NCVHS Standards Subcommittee
Report to the Full Committee

January 24 , 2022

Agenda

- Update on activities in 2021 Request for Comments and Listening Session – what we've learned

- Convergence 2.0 and 2022 work plan

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

- **2-year Subcommittee on Standards (SS) project**
  - Phase 1: Landscape Assessment
  - Phase 2: Analysis, deliberation, report and potential recommendations
- **Building on earlier SS work: Predictability Roadmap**
  - Envisioning a more industry-driven standards development and adoption
  - More timely 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/conformance

Standardization of Information for Burden Reduction and Post-Pandemic America: Subcommittee Work Plan

Intent: Build on Predictability Roadmap with appropriate innovations and priorities

➢ **Phase 1: Assess the current health data standards landscape**

- o Listening Session and Request for Written Comments (August 2021)

- o Analyze the RFC and listening session information; identify potential opportunities.

- o Conceptualize potential solutions to improve efficiency and reduce burden

- o Develop workplan for Phase II

➢ **Phase II: Develop and refine recommendations based on assessment of standards, industry consultation and NCVHS input**

- o Standards: Development/maturity, regulation, implementation, enforcement

- o Convergence: Coordinate efforts with ONC and HITAC

- o Identify other opportunities related to HHS priorities

Standardization of Information for Burden Reduction and Post-Pandemic America

Additional opportunities that may be considered for evaluation:

- FHIR and APIs
- All-Payer Claims Databases (APCD) Common Data Layout (CDL)
- Consistency of reporting and/or exchange of social risk data
- Conformance/Enforcement improvement opportunities
- Sanctioned exceptions and alternatives to HIPAA transaction standards
- Health data flows beyond traditional HIPAA and HITECH trading partners
  - Social and structural determinants of health; patient social services programs
  - Public health, infectious diseases and vital statistics
  - Pandemic-related lessons learned
  - Patient/consumer-driven data

Listening Session and Request for Comments

- 31 public comment letters received

- Four panels of industry presenters
  - ❖ Panel 1: Lessons learned from national standards coordination (beyond healthcare)
  - ❖ Panel 2: Updates from standards organizations and industry
  - ❖ Panel 3: Semantic Harmonization
  - ❖ Panel 4: Public Health and Social Risk Data updates

Top 10 Public Comment/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, HL7, CDex	HHS/ONC	Recommendation letters sent to HHS in 2016, 2018, 2019. Updated recommendation 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 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

Top 10 Public Comments/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

Themes (1)

- Data sharing across all actors and data types
  - Not limited to administrative data: clinical and social, too
  - Not limited to HIPAA Covered Entities: many new actors since HIPAA
  - Not limited to EDI transactions; HITECH clinical exchange, health, wellness & pandemic
  - No longer B2B: patients now included in communication flows for Prior Auth, Advanced EoBs (price cost transparency)
  - Data collected at any point in system does not necessarily flow to point(s) of usage, e.g., APCDs, SOGI, SDOH
- Privacy and Security beyond HIPAA
  - 3rd party apps
  - Data moves regularly beyond Covered Entities
  - Professional hacking (ransomware) now commonplace
  - Challenge to educate consumers (no practical informed choice/consent)

Themes (2)

- Regulatory challenges
  - Rule promulgation – need for greater transparency into the process
  - Conflicts between standards development processes, HIPAA legislative parameters and federal Administrative Procedures Act
  - Need for more piloting, testing and ROI determination
  - Support ability to use multiple versions or different standards
    - Trading partner agreement
    - More of an implementer-driven approach

- Conformity assessment
  - A framework for measuring and reporting conformance to the standards with a feedback loop to entities
  - Lessons from other industries

Themes (3)

- Other challenges and opportunities
  - Patient matching – ONC Report to Congress
  - Universal Device Identifier – implementation and data sharing
  - Semantic Harmonization
  - Data exchange between public health systems, states, counties, local jurisdictions
    - Need for Federal leadership (as opposed to federal pre-emption)

Other Inputs

- HITAC Intersection of Clinical and Administrative Data Task Force (ICAD)
  - Certain recommendations align with NCVHS charge
  - Read Report here: https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf

- HITAC Public Health Data Systems Task Force
  - Identify task force recommendations that may be of interest to, or have overlap with NCVHS activities
  - Read report here: https://www.healthit.gov/sites/default/files/facas/2021-07-14_PHDS_TF_2021_Recommendations_Report_0.pdf

- Electronic Prior Authorization RFI Task Force
  - Provide input and recommendations in response to RFI on ePrior Authorization
  - Inform future rulemaking and other actions in this area

Subcommittee Deliberations

- Reviewed input from each listening panel and all submitted comment letters

- Discussed themes through wide lens and from multiple perspectives, e.g., HIPAA regulations, data flows, privacy, source of truth, cost/benefit/burden, equity, traditional and non-traditional actors, state/territorial, standards development, predictability, etc.

- Many areas of subcommittee consensus

- Many more areas for further inquiry

Areas of Subcommittee Consensus (1)

- Both the HIPAA concept of standards adoption and the current HIPAA regulatory adoption processes are obsolete and require major updating.
- Need to:

  - Allow multiple standards to co-exist and be used by stakeholders, e.g., pick-and-choose among NCPDP, X12 and HL7 standards to effectively/efficiently meet business needs
  - Allow multiple versions of a standard to be in production and used simultaneously (if available and tested), e.g., X12 005010, 007030, and 008020; NCPDP D.0, F6.
  - Modify the standards adoption process under HIPAA, including consideration of the ONC Standards Version Advance process (SVAP) if appropriate
  - Eliminate the opaqueness of the current standards development, readiness and adoption process and establish a predictable and dependable cycle for adoption of any appropriate updates of standards.
    - Update HIPAA standards on a set date (e.g., June 1) of every year or of every even-numbered year
    - Adopt updates to only those standards for which an SDO certifies a need to upgrade, e.g. an update to the X12 institutional claim (837I) but not the dental claim (837D).

Areas of Subcommittee Consensus (2)

Commenter themes/areas of consensus continued:

- Amend the exception approval process for testing emerging standards to be less burdensome for beta testers and more proactively supportive of innovation
- Amend the Direct Data Entry (DDE) exemption (i.e., payer web portals) to be more user friendly and less burdensome to providers
- Develop, implement and fund a national system of testing, including test tools and test beds for standards in development
- Develop and publish criteria used to determine fiscal impact, value, return on investment (ROI), and incorporate those criteria, where appropriate, in the development path of candidate standards or operating rules adopted by HHS (e. g. for HIPAA) and other agencies where federally mandated. Ensure that the quantitative fiscal analysis is a balanced assessment of value to society rather than a cost accounting of implementation.

Areas of Subcommittee Consensus (3)

- HHS should act on previous NCVHS and industry priorities
  - Adopt a standard for health care attachments – allow for use and testing of new standards
  - Adopt a standard for acknowledgements (HIPAA)
  - Publish the regulation for the Prior Authorization API (new)

- Non-regulatory Actions for HHS
  - Implement a patient education campaign regarding patient apps and privacy policy
  - Implement training programs for providers on data exchange to support bi-directional data exchange; reduce manual transactions
  - Identify, implement, adopt standards for payers and other organizations to exchange data bi-directionally
  - Support capture of ICD-10-CM Social Determinants of Health (SDoH) data elements across the health care ecosystem (ONC is developing additional data elements)

NCVHS

- Non-regulatory Actions (continued)
  - Develop a solution for patient matching to support information exchange
  - Working with state and territorial officials and their authorized workgroups, provide and fund federal thought leadership to provide guidance for states/territories to implement locally run health and wellness data systems that collectively funnel up to provide national data for policy making and research, such as:
    - Public health emergency data collection
    - All-payer claims databases (APCD)
    - Public health surveillance
    - Infectious disease reporting
    - Contact tracing
    - Non-claims encounter data
  - Work with ANSI and standards organizations to identify an equitable method for compensating standards development work for federally adopted standards. Use that funding mechanism to ensure good SDO productivity and provide minimum-hassle availability of adopted standards to all end users and their systems/software vendors.

Areas for Further Subcommittee Exploration (1)

- Work force training and development on implementation of emerging standards

- Collaboration among advisory committees

- Collaboration among standards development organizations

- Understanding after-the-fact enforcement relative to before-the-fact conformance testing; role(s) of various "guidances"

- Per the ADA comment letter – will industry request HL7 FHIR standards to replace current X12 HIPAA standards for certain provider types.

Areas for Further Subcommittee Exploration (2)

- Code set adoption and coding guidelines for HIPAA medical code sets
- New app economy: privacy and security; consumer education
- Additional public health emergency/pandemic lessons learned
- Greater collaboration among standards organizations and among coding bodies
- Consider approaches to expanding the concept of "covered entities"
  - Workers' Comp, P&C, ERISA
  - Privacy and Security
- Virtual credit cards and Electronic Funds Transfer (HIPAA)

What Else Have We 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 is not meeting the needs of the regulated industry. 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.

Questions for NCVHS Members

- Are there points in the presentation on which you need clarification or more explanation?

- Given that the Subcommittee expects to bring recommendations to the next meeting of the full Committee, what concerns do you have about the areas of consensus? Is the direction sound? Are there gaps?

- What should the Subcommittee be aware of for its continuing work into the areas for further exploration?

- What else should the Subcommittee be mindful of?

- Other?

General Discussion and Next Steps

Reactor Panel

- National Association for Public Health Statistics and Information Systems (NAPHSIS)
- Centers for Medicare and Medicaid Services (CMS)/Center for Medicare & Medicaid Innovation (CMMI)
- Office of the National Coordinator of HIT (ONC)