



NCVHS

National Committee on Vital and Health Statistics

May 17, 2018

The Honorable Alex Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: NCVHS Recommendations on National Council for Prescription Drugs Programs
(NCPDP) Pharmacy Standards Updates

Dear Secretary Azar:

This letter conveys recommendations from the National Committee on Vital and Health Statistics (NCVHS) regarding National Council for Prescription Drugs Programs (NCPDP) Standards.

NCVHS is your advisory committee on health data, statistics, privacy, and national health information policy. NCVHS advises the Secretary of Health and Human Services (HHS) on the adoption of standards, unique identifiers and code sets under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

NCVHS holds industry hearings with stakeholders to learn about the readiness of updated standards, code sets, identifiers or operating rules to be recommended to HHS for adoption. This letter represents the findings from the March 26, 2018 hearing regarding updated pharmacy standards and the Committee's consolidation of the information provided.

Modification of Adopted Pharmacy Standards

At the request of the Designated Standards Maintenance Organization (DSMO) that NCVHS consider recommendations from the NCPDP to adopt updates to three pharmacy standards, the NCVHS Standards Subcommittee held a public hearing in March 2018. The purpose of the hearing was to obtain information about the benefits of the updated standards and why they should be recommended for adoption.

The updated versions of the NCPDP standards would replace those that had been adopted in 2009. The new versions are:

1. Version F2 to replace version D.0. The formal name is the Telecommunication Standard Implementation Guide Version F2;
2. Batch Standard Implementation Guide Version 15;

3. Subrogation Implementation Guide for Batch Standard Version 10 for Medicaid, to replace Version 3.0.

Hearing Observations

The hearing participants represented independent pharmacies, small community pharmacies, large chain pharmacies, pharmacy benefit managers (processors), pharmacy clearinghouses, software vendors, and State Medicaid agencies. Testifiers were strikingly consistent in their support for and eagerness to implement the updated standards. There was overwhelming agreement regarding the need for and value to be realized by the updated versions of the standards, as well as the approach and timing for implementation. In consideration of the testimony and review of written statements received, we offer the following high-level overview of the testimony:

- The updated versions of the standards contain specific enhancements that could be used for addressing the opioid crisis:
 - Eligibility and drug utilization review;
 - Prescription drug monitoring programs (PDMPs); and
 - Enhanced Coordination of Benefits (COB).
- Business requirements for covered entities have changed substantially since the standards were adopted in 2009, and these have been addressed in the updated versions;
- The updated standards support increased process automation and require less manual processing – they offer improved efficiency and reduce costs;
- Stakeholders shared consensus on the best time of year to implement the standard, explaining that a June implementation date avoids conflicts with other pharmacy related mandates, and timing of flu season when pharmacies are busiest.

The Committee believes there is a compelling need and strong industry consensus for the updated versions of the pharmacy standards and recommend that you support adoption of the standards. NCVHS' specific recommendations are as follows:

Recommendation 1 – Adopt the new versions of the standards

Adopt updated NCPDP standards as HIPAA standards:

- a) NCPDP Telecommunications Standard Implementation Guide version F2 (to replace version D.0);
- b) NCPDP Batch Standard Implementation Guide version 15 (to replace version 1.2); and
- c) NCPDP Batch Standard Subrogation Implementation Guide Version 10 (to replace version 3.0).

Recommendation 2 – Implementation Timing

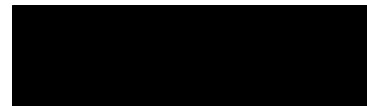
NCVHS supports the implementation approach and timing offered in industry testimony. We understand the time HHS needs to publish both a proposed and final rule and suggest consideration of the following issues in the development of your work plan:

- a) Expedite rulemaking to the extent feasible, so that a final rule is published by the end of calendar year 2019;
- b) Provide for a two-year implementation timeline following publication of the final rule, using June as the compliance month;
- c) Require that the updated version of the standard be used by the compliance date, but allow both versions of the standards to be used for a one-year period after the compliance date. This will enable an effective transition period that allows the use of the current version and the new version;
- d) Require full compliance by the end of the third year, and only allow use of the new version of the updated standards, Version F2, Batch Version 15 and Subrogation Version 10.

The Committee would like to reiterate that industry, specifically the Medicare and Medicaid programs, be given sufficient time and encouragement for thorough end-to-end testing before any go-live date.

Thank you for considering the recommendations put forth in this letter. NCVHS remains available to answer questions and will continue to support HHS efforts to advance efficiencies in the health care system, and to working with the Department to shape future guidance.

Sincerely,



William W. Stead, M.D., Chair
National Committee on Vital and Health Statistics

Attachment:

DSMO Request Letter to NCVHS

cc: HHS Data Council Co-Chairs

January 9, 2018

William Stead, MD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget and Legislation
3311 Toledo Road
Hyattsville, MD 20782

Dear Dr. Stead,

On August 17, 2000, the Secretary of Health and Human Services (HHS) named six entities as the Designated Standards Maintenance Organizations (DSMO) under the Health Insurance Portability and Accountability Act (HIPAA) in § 162.910(a). The DSMO organizations work together on the maintenance and development of HIPAA adopted administrative simplification transaction standards.

The six organizations include three standard setting organizations (SSO):

- Accredited Standards Committee X12 (ASC X12)
- Health Level Seven (HL7)
- National Council for Prescription Drug Programs (NCPDP)

And three data content committees:

- Dental Content Committee of the American Dental Association (DeCC)
- National Uniform Billing Committee (NUBC)
- National Uniform Claim Committee (NUCC)

The DSMO Steering Committee is comprised of one voting member from each of the six organizations and a non-voting liaison from HHS, specifically the Centers for Medicare and Medicaid Services' Division of National Standards. The Steering Committee convenes as necessary and is charged with establishing consensus on all requested changes to HIPAA transactions and code sets. Changes are submitted through the DSMO Change Request System, either directly or through the moving forward of a transaction or code set from the applicable maintenance body.

The DSMO is requesting the following two (2) Change Requests proceed through the regulatory process for industry adoption under HIPAA.

CRS 1201

Retail Pharmacy Claim

“The NCPDP membership is requesting a new version of the Telecommunication and Batch Standard be named in HIPAA. The Telecommunication Standard Implementation Guide is version F2. The Batch Standard Implementation Guide is version 15, which supports the Telecommunication Standard version F2 in a batch mode.

The Telecommunication Standard Implementation Guide supports the following processes:

1. Eligibility Verification
2. Claim
3. Service
4. Information Reporting
5. Prior Authorization
6. Predetermination of Benefits

Changes from version D.0 to version F2 are provided under separate cover.”

DSMO Recommendation:

“Approve. The DSMO is supportive of the work done by NCPDP to update this adopted standard and begin the process for a new version to be named in HIPAA.”

CRS 1202

Retail Pharmacy Claim

“The NCPDP membership is requesting the Subrogation Implementation Guide for Batch Standard version 10 be named in HIPAA to replace the Medicaid Subrogation Standard Implementation Guide, version 3.0 for Medicaid use only.

The Medicaid Subrogation Implementation Guide was established to address the Federal and State requirements for Medicaid Agencies to seek reimbursement from the correct responsible health plan. However, the Medicaid Subrogation Implementation Guide did not address similar requirements for other payers, such as Medicare Part D, State Assistance Programs or Private Health Plans. A standardized Subrogation Implementation Guide is needed to:

- Support compliance with requirements for recovery of federal, state and other plan overpayments
- Reduce manual processes currently required by pharmacies, PBMs and plans
- Provide a uniform approach to efficiently process post-payment subrogation claims and eliminate the numerous custom formats used in the industry today
- Achieve payment accuracy and support cost containment efforts

The Medicaid Subrogation Implementation Guide was used as the base to create the Subrogation Implementation Guide.

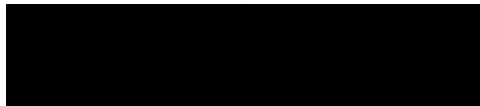
More information on this business function and background is found in the NCPDP Subrogation Implementation Guide.”

DSMO Recommendation:

“Approve. The DSMO is supportive of the work done by NCPDP to update this adopted standard and begin the process for a new version to be named in HIPAA.”

The DSMO recommends NCVHS begin the process of recommending adoption to the Department of Health and Human Services. Should you have any questions, please do not hesitate to contact me at narcisij@ada.org.

Sincerely,



Jean P. Narcisi, DSMO Chair

Cc: DSMO Steering Committee

Lorraine Doo, Senior Policy Advisor, Center for Medicare & Medicaid Services

Nicholas L. Coussoule, NCVHS Standards Subcommittee Co-Chair

Alexandra Goss, NCVHS Standards Subcommittee Co-Chair