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

NCVHS Standards Subcommittee

Listening Session on Standardization of Information for Burden Reduction and Post Pandemic America

Discussion of Certain Considerations on:

Standards Adoption, Standards Integration and Measuring Value

June 9, 2022

Agenda

- Introductions
- Update from the CMS Office of Burden Reduction and Health Informatics (OBRHI)
- Convergence 2.0 Workplan Overview
- Panel Discussions
  - *Advance HIPAA Standards Adoption for Administrative Transactions*
  - *Address Standards Integration and Collaboration*
  - *Measure the Value of Standards*
- Public Comment
- Subcommittee Discussion

Standardization of Information for Burden Reduction and Post-Pandemic America ("Convergence 2.0")

- **2-year Subcommittee project**
  - Phase 1: Landscape Assessment - complete
  - Phase 2: Analysis, deliberation, report and potential recommendations – in progress
- **Building on the Predictability Roadmap**
  - Envisioning
    - 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
  - Enforcement with conformance testing

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

What We've Learned

- The nature of e-commerce has changed dramatically since 1996 (HIPAA enactment). HIPAA framework has become obsolete, dysfunctional.
  - Evaluation would be appropriate to determine whether legislative remediation or regulatory modifications provide best glide path.
- Some standards development activities are not meeting the needs of the regulated industry. Some are moving apace. Processes need to be amended; best practices adopted to meet industry expectations.
- Standards development organizations could collaborate more to conduct effective stakeholder education for implementation.
- Subcommittee needs to understand HHS priorities to support development of recommendations.

Purpose of this Listening Session

- Obtain stakeholder reaction to the five considerations pertaining to standards adoption/advancement, integration/collaboration, and value metrics.
- Use reactions and information gleaned during the discussion to obtain insight into:
  - Participants believe the considerations should become recommendations to be sent to HHS
  - Whether or how 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

Panel Discussion Logistics

- Moderators will explain the background and problem statement behind each consideration and review the initial question set for discussion.
  - Panelists may raise other issues not included in the questions provided
- Panelists will raise hands to respond to questions or raise other issues; each moderator will create a queue and call upon panelists to speak.
- Each panelist will have 3 minutes to speak – a timer on the web will provide a count down.
- Panelists may enter the “queue” again after their 3 minutes.
- After two rounds, Subcommittee members will ask additional follow up questions of the panelists as time permits.
- Public comment will be available after each panel

Panel Topics

Panel 1: Advance HIPAA Standards Adoption

Panel 2: Address Standards Integration and Collaboration

Panel 3: Measure the Value of Standards

Panel Topics

Panel 1: Advance HIPAA Standards Adoption

Panel 1: Advance HIPAA Standards Adoption

Background and Implications

- HIPAA (1996) encountered an industry where paper claims were the norm. Providers used computers to print forms; payers scanned them or keyboarded them into their system. However, there was significant use of electronic submission. Electronic formats were based on the UB-92 and the HCFA (now CMS) 1500, but electronic formats were not consistent from payer to payer.
- HIPAA envisioned one universal standard per business function, e.g., a single standard to replace each standard paper form (i.e., hospital, professional, pharmacy and dental claims) plus automating the eligibility inquiry (a common cause of claim denial) and payment transactions.
- Transmission and processing was predominantly batch. Bandwidth was constrained and expensive. Large health plans processed on mainframes. Real-time processing was relatively rare

Panel 1: Advance HIPAA Standards Adoption (2)

Background and Implications (con't)

- 25 years later, technology has changed. Bandwidth is available and inexpensive. Processing speeds are faster. Real-time is commonplace.
- Business needs have evolved. Fee-for-service no longer dominates payments: capitation, value-based purchasing and other alternatives have achieved significant market penetration.
- Clinical data is increasingly integrated into administrative process requirements, e.g., electronic prior authorization and claims attachments.

Panel 1: Advance HIPAA Standards Adoption (3)

Background and Implications (con't)

- What industry stakeholders have told NCVHS
  - The HIPAA-adopted standards have not kept pace with industry change, neither with the evolving data requirement nor the technology changes.
  - Updates to the standards need to be more frequent, smaller and more predictable/reliable.
  - Workforce demographics are changing: new entrants into HIT are trained on newer technologies and programming. Finding/training workers for older technologies is difficult.
  - HIPAA introduced a one-size-fits-all concept of standards. That was the best of available options in 1996 but may no longer be optimal. Very broad standards carry a lot of overhead that must be custom mapped and programmed by each implementer. Newer technologies support narrower standards, easing the programming requirements and burden, especially in smaller and more specialized provider practices.

Panel 1: Advance HIPAA Standards Adoption (4)

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.

Discussion:

Problem Statement: Industry input to NCVHS strongly indicated that updates to the HIPAA transaction regulations are not keeping pace with either industry need for new data fields/codes. Nor do the regulations affirmatively encourage industry innovation. Infrequent updates tend to be massive, disruptive and very costly. How can the process be redesigned and managed to ensure maximum efficiency and value to the industry?

To reduce provider burden, to support technological innovation, we are considering the net value to the healthcare industry of allowing a strictly limited number (i.e., 2 or 3) of alternative standards for the HIPAA-named business transactions. Much like batch and real-time standards, an app-based standard might co-exist with an EDI standard. For example, and HL7 FHIR standard could be an adopted allowable alternative to an X12 standard. Provider organizations could choose the type of standard that best suits its business needs and workforce (or vendor) constraints. The different standards could be used stand-alone or in conjunction with another type of standard e.g., a FHIR-based electronic Prior Authorization transaction alone or in conjunction with an X12 278 (authorization) or an X12 275 (attachment) standard.

Panel 1: Advance HIPAA Standards Adoption (5)

Consideration 1 Questions:

- For providers, would availability of choice between an app-based standard and an X12-based standard be of value? Why or why not?
- For payers, would the increased cost of supporting multiple types of standards be offset by reduced cost of customer service support? (This assumes better data and better first-pass processing success if providers select a technology more compatible with their business requirements and capabilities.)
- For system vendors (including providers and payers who develop or maintain their own systems), would multiple alternative standards increase or decrease the complexity and cost of maintaining all the systems over the next 5-10 years? Please use a forward-looking evaluation to reflect further integration of administrative and clinical systems, as well as recognizing the policy directions of ONC's interoperability and information blocking initiatives.

Panel 1: Advance HIPAA Standards Adoption (6)

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.

Discussion:

Problem Statement: Prior input to NCVHS strongly indicated that updates to the HIPAA transaction regulations are not keeping pace with either industry need. Infrequent updates tend to be massive, disruptive and very costly. How can the process be redesigned and managed to ensure maximum efficiency and value to the industry? Some industry segments (e.g., LTPAC, specialty and sub-specialty providers) may not be affected by changes made from one standard version to the next, but they are nonetheless required to bear the cost and effort of implementing the new version.

If provider organizations were permitted to determine whether they needed the updated version of a standard based on their business needs, those who had no business need could avoid a costly transition process that returned them no value. A more flexible HIPAA policy allowing multiple versions would ensure those who needed a critical update would get it while avoiding significant cost, human resources and disruption for those who did not need it. An added benefit of multiple versions would be to eliminate the industry-wide date-certain cutover to a new version: industry segments, payers, providers and their intermediaries would have more flexibility and longer timeframes to move their trading partners onto the new version.

Panel 1: Advance HIPAA Standards Adoption (7)

Consideration 2 Questions

- What do you see as the pros and cons of allowing multiple versions? To what extent to you see multiple versions successfully addressing the problem statement components: locally unnecessary updates; avoidance of cost and disruption; easier management of update implementations?
- What is the magnitude of the burden of supporting multiple versions of a standard? NCVHS has been told that multiple versions are common in other industries. Are there complexities or barriers that multiple versions pose to healthcare?
- The NCVHS Subcommittee on Standards suggests three versions simultaneously in production would be the maximum. How many simultaneous version should be allowed? Why?

Panel 1: Advance HIPAA Standards Adoption (8)

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.

Discussion:

Problem Statement: Prior input to NCVHS strongly indicated that updates to the HIPAA transaction regulations are not keeping pace with either industry need. Nor do the regulations aggressively encourage industry innovation. How can the process be redesigned and managed to ensure maximum efficiency and value to the industry?

NCVHS has received much testimony that SDO development and/or federal adoption of updated transaction versions does not keep pace with industry's need for changes. At the same time, testimony indicates a strong industry desire that emerging standards be subjected to much more rigorous pre-adoption testing than they get now. To the subcommittee's knowledge, the CFR 162.940 exception process has been used only twice since it was created. Based on our review of the testimony, we hypothesize changing 162.940 from an "apply for permission" to a "notify and publish" approach would better support those cutting-edge organizations who want to push the standards farther faster. It could also provide detailed timely feedback to SDOs. Finally, it could provide significant value, cost and impact data that CMS needs in its rule promulgation process.

Panel 1: Advance HIPAA Standards Adoption (9)

Consideration 3 Questions

- If your organization has considered participation in testing emerging or alternative standards, was 162.940 an impediment or not? Did it ever discourage you from even considering participating in testing?
- If 162.940 were revised as we described, do you think that would make your attitude toward participating in testing more favorable, less favorable or unchanged?
- Are there other approaches you would suggest NCVHS consider in lieu of or in addition to changing 162.940?
- How might a revised exception process impact the number of versions simultaneously supports (as per Consideration 2)?

To Submit Public Comment:

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Please state your name, title, and organization

Panel Topics

Panel 2: Address Standards Integration and Collaboration

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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.

Discussion

Problem Statement: Data standardization is vital to the success of efforts to address health equity, and efforts to improve interoperability among healthcare organizations or interoperability between healthcare entities and others including public health agencies. The Subcommittee is interested in learning more about the coordination of standards between and across the system, including HIPAA and non-HIPAA data, social service data, and public health data. Challenges include:

- SDoH data are not consistently defined across data sources
- Public health relies on data systems that are often not consistent across federal, state, and local programs, or not harmonized with clinical care data standards
- There are many unique data and reporting standards requirements for organizations, and it is difficult to track and understand all of these across the healthcare system.

Panel 2: Address Standards Integration and Collaboration

Consideration 4 Questions:

- We have an existing framework of data standards harmonization between HITECH and HIPAA led by ONC and CMS. Can this approach to data harmonization be extended to harmonize data needed in all the other related areas demanding relevant data, or would a different approach speed up and broaden data harmonization, and if so how should it work?
- With a focus on innovative technologies, how can all areas of standards development, standards adoption, and standards implementation meet demands for timeliness while also improving collaboration and maintaining data quality?
- What are the barriers to consistent use of data standards at the federal, state and local levels, and how could those barriers be mitigated? What policy or operational levers might be appropriate to support change?

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Panel Topics

Panel 3: Measure the Value of Standards

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Cambia

Panel 3: Measure the Value of Standards

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.

Discussion.

Problem Statement: There was significant discussion at the last NCVHS listening session about the need for standardized ROI and non-monetary value metrics and methodologies to be published to assess emerging and revised standards. HHS has asked Standards Development Organizations (SDO's) and Operating Rule Authoring Entities (ORAE) to provide return on investment (ROI) metrics for new and updated standards and operating rules being considered for adoption under HIPAA. Industry input to NCVHS strongly indicated a need for standardized ROI and standardized non-monetary value metrics and methodologies to be published to assess emerging and revised standards. As more standards are developed to meet similar business needs, a publicly available guidance framework with recommended definitions, metrics, templates, and pilot test procedures needs to be developed to assist industry stakeholders to collect metric results, pilot test procedures for consistent evaluation and comparability of current versus emerging standards.

How and by what organization(s) could this type of guidance framework be created and maintained as well as how the collection and reporting of these metrics to streamline the evaluation of standards. What are the regulatory and nonregulatory topics to be addressed?

Panel 3: Measure the Value of Standards

Consideration 5 Questions:

- Are the business needs captured or understood for evaluation of standards across the industry? *(e.g., better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards)*
- Are the guidance framework components sufficient to measure and manage emerging and revised standards? *(e.g., 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.)*
- How could a guidance framework be created and maintained, i.e., how do you see the alternatives for the public sector or private sector?
- If a guidance framework was created, how do you envision the collection and reporting of metrics would occur to streamline the evaluation of standards - regulatory and nonregulatory.

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Next Steps

- Subcommittee on Standards will review discussion from Listening Session and consider any updates to the considerations
- Subcommittee will present outcome of this meeting to the Full Committee in July

Subcommittee Discussion

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Meeting Adjourned