



December 7, 2018

Nicholas Cassoule, Co-Chair
Alix Goss, Co-Chair
National Committee on Vital and Health Statistics
Standards Subcommittee
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically via NCVHSmal@cdc.gov

Re: NCVHS Predictability Roadmap—AHIP Comments

Dear Mr. Cassoule and Ms. Goss:

On behalf of America's Health Insurance Plans (AHIP), thank you for the opportunity to offer comments in response to the National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee Predictability Roadmap.

AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public/private partnerships that improve affordability, value, access and well-being for consumers.

AHIP is committed to the goals of administrative simplification and the Subcommittee's efforts to promote a more predictable cadence for implementing updated or new standards and operating rules. We agree that the current process is not meeting the industry's evolving business needs. A more predictable process and timeframe is needed to set expectations for all trading partners to facilitate budgeting and planning, support widespread adoption and use of standards and operating rules, and promote timely, efficient, and accurate electronic communication across the health care industry. We appreciate the Subcommittee's efforts in support of these goals.

We support revisions to the standards and operating rule development, but it is critical that new processes and timelines are responsive to industry business needs and provide a demonstrated value. While we support a regular, predictable schedule for implementing new or changed standards and operating rules, we should avoid adopting a new version just because a pre-set timeline dictates it. A business need and value should always be demonstrated. At times, this may result in evaluating the current standard or operating rule and determining that it is meeting current needs and a new version is not needed. A new standards and operating rule development

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process should also support and promote innovation, without creating unnecessary complexity or adding to administrative costs. We support the concept of a floor and/or ceiling for adoption of new versions or innovative solutions, but guardrails are needed to avoid creating new, unsustainable costs for trading partners.

AHIP's detailed comments in response to the Subcommittee's proposed recommendations is attached in the Appendix. We appreciate the opportunity to provide feedback on the NCVHS Predictability Roadmap and look forward to continuing to partner with the Subcommittee as it continues to recommend improvements to standards, operating rules, and their governing processes. If you have any questions about these recommendations, please contact Kelley Turek at kturek@ahip.org or 202-861-1459.

Sincerely,



Jeanette Thornton
Senior Vice President, Product, Employer and Commercial Policy

Detailed Comments on NCVHS Predictability Roadmap Recommendations

2019-2020: Improved education, outreach, and enforcement¹ will promote efficient planning and use of the adopted HIPAA standards and operating rules.			
Category	Draft Recommendation	AHIP Feedback	Additional Comments for Consideration
Recommendation	<p>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.</p>	Support	<p>We support increased transparency of the enforcement process. The goal of increased transparency should be to develop better documentation, guidance, and education in order to improve the industry’s understanding of the standards and implementation requirements to move the industry toward increased efficiency. For example, a feedback loop to WEDI, SDOs, and ORAE to enable additional changes or clarifications through guidance to reduce occurrences of complaints.</p> <p>Transparency should include better tracking and analytic reporting. HHS’ website should be more specific with complaints around each transaction and include details of the issue, such as volume of complaints.</p> <p>HHS should rationalize the potential impact of establishing a floor (baseline) and permitting covered entities to use voluntary standards as part of this process.</p>
	<p>2. HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those</p>	Abstain	

¹ Enforcement includes complaints, audits and compliance reviews as defined in statutory language

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	entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law.		
	7. HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.	Support	The entities that create standards and operating rules should be the primary source for instructions on their use. Thus, HHS should work with and rely on WEDI, SDOs, and ORAE to provide content for regular publication of guidance regarding the appropriate and correct use of standards and operating rules.
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.	Support	We support this recommendation, but recommend providers also be added to this call to action to ensure standards implemented by health plans and vendors achieve maximum adoption by health care providers.
	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.	Support	
	E. SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity	Support	Increasing the number and variety of participants included in would promote development of standards that consider and support all stakeholders.

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	of participants in standards development workgroups.		
	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.	Support	
Measurement	M1. HHS should disseminate results of its enforcement program regularly and publicly, to promote transparency, opportunities for education, and benchmarking.	Support	Publicly sharing the results of enforcement actions should be done in a manner that promotes transparency and educates stakeholders on the appropriate use of standards and operating rules.

2020-2021: Policy levers will successfully support industry process improvement changes.			
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Recommendation	3. HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.	Do not support <i>as drafted</i>	We agree that the DSMO, in its current state, no longer meets the industry’s needs. A re-conceptualized DSMO, whether through implementing a new process or creating a new entity, should be responsible for oversight and stewardship. However, without a clear path forward to modernize the DSMO or disband it and create a new process or entity, there may be unintended consequences. There must be careful planning, coordination, and an appropriate transition to avoid negative impacts.
	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.	Abstain	
	5. HHS should conduct appropriate rulemaking activities to give authority	Abstain	

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	to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.		
	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).	Support	We support a predictable timeframe for HHS rulemaking following recommendations for a new or updated standard or operating rule. However, we strongly recommend HHS issue such rulemaking as a notice of proposed rulemaking with opportunity for public comment to allow for additional industry feedback on requirements and implementation timeframes, rather than an interim final rule. This would ensure adequate opportunity for industry input on the proposed standard or operating rule and create a necessary lead time for budgeting and implementation.
	9. HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.	Support	Resources should be increased within the responsible division to facilitate the timely review and adoption of national standards and to provide stakeholder education to facilitate industry uptake and implementation.
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	Do Not Support	There is not a clear business need for this, as there are already compliance validation tools that have been approved for use. HHS could conduct a stakeholder listening session or issue a request for information to seek additional input on whether there is a clear business need for this recommendation.

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	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.		
	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.	Do Not Support	We do not support this recommendation as written. It is not clear how this process would interact with the current ANSI accredited governance process used by SDOs. HHS conduct an industry listening session gather further input.
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.	Support	

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Recommendation	<p>6. SDOs and ORAE should publish updates to their standards and operating rules and 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 NCVHS. 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.</p>	Support	<p>We support a predictable cycle for adopting updated standards. However, such revisions to standards and operating rules should be based upon business value and need, not dictated by a pre-set cycle for issuing updates. There should always be a demonstrated business need and cost analysis for updates. There should be a balance between a normalized publication cycle and publications for the sake of a timeline but without added business need or value. HHS should also clearly identify which entity or stakeholders determine the appropriate timing, as not all stakeholders will be able to demonstrate a positive ROI before moving forward (such a standard would significantly slow down the process).</p>
	<p>10. HHS should adopt incremental updates to standards and operating</p>	Support	<p>Consistent with #6, we agree that HHS should adopt incremental updates to standards and operating rules on</p>

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	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.		an annual basis as provided for in statute, to the extent that the updates are based on a demonstrated business value and need. Incremental updates should not represent a new and different set of requirements that would initiate a massive system overhaul for affected stakeholders.
	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.	Support	We support the concept of a floor/ceiling for willing partners. However, it does raise potential challenges with requiring entities to support too many new, updated, or innovative standards (e.g., in order to maintain relationships with multiple key providers) that it could greatly increase administrative costs and undermine the goals of administrative simplification, interoperability, and predictability. Guardrails are needed to strike the appropriate balance between supporting innovation and permitting willing trading partners to use innovative new standards.
	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	Support	See comments to recommendation 11.

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	to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.		
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.	Support	HHS should determine a frequency for this cost benefit analysis, for example one time, annually, or when a standard or operating rule significantly changes. HHS should also determine what steps HHS and the industry should take if the ROI is negative.
	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).	Support	We support a universal dictionary and recommend the ONC Interoperability Standards Advisory (ISA), as it currently contains the administrative and financial standards.