



December 6, 2018

National Committee on Vital and Health Statistics  
Subcommittee on Standards  
3311 Toledo Road Hyattsville, MD 20782-2002

Dear Ms. Goss and Mr. Coussoule,

Thank you for the opportunity to provide our comments on the National Committee on Vital and Health Statistics' (NCVHS) draft recommendations for the Predictability Roadmap. As a federally-recognized standards development organization, UHIN convened a wide-range of community members to discuss and formulate responses. While formulating our responses, we considered whether each draft recommendation, call to action, and recommended measurement would improve the Predictability Roadmap.

Whereas we believe the NCVHS recommendations offer the opportunity for improvement, we also believe that it is dependent on several variables that were not clearly outlined in the document. For example, it would be helpful to have a more thorough review of the proposed timeline compared to the existing timeline. Only by understanding whether the timelines are realistic for those that must implement these recommendations can we determine efficacy.

We are concerned that the enforcement work may distract from the predictability work and would recommend that the focus be implementing a new DSMO process and target timelines at an accelerated pace. The UHIN community supports creating predictability for planning purposes and would appreciate timelines to increase the release of versions to smaller incremental changes.

We would ask that the implementation of standards include a migration period that allows for the backwards compatibility of the prior versions of standards.

The UHIN community asks that NCVHS be mindful of the costs to maintain these changes. Predictability will assist in the allocation of costs, but a cost benefit analysis is needed for any change. Standards and updates created in response to predetermined policy requirements rather than to meet a business need monopolize limited resources. Lengthy comment periods, revisions and rollouts stymie innovation. Standards without purpose and new accreditations can result in unintended consequences such as added physician burden and unplanned reallocation of limited financial resources.

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Nevertheless, we remain optimistic that with greater clarity and a commitment to fiscal responsibility, these draft recommendations will enhance the Predictability Roadmap as intended.

**Enforcement: 2019-2020**

**NCVHS Draft 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.

**UHIN Community Comment:**

We support the goal of greater transparency. To realize this goal, once the complaint has been substantiated, we feel the entities involved should be publicly identified.

**NCVHS Draft 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 law.

**UHIN Community Comment:**

UHIN supports this recommendation. However, we do respectfully suggest a point of clarification may be useful. Our experience and research indicate that this important mechanism may already be being fulfilled by an existing organization such as the Centers for Medicare and Medicaid Services (CMS) or the Office for Civil Rights (OCR). If our assumptions are correct, is this mechanism needed, or is it currently not working successfully?

**NCVHS Draft Recommendation #7:**

HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.

**UHIN Community Comment:**

UHIN supports this recommendation. Furthermore, we join WEDI in our belief that the overall goal of CMS and HHS should be to encourage, promote and enforce broad-based adoption by all stakeholders. We respectfully suggest that these organizations should



proactively seek input, needed clarification and commentary from Standards Development Organizations (SDOs) on standards.

**NCVHS Draft 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.

**UHIN Community Comment:**

UHIN regularly convenes its broad array of stakeholders to identify the best practices for interoperability. We are more than willing to share the feedback generated with and provide additional input to the various groups we participate with, such as X12, HL7, and WEDI, as well as our association with ONC and CMS.

**NCVHS Draft 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.

**UHIN Community Comment:**

UHIN agrees with NCVHS Draft Call to Action B and supports WEDI in this role. These white papers should be broadcast to other avenues such as CMS and HHS bulletins to ensure the wider provider community has access to them.

**NCVHS Draft 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.

**UHIN Community Comment:**

UHIN supports this recommendation and currently supports this type of collaboration with the private sector. We actively work to include appropriate stakeholders from both the private and public sectors within our community in reviewing proposed changes.

**NCVHS Draft 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.

**UHIN Community Comment:**

UHIN supports the broadest possible participation. Therefore, to reduce barriers associated with travel for organizations with more limited financial and personnel resources, we encourage alternatives to in-person meetings, such as virtual meetings. Furthermore, we respectfully feel it would behoove the SDOs to reevaluate the review process to increase efficiency.

**NCVHS Draft Recommendation for Measurement M1:**

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

**UHIN Community Comment:**

UHIN agrees with this measurement and suggests that regular timelines be implemented for consistent and timely publication.

**Policy Levers: 2020 – 2021**

**NCVHS Draft Recommendation #3:**

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

**UHIN Community Comment:**

We agree that some form of change is warranted, however we are reticent to endorse a disbanding of the DSMO, rather than reform of the DSMO, without greater insight into where the issues facing the DSMO lie. The documentation does not clearly illustrate the current issues that necessitate the dismantling of the DSMO nor the anticipated improvements by the replacement. We respectfully suggest that at a minimum NCVHS publish this information. We feel a hearing to clarify the issues facing the DSMO, outline the existing causes for delays, and to clearly articulate the suggested solution may serve NCVHS well. It is also important to recognize that greater authority and funding for the DSMO will create an additional level of bureaucracy.

**NCVHS Draft 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.

**UHN Community Comment:**

Please see UHN's comments under NCVHS Recommendation #3.

**NCVHS Draft 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.

**UHN Community Comment:**

Please see UHN's comments under NCVHS Recommendation #3.

**NCVHS Draft 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).

**UHN Community Comment:**

UHN agrees with the concept of expediting the publication of regulations process and supports the use of the Notice of Proposed Rulemaking (NPRM) rather than Interim Final Rule (IFR). We also encourage NCVHS to strive to publish meaningful new and updated standards in as timely as manner as possible, ensuring the business need and cost analysis for updates.

**NCVHS Draft Recommendation #9:**

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

**UHIN Community Comment:**

We agree with this recommendation and support the effort to expedite the timely review and adoption of national standards.

**NCVHS Draft 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 3<sup>rd</sup> 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.

**UHIN Community Comment:**

UHIN is concerned that the creation of a new verification tool will become an additional burden to providers without offering any added value. Providers should be encouraged to use the existing free third-party testing tool to allow for voluntary running of transactions. In addition, UHIN is concerned that a mandated certification will add cost and burden to the systems and provider community.

**NCVHS Draft 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

**UHIN Community Comment:**

UHIN needs more detailed information to comment on this call to action and recommends a hearing to further clarify this recommendation.

**NCVHS Draft Recommendation for 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 ORAE deliverables and performance.

**UHIN Community Comment:**

UHIN agrees with the caveat that NCVHS recognize that the success of this entity is contingent on clearly defining the expected objectives.

**NCVHS Draft Recommendation for Measurement M3:**

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

**UHIN Community Comment:**

UHIN agrees that monitoring of more timely and valuable standards and updates is appropriate.

**Regulation: 2021-2024**

**NCVHS Draft Recommendation #6:**

SDOs and ORAE should publish incremental updates to their standards and operating rules to make them available for recommendation to NCVHS on a schedule that is not greater than 2 years.

Publication of a new or updated standard is intended to mean the cycle of preparation that meets ANSI requirements (if applicable) for maintaining or modifying a standard or operating rule, including the consensus process, necessary governance compliance and readiness for submission to NCHVS.

NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months.

HHS should adopt the NCVHS recommendations on a regular schedule.

**UHIN Community Comment:**

UHIN supports the recommendation, however strongly urges that a committed effort be made to ensure that each update to standards and / or operating rules address a proven business need, and that a concerted effort be made to avoid updates that only serve to fulfill a self-imposed calendar requirement.

**NCVHS Draft Recommendation #10:**

HHS should adopt incremental updates to standards and operating rules. In accordance with Sec 1174 of the Act, the adoption of modifications is permitted annually, if a recommendation is made by NCHVS, and if updates are available.

**UHN Community Comment:**

UHN agrees, and we urge flexibility as warranted to account for industry needs.

**NCVHS Draft Recommendation #11:**

HHS should publish rulemaking to enable the adoption of a floor (baseline) of standards and operating rules. This rulemaking should also consider other opportunities that advance predictability and support innovation.

**UHN Community Comment:**

UHN supports NCVHS Draft Recommendation# 11 providing that it is between voluntary trading partners and that no trading partner require baselines be met as a condition of participation.

**NCVHS Draft 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.

**UHN Community Comment:**

UHN agrees; please see above comments under NCVHS Draft Recommendation #11.

**NCVHS Draft 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.

**UHN Community Comment:**

UHN agrees with NCVHS Draft Call to Action D and supports efforts to effectively measure the value of easing administrative burden and increasing automation. We further recognize that leveraging existing entities to accomplish this will increase cost efficacy.



**NCVHS Draft 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).

**UHIN Community Comment:**

UHIN supports NCVHS Draft Call to Action H and notes that the ONC's Interoperability Standards Advisory (ISA) is the most comprehensive universal dictionary. We support both its use and continual supplementation.

Again, on behalf of the UHIN Community, we thank you for the opportunity to provide comments on the proposed Draft Recommendations for the Predictability Roadmap. If you have any questions, Andrew Burchett our CIO, or I would be happy to provide greater clarification.

Sincerely,



Teresa Rivera  
President & CEO  
UHIN