

October 3, 2022

Jacki Monson, Chair  
National Committee on Vital and Health Statistics  
CDC/National Center for Health Statistics  
3311 Toledo Road  
Hyattsville, MD 20782-2002

Dear Ms. Monson,

On behalf of the undersigned members of the Designated Standards Maintenance Organizations (DSMO), we are writing regarding X12's recently submitted claim submission and remittance advice transaction sets. Although the DSMO welcomes potential updates to the X12 standard transactions, we are writing concerning their failure to adhere to the standards development protocol established under the Health Insurance Portability and Accountability Act (HIPAA) regulations and the *Memorandum Of Understanding Among The Organizations Designated To Manage The Maintenance Of The Electronic Data Interchange Standards Adopted Under The Health Insurance Portability and Accountability Act Of 1996 (MOU)*. Specifically, we are concerned the newly proposed X12 standards have not been submitted to the DSMOs for review prior to their formal recommendation to the National Committee on Vital and Health Statistics (NCVHS), which is a departure from the long-established process for all other transaction adoptions and updates including the X12 004010 to 005010 changes. We urge NCVHS to require X12 adhere to the HIPAA regulations and MOU and first submit a change request to the DSMO for its processing. NCVHS will need to wait to begin its review until after the DSMO submits its disposition of X12's change request.

On August 17, 2000, the Secretary of Health and Human Services (HHS) named six entities as the DSMO under HIPAA. The organizations include three standard setting organizations (X12, Health Level Seven, and National Council for Prescription Drug Programs) and three data content committees (Dental Content Committee of the American Dental Association, National Uniform Billing Committee, and National Uniform Claim Committee). HIPAA regulations establish that "The Secretary considers a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following: (1) Open public access, [and] (2) Coordination with other DSMOs".<sup>1</sup> In order to ensure adequate coordination, DSMO participants have historically submitted new or updated standards to the DSMO, who would formally review the material and issue a recommendation to NCVHS.<sup>2</sup>

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<sup>1</sup> 45 CFR § 162.910

<sup>2</sup> The most recent example of this was the National Council for Prescription Drug Programs' updated Retail Pharmacy Claim Standard. The DSMO recommendation can be found at <https://ncvhs.hhs.gov/wp-content/uploads/2020/02/Letter-to-NCVHS-DSMO-Change-Request-January-21-2020.pdf>

The recent X12 submission to NCVHS has failed to adhere to this protocol. The DSMO organizations were notified of the transactions' submission when they were sent to NCVHS, eliminating our opportunity to conduct a coordinated review. Additionally, X12's DSMO notification failed to include a copy of the actual standard nor a useable change log displaying the updates that it was proposing. Instead, members of the DSMOs were asked to access the materials through X12's "Glass" online reviewer portal, a platform that requires paid membership in X12 or a purchase of a license to access. This has resulted in a continued inability to conduct an adequate post-submission review in order to prepare for NCVHS discussions on the matter.

As HIPAA authorized advisors on the development of new standards, we take our responsibility on behalf of health insurers, clearinghouses, providers, and patients seriously. To ensure the coordinated review of standards occurs as envisioned in the HIPAA regulations, we urge NCVHS to refrain from any formal recommendations on these new standards until the DSMO can provide an analysis and recommendations based on proper review.

Sincerely,

/s/  
Krishna Aravamudhan  
Vice President, Practice Institute  
Dental Content Committee of the ADA

/s/  
Terrence Cunningham  
Chair  
NUBC

/s/  
Nancy Spector  
Chair  
NUCC

/s/  
Margaret Weiker  
Vice President, Standards Development  
NCPDP

CC: Dr. Mary Greene, MD, Director, Office of Burden Reduction & Health Informatics