

# CMS Medicaid Misclassification of Drugs and Updates to Medicaid Drug Rebate Program NPRM (CMS-2434-P) Comment

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This document is submitted by the Massachusetts Health Data Consortium (MHDC) and its Data Governance Collaborative (DGC) in response to the CMS Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program NPRM (CMS-2434-P) posted in the Federal Register on May 26, 2023 and found here:

<https://www.federalregister.gov/documents/2023/05/26/2023-10934/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates>

## About MHDC

Founded in 1978, MHDC, a not-for-profit corporation, convenes the Massachusetts's health information community in advancing multi-stakeholder health data collaborations. MHDC's members include payers, providers, industry associations, state and federal agencies, technology and services companies, and consumers. The Consortium is the oldest organization of its kind in the country.

MHDC provides a variety of services to its members including educational and networking opportunities, analytics services on both the administrative and clinical side (Spotlight), and data governance and standardization efforts for both clinical and administrative data (the Data Governance Collaborative/DGC and the New England Healthcare Exchange Network, respectively).

## About DGC

The DGC is a collaboration between payer and provider organizations convened to discuss, design, and implement data sharing and interoperability among payers, providers, patients/members, and other interested parties who need health data. It is a one stop interoperability resource. The DGC primarily focuses on three areas:

1. Collaboration: Development of common understanding of and specifications for data standards, exchange mechanisms, and what it means to participate in the modern health IT ecosystem
2. Education: helping members understand their regulatory obligations, the data and exchange standards they're expected to use, and modern technology and related processes
3. Innovation: Identification and development of projects and services needed to make modern health data practices and exchange a reality

## General Comments

This section comments on the general approach taken by CMS in their proposal or comments on items that cross multiple sections of the proposed rule or that do not have questions in the proposal.

## Coordination of Rules

There are a variety of currently proposed, pending, or expected rules from CMS and ONC that are not completely independent from each other. In some cases there may be components of different rules that contradict each other and in other cases they may be written in ways that unnecessarily increase the burden on one or more parties subject to the rule. These rules should be coordinated so that their requirements are compatible and executable without placing additional burden on individuals or organizations that need to

implement more than one rule. None of these rules are implemented in a vacuum.

For example, CMS discusses requiring NDC codes for medications in this rule but the recent ONC HTI-1 proposed rule discusses the possibility of deprecating support for NDC codes in its certification programs in favor of always requiring use of RxNorm for medications. These two approaches are not compatible with each other (see comment below).

This is just one illustrative example; we ask that CMS include a review for compatibility as part of all pending, proposed, and upcoming regulations to ensure that they are consistent and compatible with each other and, when possible, include representatives from other pertinent agencies within HHS or other departments as appropriate. We understand that CMS is not responsible for the choices made by ONC (or any other entity outside of CMS), but the agencies need to work in concert to ensure that their respective rules are compatible with each other.

## Implementation Timeframes

We ask CMS to consider the need to update industry specifications that go through substantive, formal approval processes prior to a formal adoption by a standards-setting authority when setting implementation/enforcement deadlines for provisions. For example, digital insurance card specifications (such as the CARIN Alliance Digital Insurance Card FHIR implementation guide) may need an update to add BIN and/or PCN numbers or to mandate their inclusion if already present.

## Addition of BIN and PCN to USCDI

USCDI is the official minimum clinical data set expected to be supported by certified health IT, various FHIR APIs, and more. As of USCDI v3 there is a section outlining minimum standards for health insurance information. We strongly suggest coordinating with ONC around the inclusion of BIN and PCN numbers in a future version of USCDI. This would ensure that, if known, these numbers are part of data exchange and remain with medication data or payer claims data across the entire healthcare ecosystem.

## Use Existing Standards and Processes When Possible

Participants in the DGC noted that printed Medicare Part D cards (whether standalone or included in a Medicare Advantage plan) already have BIN and PCN numbers on them and thought it important to ensure consistency between Medicare Advantage and Medicaid in the way these numbers are presented if possible. In general, similar rules across different products/types of insurance should be implemented the same way to limit duplicated efforts and accidentally applying the rules from one program to patients enrolled in another.

Note that we are not identifying any inconsistencies at this time, just suggesting that being aware of and removing them would make implementing programs across product lines significantly easier.

## Issues with NDC Codes for Physician-Administered Drugs

We understand the rationale for requiring NDC codes to support manufacturer drug rebates since NDC codes are inherently organized by manufacturer first. However, in its recent HTI-1 proposed rule, ONC made it clear that it is considering deprecating support for NDC codes and requiring the use of RxNorm for medication-related certifications in the future.

It is our understanding that RxNorm does not separately capture drug manufacturer information and thus likely will not meet the needs of a drug rebate program involving direct manufacturer attribution of medications. As noted above, CMS and ONC clearly are moving in opposing directions when it comes to which drug codes to use. If NDC codes are required for any drugs they need to be supported by certified health IT supporting medications. This is particularly true for physician-administered drugs as they are most likely given in an environment using a traditional EHR system, probably one certified using the ONC certification rules.

We further note that USCDI v1 requires the use of RxNorm for medications. However, support for NDC codes was added in USCDI v3, the version ONC will start certifying health IT against in January 2025. Prior to that date, NDC support for physician-administered drugs may not be technically possible in some environments and likely will not be supported in FHIR (and maybe other) data exchanges.

## Future Standardized Exchange Between Payers, Pharmacies, and PBMs

Our Data Governance Collaborative participants raised some concerns that changes made to accommodate drug rebate programs might make future attempts to standardize data exchange between payers and PBMs (and perhaps payers and pharmacies) using FHIR more difficult if not built into rule changes around medication data formats and similar. We urge you to consider this use case as a future goal when making decisions around pharmacy/medication data requirements.

## Response to Specific Questions

This section will list specific questions asked in the proposal and provide our responses to them.

### **We are requesting comments regarding the potential impact of supporting such a policy to require Medicaid diagnoses on prescriptions on payment, health care quality, stigma and access to care, and program integrity.**

We see several benefits and several drawbacks to requiring diagnosis codes on prescriptions. Some of the benefits include:

- The ability to easily collate all data related to a particular diagnosis or condition together for examination, analysis, or exchange
- The ability to track how prescriptions are prescribed for various diagnoses/conditions across the industry
- Patients taking a medication most often but not solely prescribed for a common condition may not be assumed to have that common condition because they take that medication if the medication is clearly noted to be for something else

There are quite a few potential drawbacks as well:

- Patients using medications for less than common but medically indicated off-label use may have difficulty getting their prescriptions covered by their insurance company
- It may increase the need for prior authorization or other utilization management programs designed to limit off-label use
- It may violate patient consent rules for behavioral health, substance abuse, and other sensitive diagnoses, especially if embedded in medication data being widely exchanged as part of CMS or other exchanges requiring inclusion of all USCDI data
- It may make it easier to discover patients have had an abortion, received miscarriage care that some states may equate with abortion care, or received gender affirming care.
- Some patients may feel stigmatized by even common medical conditions such as asthma or diabetes and not want to face additional people – such as pharmacists – aware of their conditions

In addition, while not a benefit or drawback per se, medications are particularly pervasive within healthcare data systems and health data exchange. The impact of updating various specifications, health IT, APIs, workflows, e-prescribing, state controlled substance tracking systems, and other relevant data and technology systems is not minimal and may require significant leadup time prior to implementation deadlines. We do not believe this should impact any decision regarding whether to impose this change, but it should be considered in the timelines and deadlines for implementation should CMS go in this direction.

We also note that a corresponding requirement in ONC certification would likely be needed. ONC is already considering such a change; they included this topic in their HTI-1 RFI on Pharmacy Interoperability.