NCVHS Standards Subcommittee Report Out

July 20, 2023

Standard Subcommittee Update

- **NCVHS Role Related to HIPAA Standards**
  - CAQH CORE Operating Rule Proposal Recommendations
  - X12 Standard Proposal Recommendations
  - X12 Standard Proposal Request for Review 2 Under Review

- **Evolving the "Convergence 2.0" Project**
  - Subcommittee Charge
  - Background
  - Draft Scoping Document: Working title "Modernizing Standards Driven Information Infrastructure across the Healthcare Data Ecosystem (Modernization 1.0)"
  - Vision
  - Full Committee feedback

CAQH CORE Proposal on Operating Rules

CAQH/CORE Proposed <u>Updates</u>[1] to Adopted Operating Rules:

- Letter with recommendations approved at NCVHS June 14, 2023 meeting sent to Secretary
- Posted on NCVHS website

  [NCVHS Recommendations on Updated and New CAQH CORE Operating Rules to Support Adopted HIPAA Standards](#)

[1]Letter to NCVHS from CAQH/CORE, May 23, 2022. https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf

X12 Request to Update HIPAA Transactions

X12 requested[1] NCVHS review of 4 updated transaction implementation guides:

- Letter with recommendations approved at NCVHS June 14, 2023 meeting sent to Secretary
- Posted on NCVHS website

  NCVHS Recommendation on the Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020)

[1]Letter to NCVHS from X12, April 11, 2023. https://ncvhs.hhs.gov/wp-content/uploads/2023/05/Letter-to-NCVHS-X12-Standards-Request-April-11-2023.pdf

X12 Standard Proposal, Request 2 Under Review

X12 Request to Update to X12 Version 8030 under HIPAA

- X12 has requested NCVHS recommend that the Secretary adopt version 8030 for certain transaction implementation guides:
  - **Claim Status** - 008030X329 Health Care Claim Status Request and Response (276/277)
    - 202X CAQH Index adoption rates: (Medical) and (Dental)
  - **Enrollment** - 008030X333 Benefit Enrollment and Maintenance (834)
  - **Premium Payment** - 008030X334 Payroll Deducted and Other Group Premium Payment for Insurance Products (820)

- Move from Version 005010 to Version 008030
  - *5010 balloted by X12 2003; adopted under HIPAA 2009; implemented 2012*
- All other adopted transactions remain on version 5010

The letter to NCVHS from X12 is available on the NCVHS website - https://ncvhs.hhs.gov/wp-content/uploads/2023/05/Letter-to-NCVHS-X12-Standards-Request-April-11-2023.pdf

Standards Review Process

NCVHS Role related to HIPAA standards

- Receive requests for new or updated standards from Standards Development Organizations (SDOs) and/or new or updated operating rules from Operating Rule Authoring Entities (ORAEs)
- Receive input on SDO requests from the Designated Standards Maintenance Organizations (DSMOs), i.e., ADA, HL7, NCPDP, NUBC, NUCC, and X12
- Obtain industry and public input
- Determine whether the requested updates meet the requirements of HIPAA Administrative Simplification, as amended, for efficiency, effectiveness, cost/value, etc.
- Make recommendation(s) to the Secretary of HHS

Subcommittee Review Steps for X12 Proposal

- Overview presentations by X12 to Subcommittee on Standards July 2023

- Collaboration with WEDI, named advisor to HHS in the HIPAA statute:

- Develop and publish a Request for Comment
  - Expected publication early September with a 45- or 90-day comment period.

- Consultative conversations with CMS/OBRHI, CMS/NSG and HHS ONC[1]

- Obtain input from the Designated Standards Maintenance Organizations (DSMO)

- Draft recommendations

- Review draft recommendations with Executive Subcommittee then bring to full Committee for discussion, public comment and vote

[1] *HHS/CMS Office of Burden Reduction and Health Informatics; HHS/CMS/OBRHI National Standards Group; HHS Office of the National Coordinator for Health Information Technology (ONC).*

Subcommittee Evaluation Questions

- Was there industry consensus around need for the proposed changes/updates to the currently adopted version?

- Was there sufficient cost and value data, and applicable use cases, along with identification of the burden, opportunity and efficiency for proposed standards upgrades to assess impact for implementation?

- Was there availability of information to confirm backwards compatibility, since a subset of 008030 transactions versus the entire 008030 suite was proposed?

- How does the proposal address industry concerns that were expressed to NCVHS during its Predictability Roadmap and Convergence 2.0 projects?
    - Has pre-adoption testing of standards demonstrated sufficiency?
    - Consideration of burden on provider and health plan operations
    - Timing of implementation; ability to plan, budget and allocate resources

- Does the proposal further objectives of HIPAA, ACA and other applicable laws?

Evolving the "Convergence 2.0" Project

- Working title: "Modernizing Standards Driven Information Infrastructure across the Healthcare Data Ecosystem (Modernization 1.0)"

Standard Subcommittee Charge

Monitors and makes recommendations to the full NCVHS:

1. Identify issues and opportunities in health data standards;
2. Provide outreach, liaison, and consultation with, and serve as a public forum on health information technology standards for the health care industry and federal, state and local governments;
3. Make recommendations related to electronic standards and operating rules under HIPAA, privacy and security standards, health terminologies and vocabularies;
4. Make recommendations on strategies to promote a continuing process of developing, coordinating, adopting, implementing and maintaining standards. These strategies may include public information and educational efforts as well as research and development efforts;
5. Participate in development/publication of the Report to Congress on HIPAA Administrative Simplification
6. Collaborate with other Federal Advisory Committees on cross-cutting issues as appropriate and when delegated by the Full Committee.

Modernization 1.0 (*Working Title*)

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 & ICAD**
  - Harmonization and Integration of standards
  - Convergence of administrative and clinical data to meet business needs.
- **In collaboration with Privacy & Security Subcommittee**

Predictability Roadmap, 2017-19

- **Initiative** - Evaluate barriers to the update, adoption and implementation of standards and operating rules under the authorities of HIPAA and ACA.

- **Vision** - For covered entities and business associates to be able <u>to use up-to date HIPAA standards consistently</u>, garnering increased value from the standards by avoiding "one-off" work-arounds, and to <u>reliably know when updated versions will be available and adopted</u> in time to prepare systems, resources and business processes.
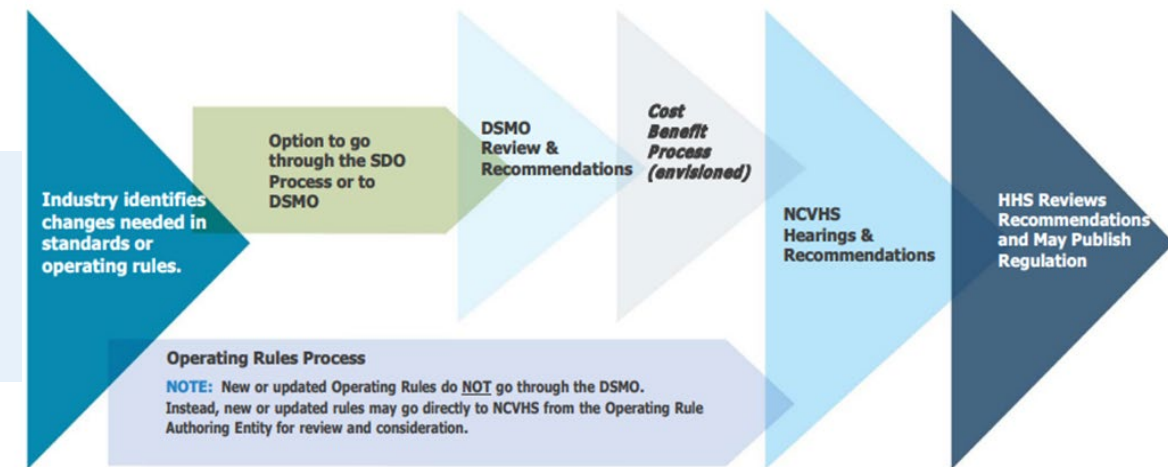
Predictability Roadmap, 2017-19

#	Recommendations, Feb. 13, 2019
1	Remove the regulatory mandate for modifications to adopted standards and move towards industry-driven upgrades.
2	Promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules.
3	Improve the visibility and impact of the administrative simplification enforcement program.
4	Provide policy-related guidance from HHS regarding administrative standards adoption and enforcement.
5	Re-evaluate the function and purpose of the Designated Standards Maintenance Organizations.

Standards Update Process - Overview
Current Process for Receiving Recommendations for Updates to Standards and Operating Rules

Industry identifies changes needed in standards or operating rules.

Option to go through the SDO Process or to DSMO

DSMO Review & Recommendations

Cost Benefit Process (envisioned)

NCVHS Hearings & Recommendations

HHS Reviews Recommendations and May Publish Regulation

Operating Rules Process
NOTE: New or updated Operating Rules do NOT go through the DSMO. Instead, new or updated rules may go directly to NCVHS from the Operating Rule Authoring Entity for review and consideration.

WEDI Policy Advisory Groups Help Industry Analyze HHS Policy After Regulations Have Been Published

Recommendations based on the original 11 Recommendations, 7 Calls to Actions, and 3 Measurement Recommendations

Convergence 1.0 & 2.0 (2020-22)

Date	#	Recommendation	Date
3/30/22	1	Publish the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7 FHIR3 standard to support Application Programming Interfaces (APIs) to automate payer and provider prior authorization workflows.	NPRM
	2	Adopt a standard or standards for electronic attachments as soon as possible to meet today's business needs.	NPRM
	3	HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards and implementation guides (IGs).	
	4	Streamline the process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely.	

Convergence 1.0 & 2.0 (2020-22)

Convergence 1.0 & 2.0			
Date	**#**	**Recommendation**	**Update**
6/22/23	1	Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.	
	2	Enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.	
	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).	
	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.

Current Use: Only one HIPAA standard is mandated for a business use. The X12 278 for PA.

Potential Future Use: PA is triggered in different locations within the revenue cycle. This includes patient scheduling, practice management system, electronic medical record. Each of these platforms are built on different standards. The X12 278 may be used in the practice management system, while an HL7 FHIR API could be used when triggered in the EMR to perform PA. Payers and their business associates would be required to support both standard implementation guides. Providers and their business associations **could choose** which standard brings highest business value to their workflows.

Potential Future Example: Provider chooses to use their practice management system to send a prior authorization that uses an X12 278 transaction with the workflow to a payer. Another provider chooses to use a Smart on FHIR app with their EMR that uses the HL7 FHIR API within the workflow.

Recommendation 2

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

Current Use: During implementation of a new version of a standard, payers support more than one version of a standard. This allows providers and their business associates to transition to an updated version when they are ready, prior to the mandated implementation date.

Potential Future Use: If the 008020 claim, professional, dental and institutional standard would be mandated, payers would support versions 005010 and 008020 claim standards. Each provider and their business associate could decide if there is business value to move to the updated version. When an additional updated version is mandated, providers and their business associates would have to move to either 008020 or the new version.

Potential Future Example: Dentists would have had the option to move to 008020 claim, dental if find business value, while those using the professional and institutional claim could remain on 005010 version. Would support testing of the business value, ROI and technical implementation cost, by those who find business value.

- Administrative and clinical data flows are frequently co-mingled and used in both the same and different systems or by the same entities; data can no longer be considered separate and distinct.

- ·Electronic exchange of both administrative and clinical data has in some cases exceeded the uses envisioned by the HIPAA framers for health plans, providers and patients; for example, aligning components of clinical data with administrative processes (e.g., patient name, demographics, laboratory results and/or social determinants of health) is critical for patient care in any setting, from acute care to public health to mobile apps; and clinical lab data may be needed to authorize a service for payment or determine medical necessity of a procedure or service and/or determine a patient's clinical care plan.

Industry Business Models, Data Flows and Technology Have Changed Since HIPAA cont.

- <u>New actors</u> are involved in health data collection and exchange. Some actors are not covered entities under HIPAA, nor subject to privacy and security requirements. The scope of data sharing across actors now encompasses social and behavioral services, public health, cost and quality assessment and research, in addition to HIPAA's original administrative uses.

- <u>Consumer-focused price transparency regulations</u>, which require health plans and hospitals to provide consumers with the cost of a covered item or service before receiving care.

- Increased focus on the collection of and initiatives to address <u>healthcare equity and disparities, social determinants of health and community health.</u>

Industry Business Models, Data Flows and Technology Have Changed Since HIPAA cont.

- Transaction processing technology has <u>migrated away from mainframe computing and batch processing (</u>for which the basic X12 transaction set was designed) and data sharing increasingly is accomplished with new technologies such as Application Program Interfaces (APIs) based on HL7's Fast Healthcare Interoperability Resources (FHIR), telehealth and telemedicine applications.

- Generative AI has altered the landscape through <u>AI's ability to translate among standards and between standards </u>to gain harmonization.

Project Scope Statement - Draft

The primary goal is to identify strategies to modernize the standards driven information infrastructure across the healthcare data ecosystem in partnership with key federal and industry stakeholders. T

The healthcare industry needs a comprehensive, integrated set of standards that fully support health information interoperability across public health, population health, administrative and clinical systems and other software programs that support the health data ecosystem, including semantic, syntactical, and structural interoperability.

Project Scope Statement – Draft cont.

Harmonization of standards across SDOs and across users will be necessary to achieve the goal. Harmonization efforts can be categorized into five strategic areas: 1) Regulatory framework 2) Information models; 3) Terminology models; 4) A security/trust framework; 5)) An information exchange framework; and 6) A common standards development and implementation methology.

Problem Statement – Draft cont.

For these reasons stated previously, the **regulatory structures** established under HIPAA need to evolve and update to meet the current and emerging business and clinical needs. NCVHS has determined that there is a broad industry requirement to **modernize the standards adoption** framework, including **harmonizing clinical, public health, administrative, financial and other standards.**

Problem Statement – Draft cont.

The NCVHS Predictability Roadmap hearings shown a light on the need for more predictability of the adoption process for HIPAA standards and operating rules.

<u>These standards are implemented by the same healthcare stakeholders as other standards, such as those found in the United States Core Data for Interoperability (USCDI).</u>

Recognizing these standards are part of the national health data ecosystem, reinforces the need for modernization of the standard adoption framework across the healthcare ecosystem.

Vision - Draft

Standardized data capture and improved availability of data across the healthcare data ecosystem that supports individual health care and wellness, health equity/SDOH, public health, health policy, price transparency, coordination of care, improve patient outcomes, burden reduction, privacy and security, and the usability of personal health information.

This standardization allows for the betterment of the administrative and clinical information exchange, and ultimately the delivery of healthcare. This benefits Patients, Providers, Payers, and the System-as-a-Whole.

Potential Projects Based on Past Work/Listening Sessions Considerations

- **Review relevance of HIPAA in the current healthcare ecosystem**

- **Examine mature and emerging standards and how they can co-exist** to support current and future business needs and their workflows. *In collaboration with HITECH and other appropriate key stakeholders.*

- **Evaluate how different industries, countries, SDO's and others assess standard readiness for national implementation** from a business use and technical implementation perspective.

- **Workgroup on Timely and Strategic Action to Inform ICD-11 Policy**

Committee Discussion

Next Steps

- Incorporate any revisions from Full Committee discussion

- Continue Standard Subcommittee discussion

- Engagement with OBRHI and ONC

NCVHS Resources

Main site for meetings, letters and reports:
https://ncvhs.hhs.gov/

- Calendars and Agendas
- Membership and Committees
- Recommendations
- Reports
- Meeting Summaries, Recordings and Transcripts
- Responses from HHS