



National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

NCVHS Standards Subcommittee
Review of Recommendation Letter on
Modernization of Standards Adoption and
Measuring Value of Standards

July 20, 2022

Recap of Subcommittee Project



- **Project:** Standardization of Information for Burden Reduction and Post-Pandemic America (Convergence 2.0)
 - Now in Phase 2: Formulating recommendations based on input
- **Ongoing Build of the Predictability Roadmap**
 - Envisioning/validation
 - industry-driven standards development and adoption
 - Regular updates: more frequent but smaller, more “digestible” updates
 - Enhanced pre-adoption testing
 - Building in value assessment – including Return on Investment (ROI), burden, and societal benefits
 - Harmonization and Integration of standards

August 2021: Request for Comments: Top 10 Public Comments or Themes (1-5, no priority order)



Public Comment	Responsible Entity	NCVHS Role/ Previous-Potential Action	Action Required
1. Test standards, evaluate return on investment (ROI) before federal adoption.	HHS/ONC	(For HIPAA standards) – Collaborate with HHS to identify requirements for documenting impact analysis; SDOs identify capabilities	Regulatory ✓
2. Adopt health care attachments standard, i.e., X12, and HL7, and CDex	HHS/ONC	Recommendation letters sent to HHS in 2016, 2018, 2019. Updated recommendation with option to use multiple types of standards could be considered based on listening session input in 2021	Regulatory; industry voluntary use ✓
3. Adopt Acknowledgements (HIPAA) standard	HHS	Recommendation letters sent to HHS in 2016, 2018 and Reports to Congress	Regulatory
4. Publish Prior Authorization API (HL7) Regulation	CMS - OBRHI	Listening session recommendations from HL7	Regulatory ✓
5. Improve regulatory process for adopting standards under HIPAA, e.g., ONC Standards Version Advance process (SVAP).	HHS	Potential recommendation consideration	Regulatory ✓

Request for Comments: Top 10 Public Comments or Themes (6-10, no priority order)



Public Comment	Responsible Entity	NCVHS Role/ Previous-Potential Action	Action Required
6. Implement a patient education campaign - patient apps and privacy policy	HHS/ONC	Potential recommendation consideration	Evaluation of Resource Impact & Identification of Funding
7. Implement training programs for providers on data exchange to support bi-directional data exchange	HHS, CMS, ONC/SDOs/ Stakeholders	Out of Scope for NCVHS	Evaluation of Resource Impact & Identification of Funding
8. Identify, implement, adopt standards for payers and other organizations to exchange data bi-directionally	HHS/ONC, HITECH/ NCVHS, SDOs	Evaluation of gaps in standards; collaborate as appropriate on developing additional recommendations	Regulatory
9. Develop a universal solution for patient matching	ONC	Out of Scope for NCVHS	Regulatory
10. Consider expansion of HIPAA to non-covered entities e.g. holders of data from covered entities	CMS/HHS/Congress	Recommendation to HHS	Legislative or Regulatory

Foundation of New Recommendations Based on June 2022 Listening Session



- NCVHS sent three recommendations to HHS in March of this year – these are a follow up.
- Consistent themes:
 - The nature of e-commerce has changed since enactment of HIPAA in 1996;
 - New standards and technology are in use by covered entities and vendors, particularly for business processes that are burdensome;
 - Some components of the HIPAA framework are either outdated or dysfunctional; objective and methodical evaluation is necessary to determine risks and define potential remediation options;
 - Standards development processes, structure and service capabilities are not comparable; best practices could be evaluated for broader use.

Purpose of June 2022 Listening Session



- Obtain stakeholder reaction to five considerations pertaining to standards adoption and advancement, integration, and measuring the value of standards.
- Obtain insight from participants about:
 - Whether the considerations should become recommendations to be sent to HHS
 - Whether the considerations could be actionable for HHS or other parties
 - Whether or how the considerations could be used to support action and/or changes by other relevant organizations
 - What other opportunities could be addressed

Considerations Discussed in June 2022



Consideration 1: Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Health plans would be required to support all adopted standards for their industry sector. Providers could choose which other proposed/adopted standard or standards to conduct with their health plans

Consideration 2: Enable HIPAA covered entities to support multiple versions of adopted standards for business functions. This provides an opportunity for innovators to be one version ahead of the current adopted version.

Consideration 3: Revise the standards exception process for HIPAA covered entities who submit an application with the required justification and business case to automatically authorize them without waiting for review. Willing trading partners would automatically be authorized to use different standards for the same transaction and for the same business purpose(s). Reporting on the use of alternative standards would be required of the willing trading partners.

Consideration 4: Identify options for improved integration of health information standards, including base standards plus standard development organization (SDO) implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices (e.g., CMS, ONC, CDC, NIH, IHS) including State, Local, Tribal & Territorial Governments.

Consideration 5: Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures, including methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards. This would enable better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards.

Proposed Recommendations



- **Recommendation 1**: Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.
- **Recommendation 2**: Enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.
- **Recommendation 3**: Recognizing ONC's existing authority to facilitate the coordination of Social Determinants of Health (SDoH) efforts across HHS agencies and offices (e.g., CMS, ONC, CDC, NIH, IHS), HHS should expand ONC's authority to include a formalized public process for convening non-federal entities (State, Local, Tribal & Territorial Governments (STLS)) and to align reporting requirements in federal funding opportunities (HRSA, SAMHSA, CMS).
- **Recommendation 4**: HHS should develop and publish a guidance framework for Standard Development Organizations and other industry stakeholders that outlines how to develop and report quantifiable estimates for new and revised standards readiness, costs and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.

Recommendation 1



Recommendation 1: Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.

Highlights

- Public testimony and NCVHS review of input received suggests that, when adopted by regulation, new technologies (e.g., application-program interface (API) standards like HL7 Fast Health Interoperable Resources (FHIR)) could be more effective and efficient for certain of the HIPAA-named transactions. This recommendation protects the installed base so as not to disrupt the use of adopted transactions that are working well for industry, but provides an on-ramp for a new generation of standards to replace those that are not well adopted or utilized by industry, e.g., prior authorization or attachments.
- In an August 2021 comment letter, the American Dental Association (ADA) stated that the use and exchange of health data is fundamental for providing equitable high-quality care, and that the use of FHIR can help to make this contribution. In its letter to the Committee, the ADA wrote that the X12 standards are not working for dentistry, and that FHIR-based solutions should be developed and replace the HIPAA transactions for dentistry.

Recommendation 2



Recommendation 2: Enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.

Highlights

- There are practical difficulties of moving to a new version of a standard in lockstep, or demonstrating industry-wide value of an updated field that is only required by some sub-segment of the industry, and a pragmatic challenge of end-to-end testing with all trading partners within the regulatorily specified transition period.
- By allowing multiple versions on a use case by use case basis, not all trading partners would be required to upgrade. That would eliminate the cost of upgrade for entities who had no need to update. It would also reduce the number of trading partners who would have to go through end-to-end testing for the upgrades.

Recommendation 3



Recommendation 3: Recognizing ONC’s existing authority to facilitate the coordination of Social Determinants of Health (SDoH) efforts across HHS agencies and offices (e.g., CMS, ONC, CDC, NIH, IHS), HHS should expand ONC’s authority to include a formalized public process for convening non-federal entities (State, Local, Tribal & Territorial Governments (STLS)) and to align reporting requirements in federal funding opportunities (HRSA, SAMHSA, CMS).

Highlights

- The Committee notes, and panelists confirmed that collaboration and coordination on harmonization of data elements, data content and data exchange exists between a number of federal agencies within HHS, including CMS, ONC, OCR, CDC.
- Building on such collaboration to attain other objectives for harmonization is complex, but has transformative potential. HHS could build on the momentum it has by considering establishment of a joint governing entity with authority to support additional work on data content, structures, and formats between diverse data sources, and development of new standards for missing use cases, implementation and test tools.
- The seamless exchange of SDOH data across public and private settings provides the potential to identify and address health disparities and increase overall population health



Recommendation 4:

Recommendation 4: HHS should develop and publish a guidance framework for Standard Development Organizations and other industry stakeholders that outlines how to develop and report quantifiable estimates for new and revised standards' readiness, costs and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.

Highlights

- Some standards development organizations are developing projects and metrics to evaluate their standards with both quantitative and qualitative measures.
- Some standards, such as HL7 FHIR standards and implementation guides undergo a process of testing in controlled environments prior to being implemented to demonstrate their capabilities, functionality and “fit for purpose.”
- An evaluation governance structure or framework could be a partnership between the public and private sector including appropriate HHS agencies, SDO's, industry stakeholders (i.e., payers, providers, patients, developers) supported with a regulation or sub-regulatory guidance from HHS.

Next Steps



- Incorporate any revisions from Full Committee discussion
- Send letter to HHS
- Continue engagement with OBRHI and ONC



National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

Committee Discussion