



July 25, 2023

Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
Attn: CMS-2434-P  
P.O. Box 8016  
Baltimore, MD 21244 -1850  
Submitted via regulations.gov

Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434-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 CMS-2434-P. Our comments focus on the following proposed changes to the Medicaid Drug Rebate Program (MDRP).

**I. Proposal to Modify the Definition of Covered Outpatient Drug**

**Summary of CMS Statements:** CMS is proposing to amend the regulatory definition of the term covered outpatient drug (COD). Specifically, clarification is added that a COD includes the direct reimbursement for a drug that may reimburse for a drug alone, or reimburse for a drug plus the service, in one inclusive payment, if the drug and the itemized cost of the drug are separately identified on the claim.

**NCPDP comments:** NCPDP agrees with CMS's proposal to amend the regulatory definition of a COD at § 447.502. Additionally, NCPDP standards support CMS's proposed amended definition of a COD and the ability of a Medicaid program to identify the itemized costs when it enters a claim into its MDRP processes.

**II. CMS Proposal Related to Managed Care Plan Standard Contract Requirements**

**Summary of CMS Statements:** CMS is proposing to require the inclusion of Medicaid-specific Bank Identification Number (BIN), Processor Control Number (PCN) and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits no later than the next rating period for Medicaid managed care contracts. CMS notes that health plans use the BIN and PCN to identify a patient's prescription health insurance benefits.



**NCPDP comments:** NCPDP has long advocated for the inclusion of the BIN, PCN and Group ID data elements on healthcare ID cards as reflected in our cooperative work with multiple organizations over more than 25 years, the adoption of our guidance by CMS in 2005 for application under the Medicare Part D Marketing Guidelines, and our continued maintenance of the NCPDP Health Care Identification Card Pharmacy.

It is important to note the BIN Number definition, format, and the field used in pharmacy claim transactions will be changing as of the next version of the Telecommunication Standard named under HIPAA. This change is expected to occur soon<sup>1</sup> and will most likely require health plans to distribute new member ID cards during the implementation period, consistent with when each health plan begins using the new standard in its systems.

BIN and PCN identifiers are submitted in the fixed length Header segment of the NCPDP vD.0 Telecommunication request transactions, within the following fields:

- 101-A1: BIN Number – Card Issuer ID or Bank ID Number used for network routing from the provider to the applicable payer/processor system.
  - This is a numeric field that requires 6 digits.
- 101-A4: Processor Control Number - Number assigned by the processor.
  - This is a situational field that can only be required on an ID card if assigned.
  - This is an alphanumeric 10-character field.

As of the next Telecommunication version named under HIPAA, the BIN Number field changed as outlined below, to align with ISO/IEC 7812-1 changes to the transaction routing IDs.

- 101-A1: IIN Number - Card Issuer ID or Issuer Identification Number used for network routing between the provider and the applicable payer/processor system.
  - This is still a numeric field but requires 8 digits.
  - Existing 6-digit BIN Numbers will still be in use; however, “00” will be added as the seventh and eighth positions to create the 8-digit IIN.

### III. Request for Information – Medicaid Use of ICD-10 on Prescription Claims

**Summary of CMS Statements:** *CMS is requesting information regarding the potential inclusion of a diagnosis on all pharmacy prescription claims to determine if the drug is being used for a medically accepted condition, and if it therefore satisfies the definition of a COD to be rebate eligible.*

**NCPDP comments:** NCPDP supports the omission of the diagnosis code on a pharmacy claim transaction. NCPDP would like to clarify the diagnosis code is not always an indication for the use of the medication on a pharmacy drug claim. Because ICD-10 codes are not intended to be the standard identifier for treatment indication, this requirement could create conflict within the detail of the patient’s medical record.

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<sup>1</sup> 87 FR 67634



Additionally, a prescriber's electronic health record (EHR) may not have assigned the ICD-10 code available at the point of prescribing which prevents the ability to proactively record the ICD-10 code on written, phone or faxed prescriptions. The industry also lacks a cross-reference file of indications to ICD-10 codes. Today, certain Medicaid programs reject claims based on their interpretation of which ICD-10 codes should be allowed for specific medications. Furthermore, there are also inconsistencies in determining what is a valid ICD-10 code value based on timing of updated lists (which occur annually in October), the written date of the prescription and the refill date (prescriptions are generally valid for one year from the written date).

In June 2022, the NCPDP Foundation awarded a grant<sup>2</sup> to the University of Arizona College of Pharmacy to research and identify barriers to using the clinical indication (SNOMED CT) or diagnosis (ICD-10) fields in NCPDP's SCRIPT and Telecommunication Standards. The grant is still in progress with results expected later this year. NCPDP looks forward to sharing the grant results with CMS, when available.

NCPDP thanks CMS for the opportunity to review and comment on its proposal. NCPDP encourages CMS to utilize NCPDP as a resource as it finalizes its proposals and reviews comments to its Request for Information (RFI) and potential approaches regarding a requirement for a diagnosis code on Medicaid prescriptions. NCPDP looks forward to collaboratively working with CMS to improve the quality of care of Medicaid patients.

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

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Respectfully,

A handwritten signature in black ink, appearing to read "Lee Ann C. Stember". The signature is fluid and cursive, written over a white background.

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

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<sup>2</sup> National Council for Prescription Drug Programs. NCPDP Foundation Awards Grant to University of Arizona R. Ken Coit College of Pharmacy to Identify Barriers to Using Indication/Diagnosis Fields in NCPDP Standards. June 27, 2022. Available at: <https://ncpdpfoundation.org/pdf/Foundation-PR-UA-Grant-062722.pdf>.