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

Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange (Modernization 1.0)

Full Committee Working Session

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November 29 & 30, 2023

Working Session Objectives

Scoping Document

Background

Review & Discussion by Full Committee (FC)

Project Topics Review & Discussion by FC (Appendix A & B)

Subcommittees' Jointly Proposed Topic

Review relevance of HIPAA in the current healthcare ecosystem

Next Steps

Scoping Document - Background

NCVHS Project Scope Documents

- Living documents on the NCVHS Website updated and
- Refreshed, as the environment changes or new topics emerge, such as ICD-11

Previous versions of this Project Scope:

NCVHS Standards Subcommittee Project Scope Standardization of Information for Burden Reduction and Post-Pandemic America ("Convergence 2.0"), June 21, 2021

NCVHS Standards Subcommittee Project Scope Development of Recommendations to Support Convergence of Clinical And Administrative Data: with initial focus on the prior authorization transactions and workflow, March 2020

Modernization 1.0

Built on <u>previous NCVHS work</u>:

- **Predictability Roadmap**
  - 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
- **Convergence 1.0 & 2.0 & Intersection of Clinical and Administrative Data Task Force (ICAD)**
  - Harmonization and Integration of standards
  - Convergence of administrative and clinical data to meet business needs.
- **NCVHS letters to the HHS Secretary**
  - PCS Subcommittee guidance that is contained within the Cybersecurity, Public Health Emergencies (PHE), Tribal and other recommendation letters to the Secretary.

Review Process Questions

What has Changed Since HIPAA →	Industry Business Models, Data Flows and Technology →	**What issues/considerations remains relevant?**
Review of historic documents, testimonies and requests for information. →	**What remains high priority issues?** →	Based on recent testimony and requests for information, SC members ranked initial areas of interest to narrow down to a manageable list for FC review.

Modernization 1.0 (Contents)

Background

What has Changed Since HIPAA

Industry Business Models, Data Flows and Technology

Problem Statement

Challenges

Project Scope

Workplan Development

APPENDIX A: Initial Areas of Interest for the Standards Subcommittee

APPENDIX B: Initial Areas of Interest for the Privacy, Confidentiality and Security (PCS) Subcommittee

NCVHS Modernization 1.0 Draft 2023-24 Work Plan

Topic	2023 Q4	2024 Q1	2024 Q2+	Process Owner
1) **Modernizing Standards-Driven Information Infrastructure across the Healthcare Ecosystem (Modernization 1.0)**	• Draft Project Scope − SS and PCS review/input • Discuss with Executive Subcommittee • Request ONC and NSG feedback • Discuss/obtain consensus at Nov FC meeting • Begin fleshing out timeline, projects identified, collaborators, resource needs and workplan	• Continue fleshing out project scope, resource needs and workplan with identified collaborators. • Discuss with ONC and NSG for additional refinement.	• Discuss at April FC meeting	Joint Standards & PCS Subcommittees

Scoping Document - Review

NCVHS Proposed Project Scope
Draft (as of Nov 14 2023)
Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange

Modernization 1.0,

BACKGROUND

The framers of the Administrative Simplification section of the Health Insurance and Portability and Accountability Act of 1996 (HIPAA) had a vision for harmonized federal electronic information and technology standards to achieve efficiency, simplicity and burden reduction in the US health care system. The vision was groundbreaking at the time the HIPAA law was enacted. For certain transactions and policies such as health care billing and payment, and a national identifier for providers, the law and its implementing regulations played a necessary role in providing standardization and uniformity. However, for other transactions and functions, such as prior authorization (mandated but underused) and health care attachments (not yet adopted) HIPAA may not be achieving its full potential for improving the effectiveness and efficiency of the health care system.

Further, in clinical systems, the American Recovery and Reinvestment Act of 2009 (ARRA) significantly advanced the standardization of common clinical data flows from provider to provider. Provisions of the 21st Century Cures Act, the Cares Act and the No Surprises Act augmented the trend of utilizing common standards to harmonize the increasingly intersecting clinical and administrative data flows. These provisions have also led to the expansion of patient access to their health information, reductions in information blocking and greater access to health data (COVID test results etc.) by public health agencies during public health emergencies.

In the 25 years since the passage of HIPAA, industry business models (e.g., fee for service, health
maintenance organizations (HMOs) value based care/purchasing) data flows, and technologies have

Initial Proposed Topics for the Subcommittee on Standards

	Topic	Anticipated Partners/Collaborators/ Keep informed
A	Where might the NCVHS vision and objectives/ recommendations fit into the ONC and HHS 2020-2025 strategic plan? How can we connect the dots and demonstrate alignment.	
B	Examine mature and emerging standards and how they can co-exist to support current and future business needs and their workflows.	ONC, CMS, DSMOs
C	Review relevance of HIPAA in the current healthcare ecosystem.	ONC, CMS/OBRHI,OCR, FTC and others
D	Harmonization of Standards and Data	ONC, other HHS offices, SDOs
E	Additional Priority Topics?	

Initial Proposed Topics for the Privacy, Confidentiality and Security (PCS) Subcommittee

Topic	Anticipated Partners/Collaborators/ Keep informed
Cybersecurity—Strengthen the HIPAA Security Rule—Consider other areas that were not included in the previous recommendation letters.	OCR, ONC, NIST, CISA
Examine "Beyond HIPAA" issues to include a long-term course of action to develop recommendations for the use and protection of health information that is not protected by HIPAA as well as non-covered entities that do not fall under HIPAA.	OMH, OWH, HRSA, NIH, Academy Health
Protection of Public Health Data—What might a public health version of HIPAA include?	OCR, CDC, IHS
Additional priority areas of interest?	

Scoping Document Discussion

WITH COMMITTEE SUPPORT FOR
PROJECT SCOPE & TOPIC AREAS,

MODERNIZATION 1.0 UPDATED
SCOPING DOCUMENT WILL BE PLACED
ON NCVHS WEBSITE AS A REFERENCE
DOCUMENT TO SUPPORT CURRENT
PROJECTS

Action Item: Discussion on Subcommittees' Jointly Proposed Topic

Topics Proposed:

SS - Review relevance of HIPAA in the current healthcare ecosystem

PCS - Examine "Beyond HIPAA" issues

Seek support for project:

Convene a joint work group with PCS, SS and others to review the current state of the HIPAA law and propose updates as needed.

	Topic	Anticipated Partners/Collaborators/Those to keep informed	Considerations	Full Committee Discussion
C	Review relevance of HIPAA in the current healthcare ecosystem.	ONC, CMS/OBRHI,OCR, FTC and others Other Federal agencies such as OMH, OWH, HRSA, other offices tracking effects of Dobbs on the ground---Jeannine Clayton – office for research on women's health, NIH, as well as Lisa Simpson, President and CEO of Academy Health and Alison Cernich, Ph.D., ABPP-Cn, Deputy Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.	Potential Considerations: • Consider the potential need to **expand the definition of covered entities,** • Consider the potential need to **expand the definition of the HIPAA standards**, • Consider the potential need to **expand policy requirements for covered entities,** for example: additional standards compliance and additional privacy & security rules. • Consider a long-term course of action to develop and implement **recommendations for the use and protection of health information that is not protected by HIPAA.** • **Sensitive health information** such as reproductive health information that is housed on health apps as well as the protection of other public health data. • **Consider implications of Dobb**, including failure to document, professional repercussions, concern about protection of gender-affirming care. • Examine the role of AI to assist with automation in standard implementation and workflow (e.g., bridging new standards and code sets). Guiderails for security of AI.	**Are there any gaps/additional considerations to consider?** **What information/SME's are needed to explore these considerations?**

Next Steps

- Identify member participation

- Continue discussions

- Develop work plan specific to topic

- Engage with appropriate Federal agencies and key stakeholders

- Full Committee discussion

- Seek industry input/feedback for potential incorporation into work plan

Initial Proposed Topics (Continued)

Full Committee Discussion

Additional Topics:

- Where might the NCVHS vision and objectives/ recommendations fit into the ONC and HHS 2020-2025 strategic plan? How can we connect the dots and demonstrate alignment.

- Examine mature and emerging standards and how they can co-exist to support current and future business needs and their workflows.

- Harmonization of Standards and Data

- Cybersecurity—Strengthen the HIPAA Security Rule—Consider other areas that were not included in the previous recommendation letters.

- Protection of Public Health Data—What might a public health version of HIPAA include?

Initial Proposed Topics Review
Subcommittee on Standards

I. **Where might the NCVHS vision and objectives/recommendations fit into the ONC and HHS 2020-2025 strategic plan? How can we connect the dots and demonstrate alignment.**

Considerations:

- For example, CMS Goal is to move 100 percent of Original Medicare beneficiaries and the vast majority of Medicaid beneficiaries into accountable care relationships by 2030. Does the HIPAA TCS support this movement?
- Provide recommendations and comments from NCVHS for HHS and pertinent agencies to consider in the development and implementation of relevant strategic plans and policies.

Initial Proposed Topics Review
Subcommittee on Standards

II. Examine mature and emerging standards and how or if they can co-exist under HIPAA to support current and future business needs and workflows.

Considerations:

- Identify mature and emerging standards and determine if there is a consensus-based standard process that is accessible and offers rigor around piloting/testing. Determine if there is consistency of requirements across the standards. (E-Prescribing and Prescription Drug Program final rule, published on November 7, 2005 (70 FR 67568k)).

- Exception Process: from Piloting to Standard Adoption

Initial Proposed Topics Review
Subcommittee on Standards

Considerations Continued:

- Removal of Named Standards - How can the standards named in HIPAA and the new, emerging standards co-exist? Do the named standards need to be removed from the HIPAA regulation to accommodate innovation. Does it make sense to place or consider placement of HIPAA standards in a tool similar to ONC's Standards Version Advancement Process (SVAP) that permits health IT developers to voluntarily update health IT products certified under the ONC.

- Cross Standards Collaboration – ensure development of a standards setting body across standards organizations (i.e., ADA, ASCX12, CPT, HL7, ICD, CAQH CORE, HL7, NCPDP, NUBC, NUCC and others) to support upcoming emerging payment models and other innovations occurring proactively within the industry.

Subcommittee on Standards

IV.   Harmonization of Standards and Data Requests

Considerations for encouraging harmonization and alignment of standards:

- Encourage harmonization across SDOs of information/data elements used in existing and future health standards.
- Encourage minimizing the number of information exchange formats required to exchange health information.
- Encourage use and harmonization/alignment or authoritative mapping of clinical and administrative vocabulary standards, including ongoing industry activities related to data dictionaries, USHIK reference and others.
- Encourage use of standards for electronic exchange of information by and with federal and state agencies as appropriate.
- Relevant federal agencies should increase adoption of standards for electronic exchange of data with and between parties as appropriate.

Initial Proposed Topics Review
Subcommittee on Standards

Considerations Continued

- Consider the elimination of barriers to adoption of standards (i.e., fees) for items such as implementation guidance and code sets with descriptions.
- Support the work of HHS and agencies such as CMS regarding SDOH and SOGI initiatives related to the use of current and new ICD-10 Modesto to capture SDOH risk, and provider, community-based education, assessment and enforcement data.
- Support ONC work on addressing a patient matching solution while funds are prohibited from being spent on development of a unique individual identifier.
- Consider if there are additional opportunities to support the standards development work of the SDOs in exchange for free access by users to adopted work products. If so, encourage HHS to consider such opportunities.
- Support HHS update of the provision in the HIPAA regulation at 162.923 (b): Requirements for covered entities, Exception for direct data entry

Initial Proposed Topics Review
Subcommittee on Standards

Considerations Continued

- Consider encouraging inclusion of instructions in code set adoption and coding guidelines (ICD does; CPT does not)
- HHS should continue to collaborate through appropriate federal agencies to encourage thought leadership for state/territorial data collection and dissemination for purposes of evaluating the current governance structure and ensuring the uniformity and comparability for state and territorial data for collection and dissemination.
- Consider Federal leadership for forums to help states standardize their data collection requirements in order to minimize the collection burden on data submitters and to maximize the completeness and accuracy of state data when it is aggregated regionally or nationally.
- Consider developing similar guidance, guidelines and framework for administrative standards certification as are available for EHR certification.

Initial Proposed Topics Review
Privacy, Confidentiality and Security (PCS) Subcommittee

I.   Cybersecurity—Strengthen the HIPAA Security Rule

This project will build off of the Committee's recent Cybersecurity recommendations submitted to HHS in 2022. The Subcommittee also will work with Cybersecurity experts, such as from OCR, ONC, NIST, Trusted Exchange Framework and Common Agreement (TEFCA) etc. to determine best practices in the area of Security including best practices to strengthen the HIPAA Security Rule.

Major areas that may be included and expanded under the previous Security letter include:
- Covered entity security control vs. business associates (BAs)
- Security risks due to third party risk, BAs, vendors, cloud, API, apps etc.
- Required language for the Business Associate Agreement
- Rule should set minimum security controls for BAs and CEs—smaller entities—sliding scale of controls.
- Need definition/examples of compensating controls.
- AI—how should it be used to secure covered entities, identify threats etc.

Initial Proposed Topics Review
Privacy, Confidentiality and Security (PCS) Subcommittee

Major areas that may be included and expanded under the previous Security letter cont.:

- Ransomware major threat—Need business continuity plans, Incident response plans etc.
- Mobile Device Security—consider security requirements by ONC.
- Consider Defense-in-Depth (layers in Risk Management)
- Risk Management and Risk Analysis (focus on the areas needed for compliance in this area since it is the larger area of non-compliance for covered entities and BAs)
- Propose adding Security Rule Provisions
- Responsible Use of AI
- Crypto Agility (minimum encryption requirements for data security and crypto agility)
- Cloud Security (subscriptions and asset management)
- Network Security (network segmentation based on user characteristics (employee vs. contractor)
- Risk Management (vulnerability management, minimum service level agreements)
- Risk Analysis
- API Security

Initial Proposed Topics Review
Privacy, Confidentiality and Security (PCS) Subcommittee

Additional Considerations ---Include Recommendations 2-4 from original letter.

- Important to keep elements from current Rule, not only recommendations for change but what should be retained.

- Admin, Physical, Technical overall structure

- Standard implementation specifications

- Reasonable and Appropriate concept

- Flexibility and Scalability

- Risk Analysis and Risk Management requirements

- Consider Security Rule to TEFCA – extending HIPAA by contracts.

- Summary of HIPAA Security Rule for reference.

- ONC, Trusted Exchange Framework and Common Agreement (TEFCA):
https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca

Initial Proposed Topics Review
Privacy, Confidentiality and Security (PCS) Subcommittee

III. Protection of Public Health Data

1. Explore: Is there a public health version of HIPAA?

2. Consider a set of recommendations that covers our concerns about:

   a) lack of data due to enforcement threats to providers and patients; and

   b) alert to protect public health data, beyond HIPAA.

NCVHS Report (June 2019). Health Information Privacy Beyond HIPAA: A Framework for Use and Protection:
https://ncvhs.hhs.gov/wp-content/uploads/2019/07/Report-Framework-for-Health-Information-Privacy.pdf

Next Steps

- Prioritization

- Continue discussions

- Develop work plan specific to topic

- Engage with appropriate Federal agencies and key stakeholders

- Full Committee discussion

- Seek industry input/feedback for potential incorporation into work plan