



NCVHS

National Committee on Vital and Health Statistics

April 22, 2020

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

Re: NCVHS Recommendations for Adoption of New Pharmacy Standard Under HIPAA

Dear Secretary Azar:

This letter conveys recommendations to the Department of Health and Human Services (HHS) to adopt updated versions of pharmacy standards developed by the National Council for Prescription Drugs Programs (NCPDP). Adoption as a national HIPAA standard would result in greater interoperability for entities exchanging prescription information, improvements in patient care, better data for drug utilization monitoring, and burden reduction for providers.

The National Committee on Vital and Health Statistics (NCVHS) is your advisory committee on health data, statistics, privacy and national health information policy. NCVHS advises the Secretary of HHS on the adoption of standards, unique identifiers and code sets under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). NCVHS proactively solicits industry stakeholder comments to learn about the readiness of updated standards, code sets, identifiers or operating rules to be recommended to HHS for adoption.

This letter presents three recommendations approved at the March 24, 2020 meeting of the Committee.

Modification of Pharmacy Standards Adopted under HIPAA

In January 2020, the Designated Standards Maintenance Organizations (DSMOs) requested that NCVHS consider recommending the adoption of an updated version of the pharmacy standard.¹ In response, the NCVHS Subcommittee on Standards requested public comment through both a *Federal Register* notice² and direct outreach to industry. The purpose of the public comment was to obtain information about the updated standard's value to industry and why the Committee should, or should not, recommend that HHS adopt this new standard. The updated

¹ Letter to NCVHS from the DSMOs (January 21, 2020): <https://ncvhs.hhs.gov/wp-content/uploads/2020/02/Letter-to-NCVHS-DSMO-Change-Request-January-21-2020.pdf>

² Federal Register, Vol. 85, No. 39, February 27, 2020: <https://www.federalregister.gov/documents/2020/02/27/2020-03981/national-committee-on-vital-and-health-statistics-meeting>

version of the NCPDP standard would replace the NCPDP version D.0 HIPAA standard that has been in effect since it was adopted in 2009 and required for use in 2012. The new version is designated F6.

In 2018, NCVHS recommended that HHS adopt the updated NCPDP version F2 to replace version D.0; however, HHS has not yet promulgated a Notice of Proposed Rule Making for F2 adoption. This new NCVHS recommendation proposes the adoption of version F6 in lieu of F2. We also recommend a specified timeline for adoption of F6.

NCVHS's specific recommendations are as follows:

Recommendation 1 – Adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6 to replace version D.0.

Version F6 brings incremental improvements over F2, including the ability to accommodate drugs that cost more than \$1 million dollars, opportunities for greater automation and interoperability between systems and less manual effort due to increased use of codes. For example, the new version removes free text fields and replaces them with codified fields. These advances lead to improvements in patient care. Other benefits identified by commenters included: mitigation of the need to split claims for high dollar claims; more robust data exchange between Long Term Care providers and Pharmacy Benefit Managers (PBMs), including information needed for prior authorizations; and enhancements to the drug utilization review (DUR) fields in the claim response transaction. This improves communication from the payer and enables the pharmacy to act more quickly to the benefit of the patient.

Recommendation 2 – Time the implementation of F6 in accordance with industry requests.

NCVHS supports the implementation approach and timing for F6 suggested by industry in their comments to the Committee.³ The Committee understands that HHS will need to publish both a Proposed and a Final Rule. We recommend the following timeline for the Division of National Standards' work plan:

- a. Expedite rulemaking so that a Proposed Rule (NPRM) is published by the end of calendar year 2020 and, assuming favorable public comments, a Final Rule by September 1, 2021;
- b. Provide a three-year pre-implementation window following publication of the Final Rule, allowing (but not requiring) industry use beginning September 1, 2024;
- c. Allow both versions (D.0 and F6) to be used for an eight-month period beginning with a September 1, 2024 compliance date and ending April 30, 2025. This will enable an effective live-testing and transition period that allows the industry to use either D.0 or F6;
- d. Require full compliance by the end of the third year, i.e., exclusive use of F6 beginning May 1, 2025.

³ Public comments posted online: <https://ncvhs.hhs.gov/wp-content/uploads/2020/03/Public-Comments-NCPDP-Change-Request-March-2020.pdf>

Note: the proposed May 1 compliance date reflects intentional, industry-requested timing. Previous HIPAA-mandated standards adoption compliance dates using a January 1 go-live date have proven problematic to the industry due to seasonally heavy organizational burdens associated with the end-of-year timeframe, such as: the processing burden for annual benefit plan changes typically effective January 1; unavailability of full staff during the holiday season preceding January 1; competing administrative obligations requiring IT/operations and corporate resources such as closing out annual books and compiling reports; and annual flu season peaks affecting both providers and IT/operations staff.

The Committee would like to reiterate that, under this proposed timeline, industry believes it has adequate time for planning and completion of necessary budget cycles, especially for the Medicare and Medicaid programs. It would also allow and encourage thorough end-to-end testing before the go-live date.

Recommendation 3 – Act on the two previous NCVHS recommendations to adopt the Batch Standard and the Medicaid Subrogation Standard put forth in the May 2018 Letter.

In the Committee’s letter of May 17, 2018, the Committee recommended that HHS adopt three updated NCPDP standards:

- Telecommunications Implementation Guide F2;
- Batch Standard Implementation Guide Version 15; and
- Subrogation Implementation Guide for Batch Standard Version 10 for Medicaid.

The new recommendation for F6 being put forth here revises **only** the previous F2 recommendation. The Committee urges HHS to act on its 2018 recommendations to adopt Batch version 15 and Medicaid Subrogation version 10⁴. Adopting these standards will accomplish the primary goals of administrative simplification to achieve cost reductions and improve efficiency.

Impact of COVID-19 Pandemic on Recommended Timeline. Given the current COVID-19 pandemic emergency, the Committee recognizes the possibility that HHS’ available resources in 2020 may be insufficient to promulgate rulemaking according to the proposed timeline, which in normal times would be ambitious. In event of a delay in publishing a proposed and/or final rule, the Committee requests that the CMS Division of National Standards be continuously transparent about its ability to achieve the timeline and to reach out to the Committee, NCPDP and the pharmacy industry to obtain input.

Summary of Public Comment Submitted to NCVHS

The commenters represented independent pharmacies, small community pharmacies, large chain pharmacies, pharmacy benefit managers (processors who are business associates of

⁴ NCVHS Letter to HHS Secretary: <https://ncvhs.hhs.gov/wp-content/uploads/2018/08/Letter-to-Secretary-NCVHS-Recommendations-on-NCPDP-Pharmacy-Standards-Update.pdf>

health insurance companies), pharmacy clearinghouses, software vendors and a federal government agency. Comments were strikingly consistent in their support for and eagerness to implement the updated standard. The updated standard includes many industry-desired capabilities that the 11-year old D.O version does not support. There was overwhelming agreement regarding the need for and value to be realized by the updated version of the standard, as well as the approach and timing for implementation. Importantly, there was not a single comment opposing adoption of F6.

Thank you for considering the Committee's recommendations. The Committee urges HHS to move forward with this work as expediently as is feasible to enable industry to keep pace with the evolution of business and technology changes.

NCVHS remains available to answer questions and will continue to support HHS efforts to advance efficiencies and burden reduction in the health care system.

Sincerely,

A black rectangular redaction box covering the signature of William W. Stead.

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

CC: HHS Data Council Co-Chairs