



Written testimony for the “Draft Recommendations for the Predictability Roadmap” hearing

By Pat Waller, Senior IT Staff Consultant for Cambia Health Solutions, to the National Committee on Vital and Health Statistics’ Subcommittee on Standards

Washington D.C.

December 12 & 13, 2018

Cambia Health Solutions is pleased to submit written testimony to the National Committee on Vital and Health Statistics’ Subcommittee on Standards regarding the “Draft Recommendations for the Predictability Roadmap.” Cambia is headquartered in Portland, Oregon, and is dedicated to transforming health care. We are a family of over [20 companies](#) that work together to make the health care system more economically sustainable and efficient for people and their families. Our solutions empower more than 70 million Americans nationwide, including more than two million people in the Pacific Northwest who are enrolled in our [regional health plans](#).

This document will address Cambia’s feedback on the Predictability Roadmap draft recommendations. This is based on decades of health care-related business and electronic data interchange experience as well as our strong partnership with consumer-directed exchange advocate [The CARIN Alliance](#), and our role with the [Da Vinci Project](#) as a founding member.

2019-2020: Improved education, outreach, and enforcement ¹ will promote efficient planning and use of the adopted HIPAA standards and operating rules.			
Category	Draft Recommendation	Comments on Recommendation	Additional Comments
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.	Cambia supports increased transparency of the enforcement process. We recommend that this process needs to have a feedback loop to WEDI, SDOs and ORAE entities so that any necessary changes or clarifications can be made to reduce occurrences of complaints.	<ul style="list-style-type: none"> One goal of this process should be to improve documentation, understanding of the standards and implementation requirements to drive the industry to increased efficiency and quality gained under administrative simplification. HHS will need to rationalize the potential impact of establishing a floor (baseline) and permitting covered entities to use voluntary standards as part of this process (recommendation 12).
	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	Cambia agrees.	<ul style="list-style-type: none"> Many covered entities (CE) utilize Business Associates (BA) to carryout various aspects of administrative simplification. As such, the requirements in the business associate

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

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	associates. Information should be publicized about the status of complaints to the extent permitted by the law.		agreement (BAA) needs to be considered as part of this process.
	7. HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.	Cambia agrees that there should be regular publications of guidance regarding the appropriate and correct use of standards and operating rules. HHS should work with and rely heavily on WEDI, the SDOs and ORAE to supply content for these publications.	
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.	Cambia agrees.	<ul style="list-style-type: none"> Many of the feedback and input processes require some level of financial and time commitment. The commitment of money and time have a limiting factor on the range of entities that actively engage in the process.
	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.	Cambia agrees and supports the continuing role for WEDI.	
	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.	Cambia agrees that additional collaboration, outreach and inclusion of a wider variety of participants is critical in the development of standards.	<ul style="list-style-type: none"> Increasing the number and variety of participants in the standards development process could slow down the process. Hopefully this potential slowing in the process results in

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			<p>standards that consider and support all constituents.</p> <ul style="list-style-type: none"> • The cost of time and money from the public sector as well as smaller CE needs to be considered so that their critical input is considered in the standards development process. • Given some of the time and cost constraints – outreach and education in the comment periods should be used to increase the breadth and depth of participation.
	<p>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.</p>	<p>Cambia agrees that leadership from the public and private sector should commit to membership in standards development organizations. Cambia also understands that each organization has limited financial and human capital to apply across the myriad of SDOs. Therefore, organizations including Cambia may need to limit membership to a subset of the SDOs.</p>	
<p>Measurement</p>	<p>M1. HHS should disseminate results of its enforcement program regularly and publicly, to promote transparency, opportunities for education, and benchmarking.</p>	<p>Cambia agrees that the results of enforcement actions should be shared publicly in a manner that promotes transparency and assists in education as to the appropriate usage of standards and operating rules.</p>	

2020-2021: Policy levers will successfully support industry process improvement changes.			
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Recommendation	<p>3. HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.</p>	<p>Cambia understands and agrees that the DSMO, in its current state, no longer meets the needs for the industry and SDOs. Cambia is concerned that without a clear path forward to disbanding or modifying the DSMO and the creation of a new process or entity to provide oversight and governance of the standards development process there will be an unavoidable impact on moving forward in a predictable manner. To avoid any impacts there must be careful planning, coordination and transition.</p>	
	<p>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.</p>	<p>Consistent with comments also submitted by BCBSA, Cambia would support HHS enabling a stewardship entity for the proposed purposes of exercising leadership to encourage effective intra-industry collaboration, outreach, evaluation, cost-benefit analysis and reporting. We recommend further consideration of whether such an entity needs or could effectively apply the authority to exercise governance activities over SDOs, given the ANSI-accredited consensus-based nature of standards identification and development.</p>	
	<p>5. HHS should conduct appropriate rulemaking</p>	<p>Consistent with comments also submitted by BCBSA,</p>	

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	<p>activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.</p>	<p>Cambia supports the enabling of a stewardship entity to improve the efficiency of the standards development process, including maintenance and modifications to adopted and proposed standards. We recommend further consideration of whether such an entity needs or could effectively apply the authority to exercise governance activities over SDOs, given the ANSI-accredited consensus-based nature of standards identification and development.</p>	
	<p>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).</p>	<p>Consistent with comments also submitted by BCBSA, Cambia agrees that new or updated standards should be adopted within one year of a recommendation, if not immediately after receipt of the recommendation from NCVHS, considering HHS' direct involvement in that recommendation development process. Early adoption, with a reasonable period for implementation before the published effective date, would signal the industry to initiate implementation preparations in earnest. We recognize the need for some flexibility for either shorter or longer timeframes, due to other strategic and regulatory activities across the industry.</p>	<ul style="list-style-type: none"> Regulations should be published as under a Notice of Proposed Rulemaking to allow for additional industry feedback on requirements and implementation timeframes. Without this additional check, Interim Final Rules may be issued that lead to industry challenges in compliance with the requirements, timeline or both.

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	9. HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.	Cambia agrees	
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.	Cambia does not agree with the recommendation as written and recommends NCVHS conduct a hearing to provide additional clarity for this recommendation and gather industry input.	
	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.	Cambia does not agree with the recommendation as written and recommends NCVHS conduct a hearing to provide additional clarity for this recommendation and gather industry input.	<ul style="list-style-type: none"> How does this interact with current ANSI accredited governance processes used by SDOs?
Measurement	M2. HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance	Consistent with comments also submitted by BCBSA, Cambia supports the development of a stewardship entity and	

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	assessment of the new entity, and oversight/enforcement of SDO and ORAE deliverables and performance.	process to encourage standards development collaboration and predictability and agrees that the effectiveness of that stewardship should be measured on an ongoing basis. With regard to grants of authority for oversight and enforcement purposes, BCBSA recommends further consideration of the need for a new governance process and the granting of such authority.	

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Recommendation	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.	Cambia is supportive of a cycle of publication and adoption of updated standards to a predictable schedule. While Cambia supports a predictable cycle for adopting updated standards, such revisions to standards and operating rules need to be based upon business value and need, not just change predicated on the need for content to fill an established cycle for issuing updates.	

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	<p>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>		
	<p>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.</p>	<p>Cambia agrees that HHS should adopt incremental updates to standards and operating rules on an annual basis as provided for in statute, to the extent that the updates are based on business value and needs. Updates should not represent a new and different set of requirements that would initiate a massive system overhaul for affected stakeholders.</p>	
	<p>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.</p>	<p>Cambia agrees with the approach of publishing a baseline for standards and operating rules. Cambia recommends the utilization of §162.940 to support any entities that wish to use an alternative to the adopted baseline. See response to 12.</p>	<ul style="list-style-type: none"> • Cambia would like to clearly understand what is meant by “baseline” as well as better understand NCVHS’s thoughts on what is included in “other opportunities that advance predictability and support innovation.”
	<p>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</p>	<p>Cambia agrees and supports pilot testing of new voluntary and innovative standards under §162.940. Cambia recommends that HHS maintain and publish of catalog of requests made including the requests current disposition and entities covered. Cambia recommends that §162.940 be used as a governor to</p>	

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	of this recommendation is to enable innovation.	reduce the risk of “piloting” too many new, updated or innovative standards that could result in higher industry costs and distract from the goals of administrative simplification, interoperability and predictability.	
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.	Cambia supports the need for cost benefit analysis on HIPAA standards and operating rules to demonstrate their return on investment. HHS should partner with and leverage existing industry efforts to achieve this goal. Duplication of efforts should be avoided if possible.	<ul style="list-style-type: none"> • HHS needs to consider how often this analysis should occur. One time, annually or when a standard or operating rule significantly changes? • If the ROI is negative, what steps should the industry and HHS take?
	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).	Consistent with comments also submitted by BCBSA, Cambia supports a universal dictionary and recommends the ONC Interoperability Standards Advisory (ISA) be that dictionary, as it currently contains the administrative and financial standards.	
Measurement	None proposed		

Summary

In closing, Cambia Health Solutions supports NCVHS Vision of the Predictability Roadmap as stated:

“For covered entities and business associates to be able to use up-to-date HIPAA standards consistently, garnering increased value from the standards by avoiding “one-off” work arounds, and to reliably know when updated versions will be updated and adopted in time to prepare systems, resources and business processes.”

Cambia encourages the support of innovation of administrative simplification in a manner that enhances the value and speed to market.

Thank you for the opportunity to provide feedback to the Subcommittee.