

December 7, 2018

Ms. Alix Goss, Co-Chair
Mr. Nick Coussoule, Co-Chair
Subcommittee on Standards
National Committee on Vital and Health Statistics

RE: Statement of the American Dental Association (ADA) on the NCVHS Predictability Roadmap to the National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards:

Dear Ms. Goss and Mr. Coussoule:

The American Dental Association is the world's oldest and largest professional dental association with over 161,000 members. As a longstanding member of the standards development community, the ADA appreciates the opportunity to comment on the Predictability Roadmap.

The administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) were intended to reduce costs, paperwork, and manual tasks through standardization of the transactions and code sets used in the electronic exchange of administrative health care information. With the adoption of the HIPAA standard electronic transactions and operating rules, the health care industry has begun to achieve these improved efficiencies and savings. However, in some instances, the implementation of the current administrative simplification provisions may lead to unintended consequences, including additional stakeholder burdens. It may be time to consider developing new and better ways of accomplishing the same tasks.

The following ADA comments are in response to the NCVHS Predictability Roadmap recommendations:

NCVHS Roadmap Recommendation 1: HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. HHS should use all appropriate means available to share (de-identified) information about complaints to educate industry.

The ADA supports the concept of greater transparency and believes after the enforcement action, the entities involved should be identified for the public.

The ADA encourages HHS to conduct additional work to analyze compliance review data for the purpose of creating more helpful industry guidance. The focus of this work should be on improving understanding across the industry regarding implementation, strengthening ongoing support of transactions, and operating rules implementation, and improving HHS's ability to track compliance issues. The goal should be to use compliance reviews to help shape industry best practices which in turn create greater administrative simplification.

NCVHS Roadmap Recommendation 2: HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law.

The ADA supports HHS complying with the statutory requirements for handling complaints against non-compliant covered entities and business associates and processing enforcement actions against those entities and business associates.

Building greater transparency into the HHS complaints handling process also feeds into the much needed, more helpful industry guidance noted above.

NCVHS Roadmap Recommendation 7: HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.

The ADA recommends HHS utilize the expertise of the entities that are responsible for the standards and operating rules in developing guidance on the standards and operating rules. HHS should provide guidance more directly around operational implementation and this guidance should be issued more proactively as industry education.

The goal of all these activities should be encouraging, promoting and enforcing broad-based adoption by all stakeholders (including all participants, commercial and government) in the industry regarding operating rules and standards.

NCVHS Roadmap Recommendation 3: HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.

NCVHS Roadmap Recommendation 4: HHS should enable the creation of an entity tasked with oversight and governance (stewardship) of the standards development processes, including the evaluation of new HIPAA standards and operating rules. HHS should provide financial and/or operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting. Oversight criteria would take into account ANSI Essential Requirements for any ANSI accredited organization; these would also provide consistency to governance of all standards and operating rule entities.

NCVHS Roadmap Recommendation 5: HHS should conduct appropriate rulemaking activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.

The ADA agrees that the DSMO should be disbanded. The DSMO was originally formed because the standards developing organizations responsible for developing

the HIPAA transactions originally did not have enough input from all of the stakeholders. The ADA believes that the current process for developing standards is now on track, however, the ADA suggests that a new entity be established for oversight and governance (stewardship) of the standards development processes, including the evaluation and approving of new HIPAA standards and operating rules and modification of current standards and operating rules.

HHS should provide financial and operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis, and reporting. Oversight criteria would take into account ANSI Essential Requirements; these would also provide consistency to governance of all standards and operating rule entities.

The process of moving to new standards is currently too burdensome and unpredictable for all stakeholders because it is held up in the regulatory process. This new entity should have the authority to publish the release/dissemination and implementation dates, as well as education of the new standards and operating rules without going through the regulatory process.

Technology is advancing at a tremendous rate, therefore, forward thinking strategies are important to remain relevant in a digital world. Moving forward, the administrative simplification regulations should be technology independent.

The ADA believes that this new entity should include representation from those named in the HIPAA statute, as well as other appropriate, qualified subject matter experts. The ADA also believes that the Workgroup on Electronic Data Interchange (WEDI) would be an excellent candidate to serve in the role as the convener or secretariat of this new entity. WEDI was established in the mid-90s with a governing structure that includes all stakeholders and is capable of bringing together groups to establish oversight of the standards development and operating rule process to ensure efficiency, effectiveness, consistency, and timely improvement in accepting new versions of standards and operating rules. WEDI could easily become the entity tasked with facilitating an effective solution.

As an advisor to the Secretary of HHS and a multi-stakeholder organization comprised of payers, providers, vendors and Standards Development Organizations, WEDI currently offers the stewardship an existing structure for collaboration. The new entity should be responsible for the development of policies and an administration framework that includes, but is not limited to the following:

- Review and analysis of existing standards for continued applicability and effectiveness as well as compliance with applicable laws and regulations.

- Identify compelling need for new or updated standards. Drivers may include new regulatory requirements, technology developments, operational needs, and identification of current issues or gaps. In addition, there should be a business need and cost analysis for updates to standards and operating rules. Implementing new standards or operating rules or making updates to existing implementations comes with associated costs to implementers. These costs must be weighed against the resulting benefit. Prior to implementation of any new standard or operating rule, the business need must be established and cost analysis completed for any updates to standards and operating rules.
- Determining whether the need should be satisfied by a policy, guideline, operating rule or standard.
- Establishing an ongoing review cycle. The review cycle should be no more than every two years.
- Developing a process for initiating, reviewing, approving, and expiring standards.
- Instituting a maintenance process that includes the review of policies, standards, operating rules and/or guidelines that may be identified as out-of-date or no longer needed. They should be retired via the same process by which they were approved.

NCVHS Roadmap Recommendation 8: HHS should publish regulations within one (1) year of a recommendation being received and accepted by the Secretary for a new or updated standard or operating rule (in accordance with what is permitted in §1174 of the Act).

The ADA recommends that HHS give the authority to the new entity, in consultation with NCVHS, for the publication of the release/dissemination and implementation dates, as well as education of the new standards and operating rules without going through the regulatory process.

NCVHS Roadmap Recommendation 9: HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.

The ADA recommends that the division(s) responsible within HHS for HIPAA have their resources increased to facilitate the timely review, maintenance, and adoption of national standards, including education and enforcement.

NCVHS Roadmap Recommendation 12: HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. Testing new standards to enable their voluntary use may be explored by testing alternatives under §162.940 Exceptions from standards to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.

The ADA supports this recommendation with the caveat that such implementations must occur between voluntary trading partners. The definition of voluntary trading partner is critical to the success of this recommendation (i.e. both parties in agreement without any undue pressure to be a voluntary party).

The desire and need for innovation should not create the situation where stakeholders are required to implement multiple, different versions of the same standard.

NCVHS Call to Action A: Health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases.

The ADA believes that WEDI should be the entity to convene all impacted stakeholders to identify best practices for mitigating barriers so that stakeholders can implement the effective use of the standards and operating rules. WEDI Workgroups and Sub-workgroups actively identify best practices and are engaged in a constant effort to identify current critical issues. This work is typically built upon prioritizing use cases, which is a component of best practice identification.

NCVHS Call to Action B: The Workgroup for Electronic Data Interchange (WEDI), through its work group structure, should continue to identify issues and solutions. WEDI should publish white papers advising on agreed upon policy implications and best practices related to use of HIPAA standards and operating rules.

The ADA supports the NCVHS call to action as recognizing the important role WEDI plays in the industry.

NCVHS Call to Action E: SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity of participants in standards development workgroups.

The ADA believes that this collaboration exists today but strongly supports increased collaborative and innovative engagement with all stakeholder groups. We encourage the SDOs to explore, and to identify, new and innovative opportunities to increase the level of participation from those currently underrepresented.

NCVHS Call to Action F: Leadership from the public and private sector should commit to membership in Standards Development Organizations, assign appropriate subject matter experts to participate in the development and update process, and facilitate improvements to operations as needed. This may enhance diversity of representation in the SDOs so that content changes meet a cross section of stakeholder needs.

The ADA supports this NCVHS Call to Action.

NCVHS Call to Action C: HHS and the SDOs should identify and fund a best of class third party compliance certification/validation tool recognized and approved by each standards development organization to assist in both defining and assessing compliance. HHS should develop and test criteria for certification, and build a program to enable multiple 3rd parties

to qualify to conduct the validation testing by demonstrating their business value. To implement this recommendation, HHS should look at successful precedents such as how the ONC certification criteria was developed for Promoting Interoperability and the eRx requirements which were a joint effort between HHS, NIST and the SDO.

The ADA recommends that NCVHS hold a hearing to further clarify this recommendation and solicit industry input.

NCVHS Call to Action G: Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance should include detailed and enforceable policies regarding business practices, including policies for identifying and implementing best practices in such an organization.

The ADA recommends that NCVHS hold a hearing to further clarify this recommendation and solicit industry input.

NCVHS Call to Action D: HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment. HHS may consider collaborating with or supporting any existing industry initiatives pertaining to such cost benefit studies to increase data contribution by covered entities and trading partners.

The ADA supports the idea that HHS should apply any and all available resources to effectively quantify the full value of administrative simplification and automation, and where possible, leverage existing industry efforts to achieve this goal.

NCVHS Call to Action H: HHS should continue to publish a universal dictionary of clinical, administrative and financial standards that are or will be available for use, e.g. the ONC Interoperability Standards Advisory (ISA).

The ADA recommends that HHS utilize and maintain the ONC Interoperability Standards Advisory (ISA), which includes the clinical, administrative and financial standards already.

NCVHS Measurement M1: HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.

The ADA recommends that NCVHS hold a hearing to further clarify this recommendation and solicit industry input.

NCVHS Measurement M2: HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity, and oversight/enforcement of SDO and Operating Rules Authoring Entity (ORAE) deliverables and performance.

The ADA supports this recommendation that metrics be established for the new entity and that these metrics be developed by HHS after appropriate industry consultation. As well, we recommend that one of these metrics be a measure of efficiency. Among stakeholders, understanding how a new process contributes to more efficient development and implementation for the industry is key to its success.

NCVHS Measurement M3: NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.

The ADA recommends that NCVHS continue to conduct stakeholder hearings and seek industry input on a regular basis to continually evaluate the progress and success of the Predictability Roadmap.

Thank you for the opportunity to provide information relative to dentistry's position on the Predictability Roadmap. If you should have any questions, please feel free to contact Ms. Jean Narcisi, director, Center for Informatics and Standards.

Sincerely,

A handwritten signature in black ink, appearing to read 'DMP', is positioned below the 'Sincerely,' text.

David M. Preble, DDS, JD, CAE
Senior Vice President, Practice Institute

DP:jn