Submitted April 14, 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 Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, 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 requests an extension for additional comments to the *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, released March 15, 2023.

NCPDP additional comments will be submitted no later than May 31, 2023. NCPDP needs additional time to engage the wide range of impacted stakeholders, such as wholesalers, pharmacies, drug data compendia, payers/plans, intermediaries/software vendors, PBMs/processors and providers or pharmacy claim reconciliation services.

The initial NCPDP comments are as follows:

Section 90.2 Monitoring of Access to the MFP

…

"For example, a pharmacy may purchase a medication for $100 per bottle and the MFP as applied to this selected package is $80. The Medicare beneficiary is enrolled in a Part D plan under which coverage of the selected drug is available, thus the beneficiary is an MFP-eligible individual. For

this example, the plan has not negotiated a lower price for the medication. The pharmacy provides the negotiated price (i.e., MFP plus a dispensing fee) at the point of sale to the Medicare beneficiary. As a result of this transaction, the pharmacy is owed $20 by the manufacturer. The pharmacy would submit the information regarding the $20 chargeback amount to its wholesaler and receive a credit from the wholesaler for that amount. The wholesaler would be compensated by the manufacturer after billing the manufacturer for the chargeback amount."

NCPDP Comment: There is not a current NCPDP standard to facilitate this requirement. NCPDP would welcome the opportunity to work with impacted industry partners such as CMS, wholesalers and pharmacies to develop a standards solution for the MFP requirements.

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

Current Unit Costs of Production and Distribution (pages 85-86 and page 89)

"For the purposes of describing current unit costs of production and distribution to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- *In accordance with section 1191(c)(6) of the Act, the term 'unit' means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.*
- *Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS): each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-9s included in the selected drug. Selections of EA, ML or GM must be made as follows:*
    - *"EA" is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of "EA" is also used to address exceptions where "GM" and "ML" are not applicable. Examples of products defined as "EA" include, but are not limited to:*
        - *Tablets;*
        - *Capsules;*
        - *Suppositories;*
        - *Transdermal patches;*
        - *Non-filled syringes;*
        - *Tapes;*
        - *Devices/Digital Therapies;*
        - *Blister packs;*
        - *Oral powder packets;*
        - *Powder filled vials for injection;*
        - *Kits; and*
        - *Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram should be billed as "one each," for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 mL.*
    - *"ML" is used when a product is measured by its liquid volume. Examples of products defined as "ML" include, but are not limited to:*
        - *Liquid non-injectable products of 1 mL or greater;*
        - *Liquid injectable products in vials/ampules/syringes;*

        - *Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and*
        - *Inhalers (when labeled as milliliters on the product).*
    - *"GM" is used when a product is measured by its weight. Examples of products defined as "GM" include, but are not limited to:*
        - *Creams (of 1 GM or greater);*
        - *Ointments (of 1 GM or greater); and*
        - *Inhalers (when labeled as GM on the product.*

NCPDP Comment: NCPDP reviewed this section of the initial memorandum and recommends making an addition to the second bullet, first sub-bullet at the eleventh sub-sub-bullet which states "Kits; and". Since NCPDP has a specific definition for "Kits" and pharmaceutical manufacturers sometimes have a different view regarding what constitutes a kit, NCPDP recommends adding the following quote from the NCPDP Billing Unit Standard *(NCPDP Billing Unit Standard Implementation Guide Version 4.0 (January 2022), Section 5.5.1, page 14)* to specifically define the term "Kits" as used in this list:

- "Kits are defined as products that contain one of the following:
    1) at least two distinct items with different billing units
    2) one product packaged with medicated or unmedicated swabs, wipes and/or cotton swabs/balls
    3) meters packaged with test strips"

NCPDP understands that CMS used the publicly available *NCPDP BILLING UNIT STANDARD FACT SHEET*(June 2020) as the reference for the list in Appendix C and the "Kits" definition is not included on the Fact Sheet. However, to avoid any possible confusion regarding kits stemming from the initial memorandum, NCPDP recommends this addition.

NCPDP thanks CMS for the consideration of our initial comments and our request for an extension to provide additional 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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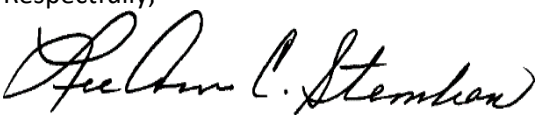
Respectfully,



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