



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

## NCVHS Standards Subcommittee Update

Tammy Banks, Co-Chair, Subcommittee on Standards

August 28, 2023

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## NCVHS' Impact



### HIPAA Standard Transactions

- Recommended adoption of Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and Adoption of a New Pharmacy Subrogation Standard (CMS-0056-P) Proposed rule for Administrative Simplification
- Recommended adoption of Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard Proposed Rule.

### Other Regulations which could intersect with HIPAA

- Advancing Interoperability and Improving Prior Authorization Processes proposed rule (CMS-0057-P) affecting CMS regulated payers and requiring HL7 FHIR based API and X12 278
- Year 2024 Medicare Advantage and Part D Final Rule (CMS-4190-F2) with price transparency and prior authorization provisions
- Mental Health Parity and Addiction Equity Act (MHPAEA) with prior authorization provision

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## NCVHS' Impact (continued)



### Other Initiatives and Actions

- Privacy, Confidentiality, and Security Considerations for Data Collection and Use During a Public Health Emergency
- Public Health Data Sharing with Tribal Epidemiology Centers (TECs) and Other Designated Tribal Public Health Authorities (ODTPHAs)
- Recommendations to Strengthen Cybersecurity in Healthcare

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## 2023 Priorities



- **Report to Congress**
- **HIPAA Standards & Operating Rules**
  - CAQH CORE Operating Rule Proposal Recommendations
  - X12 Standard Proposal Recommendations for version 8030
  - X12 Standard Proposal Request for updated standard version 8030 under consideration
- **Health Data Standards**
  - Evolving the “Convergence 2.0” Project
- **Medical Code Sets**
  - ICD-11 work group – evaluating research opportunities for next set of recommendations to HHS

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



- Develop Committee analysis and recommendations to assist and advise HHS Secretary regarding the U.S. strategy and policy for moving from ICD-10 to ICD-11.
- Draw on lessons learned from historical adoption processes and timelines taking them into account in formulating recommendations.
- Understand the extent to which implementation and use of ICD-11 can be automated in real-world settings in the U.S. – *which will require research and evaluation.*
- Avert significant avoidable transition cost and burden to the U.S. health care system, including public health, like those experienced in the transition from ICD-9 to ICD-10.

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



- Subcommittee on Standards collaborating with CMS, NIH, ONC, CDC, NCHS and other federal agencies, states and private sector on research design and communications
- **Ultimately, NCVHS will advise HHS Secretary on ICD-11 adoption and implementation (with or without a CM) as a HIPAA Medical Code Set**
- Visit [NCVHS Web site](#) for ongoing activities and outcome of the August 3 Expert Panel and Request For Information (RFI)

[ICD-11 Workgroup Meeting – National Committee on Vital and Health Statistics \(hhs.gov\)](#).

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# Transaction Standards & Operating Rules

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## Transaction Standards & Operating Rules



The HIPAA transactions **standards** are:

- Rules to standardize the electronic exchange of patient-identifiable, health-related information.
- Based on electronic data interchange (EDI) standards, which allow the electronic exchange of information from computer to computer without human involvement.

**Operating rules**, which are required by the Affordable Care Act, are defined as the:

- “Necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications.
- Business rules and guidelines that do not duplicate what is in the standard. Nor are operating rules inconsistent or in conflict with the standard. Operating rules typically go above and beyond the standard in terms of data content and other requirements.”

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## 2022 CAQH CORE Request to NCVHS



Proposed Operating Rule	Recommendation to Secretary
Eligibility & Benefits (270/271) <b>Data Content Rule</b>	Recommended for Rulemaking
Claim Status (276/277) <b>Infrastructure Rule</b> (updates + reference to updated Connectivity rule)	
Payment & Remittance Advice (835) <b>Infrastructure Rule</b> (reference to updated Connectivity rule)	
Eligibility & Benefits (270/271) <b>Infrastructure Rule</b> (updates + reference to updated Connectivity rule)	
Connectivity Rule vC4.0.0 (includes updates to the <b>Connectivity Rule</b> included in existing operating rules) Replaces existing connectivity requirements in infrastructure components of adopted operating rules and adds new requirements to all operating rules	
Eligibility & Benefits (270/271)	
Single Patient Attribution Data Content Rule	

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## 2022 CAQH CORE Request to NCVHS\*



Proposed Operating Rule	Recommendation to Secretary
Attachments Prior Authorization <b>Infrastructure Rule</b> * Attachments Prior Authorization <b>Data Content Rule</b> * Attachments Health Care Claims <b>Infrastructure Rule</b> * Attachments Health Care Claims <b>Data Content Rule</b> *	Not Recommended, encourage review and resubmission after <b>HHS</b> decision on attachment rule.

\*The letter from CAQH/CORE is available on the NCVHS website: <https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-reNew-Updated-OR-052322-508.pdf> The letter Letter Recommendations approved at NCVHS June 14, 2023 meeting sent to Secretary: [NCVHS Recommendations on Updated and New CAQH CORE Operating Rules to Support Adopted HIPAA Standards](#)

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## What is Next for Recommended Operating Rules?



Secretary considers the recommended operating rules for rulemaking.

If agrees to move forward, subject to:

(C) EXPEDITED RULEMAKING.—The Secretary shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics pursuant to paragraph (3). The Secretary shall accept and consider public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.

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## X12 Request to Update HIPAA Transactions



- X12 requested<sup>1</sup> NCVHS review of 4 updated transaction implementation guides:
  - **Claims (837 Professional, Institutional and Dental)**
    - 2022 CAQH Index adoption rates: 97% (Medical) and 86% (Dental)
    - 008020X323 Health Care Claim: Professional (837)
    - 008020X324 Health Care Claim: Institutional (837)
    - 008020X325 Health Care Claim: Dental (837)
  - **Payment/Remittance Advice (835)**
    - 2022 CAQH Index adoption rates: 83% (Medical) and 36% (Dental)
    - 008020X322 Health Care Claim Payment/Advice (835)
- Move from Version 005010 to Version 008020
  - *5010 balloted by X12 2003; adopted under HIPAA 2009; implemented 2012*
- All other adopted transactions remain on version 5010

<sup>1</sup>Letter to NCVHS from X12, June 7, 2022. <https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf>

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## NCVHS Evaluation



- 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 008020 transactions versus the entire 008020 suite was proposed.
  - Next subset proposed is version 008030 for three transactions (April 11, 2023)
  - Version 6020 is in the NPRM for health care claims and prior authorization attachments
- 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 X12 proposal further the objectives of HIPAA/ACA

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## NCVHS Recommendation



**NCVHS recommends that HHS not adopt the version 008020 update to the four specified transactions (i.e., Health Care Claim (Institutional, Professional and Dental) and the Claim/Remittance Advice) at this time.**

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 \(Version 008020\)](#)

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## NCVHS Recommendation *continued*



- Adopting a subset of 008020 transactions versus the entire 008020 suite would result in multiple transaction versions (i.e., some 005010 and others 008020) with unknown compatibility issues, potentially causing disruption across industry trading partners. Evidence of the 008020's backward compatibility (cross-compatibility) to existing 005010 transactions is needed.
- Insufficient cost and value data from a business and technical perspective
- Another upgrade needed to replace:
  - ICD-10 with the World Health Organization's adopted ICD-11's variable-length cluster codes for current and future industry uses.
  - National Drug Code (NDC) modified format within a recently published proposed rule.

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## NCVHS Recommendation *continued*



**Table 1: List of HIPAA X12 Standard Transactions**

Note: Does not include NCPDP Pharmacy Standards

X12N Standards – Current Version 005010 8 Mandated and 2 Proposed Standards							
HIPAA Mandated Standard	Standard	Transaction	Current HIPAA Version	Subject Of 1/2023 Hearing	HHS Attachments NPRM(12/22)	Proposed X12 05/2023	Expected by 12/2023
1	837P, 837I, 837D	Health Care Claims (Institutional, Professional, and Dental)	005010	008020			
2	835	Health Care Claim Payment/Advice	005010	008020			
3	276/277	Health Care Claim Status Request and Response (276/277)	005010			008030	
4	834	Benefit Enrollment and Maintenance	005010			008030	
5	820	Payroll Deducted and Other Group Premium Payment for Insurance Products	005010			008030	
6	278	Referral Certification and Prior Authorization	005010		006020		
Proposed	275	Additional Information to Support a Health Care Claim or Encounter (NEW) Additional Information to Support a Health Care Services Review (NEW)	005010		006020		
Proposed	277	Health Care Claim Request for Additional Information (NEW)	005010		006020		
7	270/271	Eligibility and Benefit Verification	005010				?
ACH & X12N Standard							
8	ACH CCD+Addenda ASC X12N 835	Claim Payment (or EFT, electronic funds transfer)	005010				?

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## Need for Updated Version



NCVHS acknowledges the obsolescence of version 005010 and the need to move to an updated version of the X12 standard; however, concerns over accommodating multiple versions across transactions, accommodating changes in code sets and the long lead-time for regulatory processes need to be addressed. The Committee urges X12, in conjunction with industry and regulators, to speedily address the needs and submit a new version for adoption under HIPAA.

The Committee commends X12 and the participating stakeholders in its proof of concept (POC) and looks forward to the results that may shed more light on backward and cross standard compatibility. In addition, the POC could provide supplemental value data to support X12's future proposal to move the next version of these standards forward.

The Committee encourages stakeholders to submit benefit and return on investment data either to NCVHS or CMS upon request to assist in the review of all future proposals.

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## X12 Standard Proposal, Version 8030 Under Review

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## 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>

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## Your Input Is Vital to the Process



NCVHS obtains industry input/consensus about a proposed standard/operating rules brought forward concerning topics, such as:

- Need for the proposed changes.
- Need for the updates to the currently adopted version
- Consensus around the proposed version
- Available cost benefit information to assess impact for implementation.
- How the requests support the objectives of HIPAA and ACA.
- Other priorities provided through oral and written comment

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## NCVHS and its Role with Health Data Standards

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## 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.

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## Evolving the “Convergence 2.0” Project

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

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## Modernization 1.0 (*Working Title*)

Built on previous NCVHS work:

- **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**

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



- 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.

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



- New actors 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.
- Commercially available data, including PHI are non-covered disclosures under HIPAA (used by noncovered entity under HIPAA). This data includes purchase history at the drug store.
- Consumer-focused price transparency regulations, 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 healthcare equity and disparities, social determinants of health and community health.

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



- Transaction processing technology has migrated away from mainframe computing and batch processing (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 AI's ability to translate among standards and between standards to gain harmonization.

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## 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, healthcare quality and safety, burden reduction, privacy and security, and the usability of personal health information. Real-world data (RWD), including patient generated data will become increasingly important over time.

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.

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## Potential Projects Based on Past Work/Listening Sessions Considerations



- **Review relevance of HIPAA in the current healthcare ecosystem** (e.g., need to consider covered entity expansion, alternative standards, innovation). This Innovation includes value-based care or use of Artificial Intelligence to assist with automation in standard implementation and workflow (e.g., bridging new standards and code sets). *In collaboration with OBRHI/NSG and other appropriate key stakeholders.*
- **Examine mature and emerging standards and how they can co-exist** to support current and future business needs and their workflows. *In collaboration with HITAC and other appropriate key stakeholders.*
- **Evaluate how different industries, countries, SDO's and others assess standard value for national implementation of different version of standards** from a business use and technical implementation perspective. Challenge of determining the value, cost to implement and is the value worth the cost. Examine how costs and benefits are distributed across HIPAA and non-HIPAA use cases. *In collaboration with OBRI/NSG and other appropriate key stakeholders.*

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## Next Steps



- Continue Standard Subcommittee discussion
- Develop Work Plan
- Engage with OBRHI and ONC
- Full Committee discussion
- Seek industry input/feedback for potential incorporation into work plan

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## 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

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## Questions & Feedback Welcome

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