September 11, 2023

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244 – 1850
Submitted via regulations.gov

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (CMS-1784-P)

To Whom It May Concern:

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.

NCPDP appreciates the opportunity to review and submit comments to the Centers for Medicare and Medicaid Services (CMS) on its proposed CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Programs. Our comments focus on proposed updates to standards for the CMS Electronic Prescribing of Controlled Substances (EPCS) Program and CMS's RFI on drugs and biologics which are not usually self-administered by the patient.

I. Standard for CMS EPCS Program; Updates to the NCPDP Standards

CMS Proposal: *CMS is proposing to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirements and to redesignate paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively. They also propose to add "subject to the exemption in paragraph (a)(3)(iii) of this section" to § 423.160(a)(5). CMS seeks comment on the proposals to remove the same entity exception and expand the available standards for same legal entities within the CMS EPCS Program.*

NCPDP comments: NCPDP agrees with CMS's proposal to remove the same entity exception and include an exemption to allow the use of HL7® when transmitting controlled substance prescriptions between systems. Usage of the Prescription Origin Code will, per NCPDP's Data Dictionary definition of

"Prescriptions obtained via NCPDP SCRIPT or HL7® Standard transactions, or electronically within closed systems", allow CMS to accurately report on all electronic Part D prescriptions of Schedule II, III, IV, and V.

II. *Request for Information (RFI): Drugs and Biologicals Which Are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding*

CMS Statement: *CMS states that, "Drugs that are put on a self-administered drug (SAD) list are excluded from Part B coverage, but in those situations, they are almost always covered by Medicare Part D prescription drug coverage. For several years, interested parties have requested that we update and clarify this SAD list guidance. These parties believe that the current guidance may not adequately address circumstances posed by newly approved drugs." CMS is soliciting comments regarding its policies for the following items:*

- *The process for determining which drugs are classified as those ''not usually self-administered by the patient.''*
- *The process for issuing decisions on which drugs are classified as those ''not usually self-administered by the patient,'' and the process for issuing any changes to those classifications.*

NCPDP comments: CMS's RFI is significant to the pharmacy industry as it relates to the process of classifying drugs ''not usually self-administered by the patient'' due to the resulting Medicare B versus D claim billing rules. Drugs considered to be usually self-administered by the patient would be billed to the Medicare Part D benefit using the NCPDP Telecommunication Standard. To streamline the real-time claim adjudication process used within the pharmacy industry and to mitigate patient access to care delays, the following considerations may be beneficial in formulating program changes.

The process for determining which drugs are classified as those ''not usually self-administered by the patient'."

The Food and Drug Administration (FDA) requires drug manufacturers to provide product information within the Structured Product Labeling (SPL) format. This format currently includes Dosage and Administration details, inclusive of the sub-cutaneous, intramuscular, intravenously etc. route of administration descriptions. Based on the specific drug, it may also include language such as "treatment should be supervised by a healthcare provider." NCPDP encourages CMS to coordinate with the FDA in identifying potential updates to the SPL to clearly identify drugs that can be self-administered, eliminating discrepancies in classifications across the multiple Medicare Administrative Contractors and Medicare Part D plans.

Medicare coverage rules which layer additional exceptions to the self-administered not covered under Medicare B classification.

While drugs that are put on the SAD list are excluded from Part B coverage are almost always covered by Medicare Part D prescription drug coverage, there are additional Medicare coverage rules that may require the drug to be billed to Medicare Part B. The Medicare B versus D conflict has escalated specifically for insulin products. While insulin is self-administered, when delivered through a durable insulin pump it

is covered under Part B. If delivered through any other delivery device including a disposable pump, it is covered under Medicare Part D. The current Medicare B versus Medicare D insulin coverage rules result in:

- Gaps in real-time claim adjudication processes, where neither the pharmacy nor the payer can systematically validate the patient uses an insulin pump
- Compromises Medicare Part D DUR, adherence measures and MTM efforts, as the Part D plan does not have full visibility to the patient's insulin intake
- Compromises patient access to care due to plan benefit confusion, resulting in the potential need to use multiple providers to service patient's insulin needs

Below are some examples where multiple Medicare coverage rules create conflict in interpretation, inconsistency in processes, claim billing confusion and ultimately access to care delays.

1. *Medicare Benefit Policy Manual Chapter 15: 320.7.1 - Determining Qualifying Home Infusion Drugs*

   The drugs and biologicals identified in the DME Local Coverage Determination (LCD) for External Infusion Pumps (L33794) qualify as home infusion drugs as long as they are infused intravenously or subcutaneously over a period of 15 minutes or more, ***are not classified as insulin for insulin pump use****, and are not on a self-administered drug exclusion list. These drugs continue to be paid for under the DME benefit as supply drugs to the covered infusion pump. Any additional training and education services needed for the patient to administer these drugs at home would be covered under this home infusion therapy services benefit.*

2. *SSA Section 1927 (k)(2)*

   (*2) COVERED OUTPATIENT DRUG*

   (C) ***insulin*** *certified under section 506 of the Federal Food, Drug, and Cosmetic Act.*
   (3) LIMITING DEFINITION — The term "covered outpatient drug" does not include any drug, biological product, or ***insulin*** *provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):*
   (A) Inpatient hospital services.
   (B) Hospice services.
   (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.
   (D) Physicians' services.
   (E) Outpatient hospital services.
   (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
   (G) Other laboratory and x-ray services.
   (H) Renal dialysis.

NCPDP supports CMS in any efforts to coordinate program policy updates or facilitate legislative action that will simplify the Medicare coverage rules for insulin products, agnostic to the delivery method or patient's residence. The consolidation of insulin claims under a single Medicare program (e.g., Part D) will streamline diabetes care management programs, utilization reviews and patient outcomes.

Additionally, streamlining the Medicare B versus D coverage rules to allow coverage under Part D as a default would better support system solutions to address the Maximum Fair Price provision in the Inflation Reduction Act.

NCPDP thanks CMS for the opportunity to review and comment on its proposal and RFI and encourages CMS to utilize NCPDP as a resource. NCPDP looks forward to collaboratively working with CMS to improve the quality of care of Medicare and Medicaid patients.

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

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Respectfully,

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