extremely complex, and pharmacies would have to navigate the details of the 340B program as it relates to the relationship between the CE and the TPA.

Even if pharmacies could be able to retroactively identify claims, pharmacies would be saddled with administrative burden and financial risk to reprocess claims with a 340B indicator. Many pharmacy benefit managers (PBMs) have a specific timeframe for allowing claims to be reprocessed. Reprocessing outside this window in order to comply with this proposed rule could mean that the pharmacy would have to forfeit all third-party reimbursement for a prescription

that has already been dispensed to the patient. And, similarly to what was described above, PBMs may take advantage of knowing 340B pharmacy claims to pay the pharmacy less, leaving less to pass back to the Covered Entity. Disclosure of 340B pharmacy claims would likely result in a windfall to PBMs at the expense of Covered Entities.

For the reasons above, NCPA opposes CMS requiring pharmacies to retroactively identify 340B units, as this would result in a significant, unfunded administrative burden for pharmacies. NCPA suggests alternative proposals, below. On the other hand, pharmacies are reliant on the TPAs they use to navigate the intricacies of the 340B program, so TPAs would be a much better fit for being able to supply CMS with that information. Eligibility under the 340B program is also determined by a Covered Entity via a Third-Party Administrator (TPA) through a retrospective analysis.

PDE Record

CMS stated in its solicitation for comments that it believes that requiring that a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D. CMS also stated that this indicator would need to be included on all pharmacy claims where a drug subject to a 340B discount was dispensed to a Part D beneficiary so that units submitted on such claims can be excluded from the inflation rebate calculation. CMS has stated on a NCPDP WG9 Medicare FAQ call that CMS intends to expand the PDE layout of 1000 characters to accommodate new fields. Further, the new field in Version F.6 is Submission Type Code (D17-K8) with a value of "AA" for 340B. **NCPA opposes CMS requiring plans to require pharmacies to provide any of this information. As stated above, pharmacies are not the entity best suited to report this information. Instead, NCPA recommends that a TPA provide this information to CMS.**

Alternative Proposal #1: Third-Party Administrator (TPA) Provides the Data to CMS

NCPA supports an alternative solution where Third-Party Administrators provide 340B data to CMS. The most reliable entity that would have 340B data would be the Third-Party Administrator (TPA). NCPDP has also recommended that they compile such data, as they are the best situated and capable of doing so. TPAs already collect this type of data, so NCPA believes that it would not be difficult to provide this information to CMS as well. HRSA could also make the provision of this information a condition for Covered Entities to participate in the HRSA program.

Additionally, entrusting the TPAs and not the PBMs with this data would contribute less additional administrative burden in administrating the 340B program generally, and, as mentioned above, would reduce the likelihood that PBMs will use this information to give themselves more money at the expense of Covered Entities.

Alternative Proposal #2: Manufacturers Report to CMS Aggregate, Approximate 340B Units Dispensed

CMS may also be able to get manufacturers to use their own data to approximate the total 340B units dispensed in Medicare Part D**.** If manufacturers know the percentage of drugs sold at a 340B price, the amount of Part D rebates they receive, and what percentage of their drugs are Part D,

manufacturers may be able to extrapolate to get an approximate amount of 340B units dispensed in Part D. **NCPA is unsure of the viability of this option and recommends that CMS look into this proposal in more detail.**

Conclusion

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association