



# Pharmacy Standards Updates Proposed Rule

***HIPAA National Listening Session***

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Wednesday, November 30, 2022  
2:00 to 3:30 pm ET***



# AGENDA



- Introduction*
- Background*
- Overview of Provisions*
- How to submit comments*

# Acronyms in this Presentation

- **ACA** – Affordable Care Act
- **ASC** – Accredited Standards Committee
- **CFR** – Code of Federal Regulations
- **EDI** – Electronic Data Interchange
- **EHR** – Electronic Health Record
- **FR** – Federal Register

# Acronyms in this Presentation

- **HIPAA** – Health Insurance Portability and Accountability Act of 1996
- **HL7** – Health Level Seven
- **LOINC** – Logical Observation Identifiers Names and Codes
- **NCPDP** – National Council for Prescription Drug Programs
- **NCVHS** – National Committee on Vital Health Statistics
- **TR3** – Technical Report Type 3

# Introduction

- HIPAA addresses the adoption of standards to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information.
- HIPAA transactions involve the electronic transmission of information between two parties to carry out health care-related financial or administrative activities, such as health insurance claims and prior authorization requests, and HHS-adopted standards for those transactions represent uniform requirements for electronic data interchange (EDI) transmissions.

# Introduction

- This proposed rule proposes to adopt updated versions of the retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- Should these proposals be finalized as proposed, these updated versions would be modifications to the currently adopted standards for the following retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits-related transactions.
- The proposed rule would also broaden the applicability of the subrogation standard to one that will be applicable to all entities subrogating pharmacy claims rather than just to Medicaid claims. To that end, the rule would rename and revise the definition of the current subrogation for Medicaid and establish an initial standard for all other entities.

# Background

- The law generally requires at section 1172(c) of the Social Security Act, that any standard adopted under HIPAA be developed, adopted, or modified by a Standard Setting Organization (SSO).
- Section 1171 of the Act provides that an SSO be accredited by the American National Standards Institute (ANSI), which includes NCPDP – the SSO applicable to this proposed rule – that develops standards for transactions, data, or any standard that is necessary to, or will facilitate the implementation of Administrative Simplification.

# Background

- Section 1174 (b)(1) of the Act requires the Secretary to review the adopted standards and adopt modifications to them, including additions to the standards, as appropriate, but not more frequently than once every 12 months, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.
- Section 1175(b)(1) of the Act provides for a compliance date not later than 24 months after the date on which an initial standard or implementation specification is adopted for all covered entities except small health plans, which must comply not later than 36 months after such adoption.

# Background

- Section 1175 (b)(2) states that if the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than 180 days following the date of the adoption of the modification.
- This section also states that the Secretary must consider the time needed to comply due to the nature and extent of the modification when determining compliance dates and may extend the time for compliance for small health plans if the Secretary deems it appropriate.

# Background

- In January 2009, the Secretary adopted the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) (hereinafter collectively referred to as Version D.0) for the following retail pharmacy transactions: health care claims or equivalent encounter information; referral certification and authorization; and coordination of benefits. **(74 FR 3295)**
- The same rule also adopted the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0) for State Medicaid Agencies seeking reimbursement from a responsible health plan for a pharmacy claim a state Medicaid agency paid on behalf of a Medicaid recipient.

# Overview of Provisions

- **Modifications to the NCPDP Telecommunication Standard Implementation Guide Version F6 and Equivalent Batch Standard, Version 15 for Retail Pharmacy Transactions**
  - We are proposing to adopt modifications to the current HIPAA retail pharmacy standards for the following transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits.
  - These modifications would replace the Version D.0 with the NCPDP Telecommunication Standard Implementation Guide, Version F6 and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (hereafter, Version F6).

# Overview of Provisions

- **Modification to the Description of Medicaid Subrogation Transaction**
  - We are proposing to broaden the scope of the subrogation transaction to apply to all health plans, not just State Medicaid Agencies. The current transaction is called the Medicaid pharmacy subrogation transaction, and the definition is applicable only to State Medicaid Agencies in their role as health plans.
  - The current transaction only allows State Medicaid Agencies to collect reimbursement from the responsible health plan for a pharmacy claim the state has paid on behalf of a Medicaid recipient.
  - To support the broader use of the transaction by other health plans, we propose to define the transaction as the transmission of a request for reimbursement of a pharmacy claim from a health plan that paid the claim, for which it did not have payment responsibility, to a health plan it believes is responsible for the claim. Accordingly, we are proposing to revise the name of the transaction at 45 CFR 162.1901 from “Medicaid Pharmacy Subrogation transaction” to “Pharmacy Subrogation transaction.”

# Overview of Provisions

- **Modification of the Pharmacy Subrogation Transaction Standard for Medicaid Agencies, and Initial Adoption of the NCPDP Implementation Guide, Version 10 for Pharmacy Subrogation Standard Transaction for all Health Plans**
  - We are proposing to adopt the NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10, as the standard for the Pharmacy subrogation transaction, which we would reflect at 45 CFR §162.1902. This would be a modification for Medicaid agencies and an initial standard for all other health plans.

# Overview of Provisions

- **Proposed Compliance Dates**
  - We are proposing that the compliance date for these standards would be 24 months after the effective date of the final rule for all covered entities.
  - For the initial adoption of the Pharmacy transaction only, small health plans would have 36 months after the effective date of the final rule.

# When & Where to Submit Comments

- To be assured consideration, comments must be received through one of the methods described on the next slide by January 9, 2023.
- Instructions for submitting comments can be found in the proposed rule; FAX transmissions will not be accepted
- You must officially submit your comments in one of the following ways:
  - electronically through [Regulations.gov](https://www.regulations.gov)
  - by regular mail
  - by express or overnight mail
  - by hand or courier
- When commenting, please refer to file code CMS-0056-P.

# Resources

- For more information about Administrative Simplification requirements, visit the [CMS website](#).
- For the latest news about Administrative Simplification, [sign up for Email Updates](#).
- NSG has created a special mailbox to receive questions, comments and feedback on Guidance Letters, Bulletins, and FAQs, and any other related matters. The address for that mailbox is [AdministrativeSimplification@cms.hhs.gov](mailto:AdministrativeSimplification@cms.hhs.gov).

Thank You

**Thank You!**