• 24654 N. Lake Pleasant Parkway • Suite 103 #275 • Peoria AZ 85383 •

November 30, 2018

Nick Coussoule and Alix Goss
Co-chairs, NCVHS Subcommittee on Standards
NCVHSmail@cdc.gov

Nick and Alix,

It is clear the NCVHS Subcommittee on Standards put a lot of time, effort, and thought into the recently issued *Draft Recommendations for the Predictability Roadmap***.** On behalf of X12's Board, officers, and members, I thank you for your diligence and for the opportunity to provide feedback on the proposed recommendations.

X12 supports the premise that the federal adoption process must be predictable if the healthcare industry is to derive benefit from enhancements to the named standards or from newly named standards. We applaud your efforts to bring predictability to the federal adoption process.

X12 agrees that the current situation can be improved related to predictability and we appreciate that focus in the NCVHS recommendations and calls-for-action. We think it is important to note that predictability improvements, as well as other types of improvements, also originate directly from various industry groups individually and in the form of joint initiatives between the groups. For example, earlier this year, X12 initiated internal policy and process changes at the organizational and subcommittee level which will culminate in annual publication of all X12 work products. Once these policy changes are fully implemented, X12 will have a predictable and consistent publication schedule which can feed, in-turn, into a predictable adoption process.

Related to technology innovations, X12 respectfully submits that the Standards Development Organizations (SDOs) are in fact developing solutions based on advancing technology but that the current adoption process is not conducive to supporting use of those technology innovations. For example, in addition to the EDI Standard format mandated in the Federal Rules, X12 transactions can be represented in XML based upon several schema definitions, and X12 continually meets with implementers to determine other syntaxes that would be useful to implementers.

Related to the ***Standards Update Process – Overview***, the heading indicates the slide reflects the current process but the details on the slide include descriptions for both current and potential process steps. Regarding the path between identification of changes needed and NCVHS Hearings

and Recommendations, we urge NCVHS to consider one path for both standards and operating rules.

Regarding the recommendation to disband the DSMO, X12 suggests this recommendation needs more detail or may need to be reconsidered as the situation has several nuances. Final Rules define what a Designated Standards Maintenance Organization (DSMO) is, name specific organizations as DSMOs, and require that HHS consult with the named DSMOs related to future rulemaking. Those Rules are somewhat separate from the group of DSMOs that operate as "The DSMO" and meet and act cooperatively and collaboratively. "The DSMO" was formed via a Memorandum of Understanding (MOU) between the participating organizations, not by Rulemaking, and HHS is not a party to the MOU. If "The DSMO" elected to disband, the requirement for HHS to consult with the individual organizations would remain in place until overturned by subsequent regulation. Any recommendation related to DSMOs needs to be clear as to whether it is a recommendation for regulation change or a recommendation for the MOU based collaborative group.

Related to the recommendation for the creation of an entity tasked with oversight and governance of the standards development processes, Page: 2
NCVHS should clarify how the addition of this new entity would improve the overall adoption processes. Other details, such as whether this new entity would be a federal, industry, or non-profit group and specifics about external input and how consensus would be achieved, should be part of any final recommendation. Based on these clarifications, additional concerns regarding scope, authority, fairness, reasonableness, and balanced representation may need to be addressed prior to a recommendation for action. Without this foundational clarity, it will be difficult to add a productive and effective entity to the current mix without negatively impacting existing industry stakeholders. X12 is not certain that adding a new organization into the already lengthy and complex adoption process is the most efficient and effective solution and believes more analysis is needed to ensure there are no unintended negative impacts. In addition, NCVHS should reconsider the portions of this recommendation dealing with oversight and governance of the standards and operating rules development processes. The Federal Rules purposefully name independent ANSI-accredited Standards Development Organizations as the standards maintainers, allowing the government to adopt standards developed as the collaborative work of industry groups representing a broad section of the affected parties, rather than developing its own proprietary standards. The proposed recommendation effectively puts the government in direct control of development and publication of mandated standards, completely removing the separation intended to ensure the autonomy of the standards developers which protects consensus. ANSI accreditation gives credibility and authority to SDOs by assuring that the policies and processes of the SDO meet highly rigorous standards for consensus, fairness, openness, and participation. An ANSI accredited SDO cannot be "overseen and governed" by a separate organization. In addition, neither NCVHS nor Congress should dictate the policies and processes of corporations operating individually with distinct legal recognition, bylaws, and governance, to do so would result in federal control of private enterprise.

X12 supports the concept of HHS providing financial support for collaboration, outreach, evaluation, cost-benefit analysis and other reporting related to adoption of mandated standards and operating rules. X12 also concurs with the premise that a more efficient adoption process is needed for suggesting, evaluating, and naming new HIPAA standards and operating rules, including the naming of more current versions on a regular basis.

X12 concurs with the philosophy of normalized, incremental, updates published on a reliable schedule and is currently transitioning to an internal process that supports annual publication of all X12 work products. Once the annual publication cycle is implemented, X12 will be positioned to recommend a new version for individual transactions, based on enhanced functionality, on a predictable basis all of which support the proposed recommendation. Further, we support the recommendations for timely NCVHS review and recommendations and timely HHS adoption.

X12 agrees that HHS should regularly publish guidance regarding its policies and clarification of rulemaking matters. We also support HHS being charged with promoting the guidance of each SDO and ORE related to the appropriate and correct use of the standards and operating rules they maintain. However, it should be made clear that only the SDO or ORE that maintains a standard or operating rule has the authority to define guidance regarding the appropriate and correct use of their works.

X12 supports a recommendation that rulemaking sets the proverbial floor and defines other factors to regulate the proverbial ceiling so long as care is taken to ensure the flexibility introduced does not diminish the standardization that is the heart of Administrative Simplification. Allowing too many options between the floor and ceiling may return the industry to the days when trading partners had to support many variations of the business processes that have been painstakingly standardized since the first HIPAA mandate was enacted. Any space between the floor and ceiling may need to be fairly limited initially to allow for assessment of the industry's tolerance for variability. Additionally, any recommendation should address concerns about the power balance between trading partners, for example preventing larger trading partners from usurping authority over the mandate by coercing smaller or subordinate trading partners into moving, or not moving, to a permitted version as a condition of doing business. Consideration also needs to be given to issues that will or could arise related to upgrading or downgrading functionality, ensuring data integrity when converting data between versions, and clarification of who is responsible for accuracy if data is transformed. A recommendation should be informed by a clear understanding of how the costs, impacts, and benefits of maintaining different versions of a transaction for different trading partners will impact various types of covered entities. It is likely that NCVHS will need to do additional analysis to create a more detailed recommendation that ensures the resulting rulemaking is implementable and tenable to the health care industry.

X12 supports innovation, advancing technology, and allowing for use of various syntaxes to accomplish the standardization that HIPAA is built on, for example continuing to mandate the named NCPDP and X12 transactions as the floor that all implementers must support while allowing willing trading partners to implement other syntaxes, such as XML , so long as the alternative

syntax maintains the data, semantic relationships and conditional requirements specified in the floor mandate. This would be similar to the DDE exception already provided for in the current legislation. X12 encourages NCVHS to specifically limit this recommendation such that the efficiencies and cost-reduction benefits of standardization are not diluted based on mandating or permitting implementation of disparate standards for one business purpose.

X12 concurs with the recommendation encouraging health plans and vendors to identify and discuss barriers to effective use of the transactions, however we suggest that this recommendation should be more specific. NCVHS should consider clarifying that this includes several types of barriers including but not limited to policy barriers, infrastructure barriers, training or education barriers, resource barriers, and data content barriers. Regarding any data content barriers, consider adding a recommendation that such data content barriers be presented to the SDOs in a timely fashion as maintenance requests. Similarly, barriers that could or would potentially be eliminated with an operating rule should be expeditiously presented to the appropriate ORE as maintenance requests.

Related to the recommendation that WEDI be charged with identifying issues and solutions and publishing white papers related to the use of HIPAA standards and operating rules, X12 suggests caution on issuing recommendations that give a third-party implied authority over best practices related to the work products of an SDO or ORE. Only the SDO or ORE that maintains the work can collaboratively identify its appropriate or intended use. We support WEDI's ongoing efforts to gather and analyze industry input, publish collaborative white papers advising on policy implications and other best practices related to issues outside of the standards and operating rules, and provide informative input to the appropriate SDO or ORE when applicable.

X12 suggests the recommendation related to compliance certification/validation tools be revisited and would support the concept of SDOs and OREs providing or endorsing certification/validation tools related to use of their standards or operating rules as they deem appropriate. X12 supports the concept of HHS participation and joint funding in such ventures.

X12 supports and encourages increased participation in standards development and maintenance activities. The SDOs and OREs already collaborate with many public and private sector stakeholders related to outreach. Further clarification of the new activities or actions being recommended would be helpful.

X12 supports the recommendation related to organization committing to membership in the SDOs, and suggest NCVHS make the recommendation even more inclusive by naming public and private sector health plans, provider organizations, and vendors specifically, as is done in related bullet A. In addition, we suggest a related recommendation that health plans, provider organizations, and vendors who don't participate in the ongoing SDO collaborations should provide feedback on proposed enhancements at the earliest possible point in the maintenance process. This would reduce the need for rework and reconsideration over time.

Regarding the recommendation for a single governance process, X12 has several questions related to this call to action. For example, what public and private stakeholders should collaborate? Who would coordinate? What is the scope of the proposed single governance process? How would such a governance process be disseminated and maintained? Who would enforce adherence to the process?

The recommendation labeled M2 presupposes the establishment of a new entity which may or may not happen. The recommendation could be revised such that the concept is applicable with or without establishment of a new entity. For example, The SDOs and OREs could be called to cooperatively propose common metrics as a voluntary reporting mechanism.

Related to the Hearing Discussion Questions, X12 submits the following for consideration.

Would these recommendations as a whole improve the predictability of the adoption of administrative standards and operating rules?

A number of these recommendations could have a positive impact on the predictability of administrative standards and operating rules adoption, though some of them seem to deviate from that narrowly defined focus.

In addition, it's crucial to note overall progress in the predictability of the adoption of administrative standards and operating rules is predicated on implementation of a combination of these recommendations. As a group, the recommendations related to predictability of the adoption of administrative standards and operating rules may indeed lead to improved predictability, but if some portions are ignored or eliminated, the remaining recommendations will not result in meaningful improvements. For example, if all the SDOs and OREs tighten their processes in such a way as to ensure predictable publication schedules and NCVHS tightens its processes to ensure timely recommendations on new versions but the rulemaking process is not enhanced to ensure timely mandates, then no improvement to predictability will be realized. It is important that recommendations that would or might impose new costs or increase costs to implementers, SDOs, OREs, or other industry stakeholders be implemented only if corresponding recommendations related to the adoption and rulemaking process are also implemented.

Are there potential unintended consequences? What are those and how can they be mitigated with modifications to the recommendations.

Several recommendations could potentially result in negative unintended consequences. It's imperative that the health care industry not lose the efficiencies that have been realized via the mandated use of standard transactions. Allowing covered entities to choose from multiple standards would result in the return to an inefficient environment, redundant costs, and unbalanced demands from the covered entities in the position of power in a trading partner relationship. This can be mitigated by emphasizing the value of rulemaking that recognizes a single standard as presented in various syntaxes, each of which meets a specific industry need.

For example, X12 transactions can be represented in the EDI Standard syntax, which implementers are most familiar with, but they can also be represented in other syntaxes including XML based upon several schema definitions, JSON, direct data entry systems, and others. The essential factor is that the substantive data content, semantic relationships and conditions remain the same across the syntaxes, supporting administrative simplification while also supporting the quick and easy enabling of new technologies, thereby positioning the industry for flexibility and adaptability.

Recommending imposed oversight processes to control non-government consensus-driven organizations is of grave concern. The SDOs and OREs are individual entities, managed independently. The SDOs are accredited individually. Attempting to control and dictate to these organizations could have a devastating impact on their ability to maintain consensus-driven processes for the mandated standards and operating rules and on their ability to retain their ANSI accreditation.

Again, we appreciate the effort put forward by the NCVHS Subcommittee on Standards and the opportunity to provide feedback prior to the recommendations being finalized. X12 shares and
Page: 6
supports the NCVHS vision for effective and productive processes and consistent implementations of mandated standards. X12 will work cooperatively with NCVHS, other SDOs and OREs, and industry representatives to ensure the successful realization of standards-related improvements within the health care industry.

As in-context comments can be helpful for clear understanding and discussion purposes, X12 has also attached a set of in-content comments applied to the NCVHS presentation deck. We hope this is a useful aid.

Sincerely,

Cathy Sheppard
X12 Executive Director

Gary A. Beatty
X12 ASC Chair