



## Modifications to the National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of Medicaid Subrogation Standard Final Rule (CMS-0056-F)

The Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), issued a final rule that adopts updated versions of the National Council for Prescription Drug Programs (NCPDP) retail pharmacy standards for electronic retail pharmacy transactions. These updates are designed to significantly improve the efficiency and accuracy of electronic retail pharmacy transactions, which is vital for the entire health care industry — especially pharmacists and the people they serve.

These standards are adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), legislation that governs the exchange of certain electronic health information.

These updated standards modify the current 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. These standards are informed by recommendations from the National Committee on Vital and Health Statistics (NCVHS). This final rule also modifies the standard for the Medicaid pharmacy subrogation transaction.

### Background

On August 21, 1996, Congress amended Title XI of the Social Security Act (the Act) to add a new Part C, titled “Administrative Simplification,” which required the HHS Secretary to adopt standards for certain electronic transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information. HIPAA applies to covered entities (health plans, health care clearinghouses, health care providers who conduct certain financial and administrative transactions electronically) and their business associates. The Secretary delegated the responsibility for HIPAA rulemaking to CMS.

The Patient Protection and Affordable Care Act (P.L. 111-148) requires that the Secretary adopt and regularly update electronic transaction standards, as well as operating rules for the electronic exchange and use of health information. The retail pharmacy transaction standards being modified in this final rule were initially adopted in a final rule that appeared in the Federal Register on August 17, 2000 (65 FR 50312) and last modified in a final rule that appeared in the Federal Register on January 16, 2009 (74 FR 3296).

The Secretary of HHS received recommendations from the National Committee on Vital and Health Statistics (NCVHS) in 2018 and 2020 to update retail pharmacy and pharmacy subrogation standards<sup>1</sup> to the newest versions as follows:

- NCPDP Telecommunications Standard Implementation Guide Version F6 (to replace Version D.0).
- NCPDP Batch Standard Implementation Guide Version 15 (to replace Version 1.2); and
- NCPDP Batch Standard Subrogation Implementation Guide Version 10 (to replace Version 3.0).

<sup>1</sup> <https://ncvhs.hhs.gov/wp-content/uploads/2018/08/Letter-to-Secretary-NCVHS-Recommendations-on-NCPDP-Pharmacy-Standards-Update.pdf>  
<https://ncvhs.hhs.gov/wp-content/uploads/2020/04/Recommendation-Letter-Adoption-of-New-Pharmacy-Standard-Under-HIPAA-April-22-2020-508.pdf>

The recommendation also advised that the Secretary set specific compliance dates, which CMS adopted in the final rule as follows:

- **Version F6 and Version 15:** 36 months after the effective date of the final rule.
  - **Applicability:** All covered entities
  - **Transition Period:** Begins 28 months after the effective date of the final rule. Covered entities and trading partners may agree to use either Version D.O, Version 1.2, Version F6, or Version 15 during an 8-month transition period prior to the full compliance date.
- **Version 10:** 36 months after the effective date of the final rule.
  - **Applicability:** State Medicaid agencies only
  - **Transition Period:** Begins 28 months after the effective date of the final rule. State Medicaid agencies and trading partners may agree to use Version 3.0 or Version 10 during an 8-month transition period prior to the full compliance date.

## Major Provisions of the Final Rule: Modifications to the NCPDP Retail Pharmacy Standards and the Medicaid Pharmacy Subrogation Standard

This final rule adopts 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). These updated versions are 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. This final rule also adopts a modification to the standard for the Medicaid pharmacy subrogation transaction.

HHS originally proposed to broaden the scope of the subrogation transaction to all health plans, attempting to recover reimbursement from the responsible payer and renaming the transaction the Pharmacy subrogation transaction. HHS proposed to adopt Version 10 to replace Version 3.0 as the standard for the subrogation transaction. This would have been a modification for State Medicaid agencies and would have been an initial standard adoption for non-Medicaid health plans. We did not finalize this provision as proposed.

Based on comments received on the proposed rule, HHS heard from stakeholders that Version F6 would bring much-needed upgrades over Version D.O, such as changes to the quantity prescribed field to permit accurate reporting of partial fills of Schedule II drugs. This change will enable refills to be distinguished from multiple dispensing events for a single fill, which will increase patient safety. Version F6 provides more specific fields to differentiate various types of fees, including taxes, regulatory fees, and medication administration fees. Finally, Version F6 increases the dollar amount field length and will simplify coverage under prescription benefits of new innovative drug therapies priced at, or in excess of, \$1 million.

Taken together, these enhancements in this final rule will significantly improve the efficiency and accuracy of retail pharmacy transactions, particularly for pharmacies and the patients they serve.

## Implementation Timeline

As discussed in the proposed rule, we believe that HIPAA-covered entities, or their contracted vendors, have already largely invested in the hardware, software, and connectivity necessary to conduct the transactions with the updated versions of the retail pharmacy standards and the Medicaid pharmacy subrogation standard. However, the final rule allows covered entities an 8-month transition period to enable an effective transition to the new versions of the standards based on their trading partner agreements, prior to the compliance date, which is 36 months after the effective date of the final rule.

For more information, please visit the [Federal Register](#).

