Submitted March 10, 2023
Sent via Electronic Mail

Dr. Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare
Center for Medicare and Medicaid Services

RE: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Dear Dr. Seshamani,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in Health Insurance Portability and Accountability ACT (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in Medicare Modernization ACT (MMA).

NCPDP submits the following comments in response to *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*, released February 9, 2023.

Section 40.2.5 Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk To AMP Units
The statute defines "units" as the lowest dispensable amount (such as tablet or capsule, milligram of molecules, or grams) of the Part D rebatable drug, as reported under section 1927(b)(3). Part D PDE data would be used to determine the total number of units of the Part D rebatable drug dispensed under Part D during each 12-month applicable period for the inflation rebate calculation.

From the PDE data, CMS intends to obtain the total number of units of the Part D drug from the field "Quantity Dispensed" for each dosage form and strength, and the NDC of the drug from the field "Product Service ID" for each 12-month applicable period. Units reported in the Quantity Dispensed field on the PDE record are industry standard National Council for Prescription Drug Programs (NCPDP) defined values of each, milliliter, and grams. The unit for each NDC is not reported on the PDE record, but this information is available on FDA's Comprehensive NDC SPL Data Elements File (NSDE) in the "Billing Unit" field. In order to identify the NCPDP billing unit for each NDC, CMS intends to crosswalk the information from the PDE record to the NSDE file matching on the NDC.

In contrast to how units are reported under Medicare Part D, manufacturers can report the AMP for their drugs in the MDP with 10 different unit types (e.g., each, capsule, tablet, suppository, transdermal patch, injectable anti-hemophilic factor, millicurie, microcurie, gram, and milliliter). Given the difference between how units are reported between the two programs, in order to calculate Part D drug inflation rebates, CMS intends to compare the Part D rebatable drug units reported in the PDE record to the units reported in MDP for the monthly AMP. Based on initial analyses, CMS expects that the majority of units of the dosage forms and strength of each Part D rebatable drug reported in the PDE record will match the AMP units reported.

However, in the limited instances where the units do not match, CMS intends to convert the total units reported from the PDE to the AMP units that are reported by the manufacturer for the drug under section 1927. For example, if an NDC is reported as a unit of "each" in the PDE record, and as a unit of "grams" to Medicaid, CMS intends to multiply the unit of "each" times the total "grams" for each unit to convert the PDE units to AMP units. For example, if the product is dispensed in a 10-gram tube and the PDE record has this recorded as a unit of "1" for "each," this will be converted to "10" for the purposes of Part D drug inflation rebates to conform to the Medicaid units of "grams" for this product.

CMS is exploring the option of adding a field to the PDE file layout to collect how the amount reported in the PDE "quantity dispensed" field is measured (e.g., each, milliliter, gram). This additional data element would facilitate the identification of unit types for each NDC and add an additional level of assurance for CMS and manufacturers that the unit used to calculate inflationary rebates is accurate. CMS recognizes that requiring the plans to report a unit type for each Part D rebatable drug on the PDE record would create a new reporting burden, create possible opportunities for error, and would still require a conversion to the AMP units. CMS is soliciting comment on this option. As discussed in more detail below, beginning in calendar year 2026, the Part D rebatable drug units identified as having been filled with a 340B acquired drug would be removed from the total units of Part D rebatable drugs that will be subject to a rebate as provided under section 1860D-14B(b)(1)(B).

> **NCPDP Comment:** NCPDP recommends CMS not make Unit of Measure (UOM) a required field on the PDE. If CMS makes UOM a required field for PDE reporting, it would require the pharmacy to submit the UOM on the claim billing at point of sale (POS). This could cause unnecessary hardship to beneficiaries if the claim is rejected due to a missing UOM, making the beneficiary unable to obtain their medication. The processors would need to retain the claim UOM and report it on the PDE, adding a large burden on processors and pharmacies. Additionally, pharmacies have various software systems that use data from different sources. In order for all of the pharmacies to submit the UOM identically, they would need to use the same data source.
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> The NCPDP Billing Unit Standard is in place so every pharmacy bills, processor adjudicates and compendia reports the prices of the product in the same way. When occasional discrepancies are found in the compendia there are existing processes to resolve these. Most processors/payers do a lookup on the submitted NDC to validate units and pricing. There is no need to add an additional field on the PDE for the UOM provided at POS if CMS will be completing their own similar check behind the scenes.
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> If the UOM is required to be included on the PDE, the UOM will be inaccurately reported on the PDE if it was inaccurate at POS.

NCPDP additionally recommends the Food and Drug Administration (FDA) and CMS request the NCPDP billing unit and billing quantity data from each manufacturer to create the complete crosswalk file suggested.

Section 40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements
Section 1860D-14B(b)(1)(B) requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a dosage form and strength for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Drug Pricing Program. Because this requirement starts after the first quarter of the applicable period that begins in October 2025, CMS intends to exclude the 340B units starting in January 2026.

The current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does not require a pharmacy to identify which drugs that were dispensed were 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. In addition, the standard specifies that the indicator can only be used prospectively, so a pharmacy that makes the retrospective determination that the drug was purchased at 340B pricing cannot apply the modifier retrospectively to the claim. 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. Consequently, CMS does not currently require or even accept a 340B indicator on the PDE record.

CMS 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. 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 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. In other words, CMS is interested in ascertaining 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.

NCPDP Comment: NCPDP reviewed this section of the memo and was unable to reach a consensus on a viable 340B option. NCPDP agrees 340B must be identified retrospectively and concurs with CMS' statement that the N1 is not widely implemented within the industry.

NCPDP thanks CMS for the opportunity to provide comments and for the consideration of our comments. NCPDP looks forward to continuing its work with CMS.

For direct inquiries or questions related to this letter, please contact:
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Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)