Proposed Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and Adoption of a New Pharmacy Subrogation Standard (CMS-0056-P)

The U.S. Department of Health and Human Services (HHS) issued a proposed rule to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) Version D.0 standard to the Telecommunications Standard Implementation Guide Version F6 and the equivalent Batch Standard Implementation Guide Version 15 (hereinafter collectively referred to as Version F6). This rule also proposes to adopt the NCPDP Batch Standard Subrogation Implementation Guide Version 10 (Version 10), to replace the currently adopted Medicaid Pharmacy Subrogation transaction standard and extend the applicability of the pharmacy subrogation transaction beyond state Medicaid agencies to all health plans.

Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (P.L. 104-191) required the Secretary of HHS to adopt standards for electronic health care administrative transactions conducted between health care providers, health plans, and health care clearinghouses. Under HIPAA, the National Committee on Vital and Health Statistics (NCVHS) must recommend standards to the Secretary of HHS following review and approval of new or updated standards developed by Standards Development Organizations (SDOs).

In January 2009, HHS 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. The same rule also adopted the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0) for Medicaid pharmacy subrogation transactions, which Medicaid agencies use in transmitting claims to payers for the purpose of seeking reimbursement from the health plan responsible for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

In 2018, the Secretary of HHS received recommendations from the NCVHS to adopt the following standards:

- 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).

These recommended standards were developed through consensus-based processes, which included the opportunity for public comment. This public comment indicated that these updated standards are needed for current and future business processes.

Major Provisions of the Proposed Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and the Adoption of a New Pharmacy Subrogation Standard

The provisions in this proposed ruled would adopt the NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15); and NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10, for non-Medicaid health plans. These updated standards would replace the currently adopted NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and the equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2); and NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, Release 0.

Industry stakeholders report that Version F6 would bring much needed upgrades over Version D.0, such as improvements to the information attached to controlled substance claims, including refinement to the quantity prescribed field. This change would enable refills to be distinguished from multiple dispensing events for a single fill, which would 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 would simplify coverage under prescription benefits of new innovative drug therapies priced at, or in excess of, $1 million. The current adopted Version D.0 does not support this business need.

The current Medicaid Subrogation Implementation Guide Version 3.0 (Version 3.0) was adopted to support federal and state requirements for state Medicaid agencies to seek reimbursement from the correct responsible health plan. However, industry stakeholders reported that there is a need to expand the use of the subrogation transaction beyond Medicaid agencies and noted that the use of a subrogation standard that would apply to other payers would be a positive step for the industry. Whereas HIPAA regulations currently require only Medicaid agencies to use Version 3.0 in conducting the Medicaid pharmacy subrogation transaction, all health plans would be required to use the Pharmacy Subrogation Implementation Guide for Batch Standard, Version 10, to transmit pharmacy subrogation transactions, which would allow better tracking of subrogation efforts and results across all health plans, and support cost containment efforts.

Should these proposals be adopted as proposed, they would require covered entities to comply 24 months after the effective date of the final rule.

Summary of Costs and Benefits

We estimate that the overall cost for pharmacies, pharmacy benefit plans, and chain drug stores to move to the updated versions of the pharmacy standards and the initial adoption of the pharmacy subrogation transaction standard would be approximately $386.3 million. The cost estimate is based on the need for technical development, implementation, testing, initial training, and a 24-month compliance timeframe. 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 pharmacy standards.