December 7, 2018

Nicholas Coussoule, Co-chair, Subcommittee on Standards
Alix Goss, Co-chair, Subcommittee on Standards
National Center on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782

Re: NCVHS Draft Recommendations for the Predictability Roadmap

Dear Mr. Coussoule and Ms. Goss

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the National Committee on Vital and Health Statistics’ (NCVHS) draft recommendations for the predictability roadmap. The roadmap would develop actionable recommendations for the secretary of the Department of Health and Human Services (HHS) on administrative standards and operating rules under HIPAA. These recommendations focus on improving enforcement of the regulations, improving guidance and timeliness of standards development, and upholding value of the standards.

The AHA commends NCVHS’s efforts to collaborate with industry stakeholders to improve the standards and operating rules development, adoption and implementation process. Near universal adoption of the electronic claims standards has resulted in $353 million in cost savings. If full adoption of just seven of the electronic transactions were to be achieved, the commercial health care industry could save more than $11 billion in direct administrative costs annually. More needs to be done to achieve these cost savings. We support the need to create a more predictable process so that covered entities and business associates can reliably know when updated versions of the electronic standards will be available and adopted. Specifically, we agree there is a need to improve industry compliance with the standards and operating rules; improve oversight and governance; increase innovation; and increase membership and diversity of participants in the standards development workgroups.
However, we believe some of the proposed recommendations are not clear and could have unintended consequences on the standards and operating rules regulatory process and the stakeholders that use them. Specifically, we are concerned that a new governing body with HHS’s oversight could inadvertently increase the development, adoption and implementation cycle. We recognize the need to ensure a strong business case to support incremental updates to standards and operating rules. Further, the proposals to enable the adoption of a baseline standard while enabling voluntary use, testing and innovation could create unintended burdens and reduce the standardized and automated efficiencies that have been achieved through administrative simplification.

Our detailed comments follow.

**GOVERNING BODY**

The predictability roadmap recommends disbanding the Designated Standards Maintenance Organization (DSMO) that is charged with managing the maintenance of the electronic data interchange standards adopted under HIPAA. The roadmap further recommends HHS create a new entity tasked with oversight and governance of the standards development process. Current governance and oversight of the standards development processes are designated by the HHS secretary and named in the Aug. 17, 2000 Transactions and Code Sets Rule. Section §162.910 identifies the organizations involved with the development and maintenance of the transaction standards. They include three American National Standards Institute accredited standards development organizations – ASC X12, Health Level 7 and National Council for Prescription Drug Programs – and three data content organizations – the National Uniform Claim Committee, the National Uniform Billing Committee, and the Dental Content Committee of the American Dental Association.

These standards development and data content organizations are important to the standards process for many reasons, including but not limited to:

- Each organization supports a critical component of the standards process, while no one organization or committee has overall governance, thereby creating a cooperative and coordinated change request process.
- Each organization has a governing structure that engages industry participation from multiple stakeholders and relies primarily on work done by volunteers.
- Each organization encourages cooperation with the other governance committees to ensure all aspects of a proposed standards change is considered.

The roadmap does not state why a new entity would improve the standards process. Further, it is unclear in the NCVHS recommendations what the scope of work, oversight and governance for the replacement entity would have over the existing standards development processes. It also is unclear what the need is for this additional level of
governance. We are concerned that such a structure under HHS would create duplication of existing efforts of other standard development and data content organizations currently in place. In addition, we question the tremendous uncertainty this transition may cause to the existing standards development and maintenance process.

We ask that NCVHS retain the current DSMO governance structure, while it further researches the role of the DSMO and how it interacts with the existing standards development and data content organizations. In addition, NCVHS should analyze the findings to determine what needs are not being met, and if applicable, develop additional oversight criteria to modernize the process and expand participation to ensure support of industry process improvement changes.

**UPDATES TO STANDARDS AND OPERATING RULES**

We agree with the recommendation for timelier adoption, testing and implementation of updated or new standards and operating rules. We encourage NCVHS to evaluate the approach of reviewing incremental updates to distinguish those that are substantive versus non-substantive, and determine the impact of disruption and cost to comply. Interim updates that are non-substantive (i.e. minor updates, guidance and/or maintenance) releases could go through a modified or fast-track approval process. Substantive changes and/or new standards, however, should go through the typical regulatory process. For any substantive updates (modification of the structure of the transaction), there should be a strong business case and cost benefit analysis prior to adoption. This would support the NCVHS goal of creating a regular, reliable schedule.

**BASELINE STANDARD**

The predictability roadmap would benefit from a clearer statement of how NCVHS’s recommendation to explore other opportunities to advance predictability and innovation above the established baseline of standards and operating rules would actually work. The purpose of establishing a baseline is to ensure standardization of the data content among all trading partners. As proposed, we are unsure of how trading partners would innovate and/or advance predictability without impacting data content, which would minimize the effectiveness of the current administrative transaction standards. In addition, while we agree that testing the standards prior to adoption would enable a smoother industry transition, we are concerned with the recommendation to enable testing to permit proposed modifications after a standard has been published. While we support innovation, we are concerned that without any recommended guidelines for the testing and how to introduce modifications, this recommendation could result in wider variation across the industry. **We strongly encourage NCVHS to provide further clarification and guidance around this concept to ensure better understanding of the intent of this recommendation.**
Please contact me if you have any questions or feel free to have a member of your team contact Suzanne Lestina, AHA director of administrative simplification policy, at slestina@aha.org or (312) 468-9998.

Sincerely

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development