Statement of the Designated Standards Maintenance Organizations to the National Committee on Vital and Health Statistics Subcommittee on Standards January 18, 2023

The members of the Designated Standards Maintenance Organizations (DSMO) thank the National Committee on Vital and Health Statistics' (NCVHS) Subcommittee on Standards for inviting our input on X12's June 7th proposal to adopt updated Health Care Claim: Professional (837), Health Care Claim: Institutional (837), Health Care Claim: Dental (837) (hereafter collectively referred to as the "claim" transaction), and Health Care Claim Payment/Advice (835) transactions. The following commentary reflects the views of the DSMO, but we note that X12, HL7, and the Dental Content Committee do not share in this collective viewpoint.

Background

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". 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.

X12 Recommendations

Inconsistent with these established processes, the DSMO organizations were notified of the X12 transactions' submission on June 8th, 2022, the day after the recommendations were sent to NCVHS. X12's DSMO notification failed to include a copy of the actual standard nor a usable change log displaying the updates that it was proposing. As a result, unlike previous recommendations to NCVHS, these submissions were not subject to a coordinated review and analysis in advance of their submission. While we strive to address DSMO coordination dynamics, we encourage NCVHS to support DSMO efforts to re-enforce the consultation requirement found in Public law 104-191 and related/subsequent regulations.

Over the past months, the DSMO and its participant organizations have engaged in a review and analysis of the X12 8020 claims and electronic remittance advice transactions. Three major themes arose from such review:

- The standards need additional pilot testing to ensure that the transactions will function properly and meet industry needs;
- The industry should not move to adopt new versions of the claim or remittance advice transaction without significantly greater cost/benefit analysis; and
- The industry needs additional clarity about the NCVHS recommendations that multiple versions or standards be permitted simultaneously.

Need for Additional Pilot Testing of Transactions

As of the date of the request for consideration, there has not been any real-time pilot testing of the proposed transactions. Such testing is an essential step in evaluating the effectiveness of a new standard, as it will also aid efforts to identify accurate impact analysis and reveal the benefits of adopting the proposed upgrades. In addition to enabling the evaluation of the specific standards, the pilot testing needs to ensure that the transactions can work across versions because of the piecemeal rollout process. The 8020 claim and remittance transactions must successfully function when being inserted with the other 5010 transactions that will remain in effect until X12 proposes their next round of updates. Such a rollout process necessitates substantial cross-version piloting before stakeholders can adequately engage in a cost-benefit analysis.

Further underscoring the need for robust cost-benefit analysis and subsequent testing is the need to avoid claim and remittance transmission disruptions, particularly at a time in which many industry participants are experiencing financial strain resulting from the multi-year effects of the COVID-19 pandemic.

Cost-Benefit Analysis and Return on Investment

In the letter recommending adoption, X12 provided estimated implementation costs for each of the offered standards. The DSMO strongly agrees that clear implementation cost and benefit estimates are essential parts to an actionable recommendation, but we do not believe that the offered estimates provide sufficient clarity to support a recommendation at this time. Specifically, the X12 estimates generalize across all stakeholders and sizes, treat all “enhancements” as equal to one another when providing “per enhancement” estimates, and fail to detail clearly how their estimates were created. As a result, we do not believe that these estimates are reliable nor usable for stakeholders.

We believe a cost-benefit analysis is extremely important in order to determine whether to update these standards. This analysis needs to review information gathered from pilot testing so that the industry can accurately understand how much the transactions will cost to support, how much time and resources they will save, and ultimately, what the return on investment – whether quantitative or qualitative - will be for each stakeholder group. Such analysis will ensure confidence in a recommendation for adoption and will make rollout and explanation easier.

Need for Clarity on NCVHS Proposal for Multiple Standards and/or Versions

In a July 28, 2022, letter titled “Recommendations to Modernize Adoption of HIPAA Transaction Standards”, NCVHS recognized that new drivers of transformation in healthcare data exchange are within HHS’s purview. NCVHS recommended HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Additionally, the letter calls for HHS to enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions. HHS has yet to respond to these recommendations.

We believe a significant unanswered factor in a prospective cost-benefit analysis is whether more than one version of a standard’s implementation specification or more than one standard per business function will be allowable and/or required. Should stakeholders be required to support multiple implementation guide versions or standards simultaneously, the tools and framework needed to support the adopted standards may increase costs for stakeholders. However, in the absence of federal policy response to the idea, impacts are unclear in assessing costs and benefits derived. Moreover, should the standards setting organizations advance modification recommendations every year or every other year, covered entities and their vendors may need to hire fulltime teams to review and implement new versions of implementation guides, which would necessitate a sustained capital investment.

Conclusion

As a result of these aforementioned concerns, DSMO finds that the X12 transactions have not undergone adequate testing and piloting to ensure that the proposed updates to the currently mandated standards will produce legitimate benefits and not have unintended consequences for the industry. Furthermore, HHS insights regarding recommendations for multiple standards and implementation specification versions is crucial to engage in necessary industry review of proposed standards updates.

As a result, the DSMO does not recommend that NCVHS pursue adoption of the proposed standards until:

- **completion of real-world pilot testing demonstrates their functionality,**
- **completion of a more detailed cost-benefit analysis, and**
- **we have greater clarity on whether multiple standards or versions for the same business function will be allowed.**