



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

Subcommittee on Standards Report Out

Tammy Banks, Chair, Subcommittee on Standards

November 30, 2023

Subcommittee on Standards



Committee Members

- Tammy Banks, MBA
- Jamie Ferguson
- Michael Hodgkins, MD, MPH
- R. Lenel James, MBA
- Richard Landen, MPH, MBA
- Debra Strickland, MS
- Steve Wagner, MBA

Executive Staff

- Rebecca Hines, MHS, NCHS,
Executive Secretary

NCVHS Staff

- Lorraine Doo, MPH, CMS
- Marietta Squire, NCHS
- Gwen Mustaf, NCHS

Standards Subcommittee Year in Review



X12, CAQH CORE Proposals

Public Correspondence

Collaborations/Presentations

Planning Documents

NCVHS Proposed Project Scope Draft

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

Other Emergent Projects, as Assigned by Full Committee

X12, CAQH CORE Proposals



Letters to Secretary

X12 Set 1 Proposal

[June 30, 2023 - Recommendation Letter-Updated and New CAQH CORE Operating Rules to Support Adopted HIPAA Transactions](#)

CAQH CORE

June 14, 2023 - Recommendation Letter-Updated Version of X12 Standard for Claims and Electronic Remittance Advice



Open Issue

X12 Set 2 Proposal

Public Correspondence



NCVHS Values Your Input!



Request for Information



Testimonies



Post-recommendation correspondence
received in follow up to the June 14, 2023,
X12 Version 008020 recommendation

Post-recommendation Correspondence Received re X12 008020 Recommendation

Date	From	Topic
July 27, 2023	X12 Cathy Sheppard, X12 CEO	<ul style="list-style-type: none"> Point by point review of NCVHS's rationale for the recommendation. Request for reconsideration of the Committee's recommendation.
Sept 12, 2023	The Cooperative Exchange Pam Grosze, Board Chair	<ul style="list-style-type: none"> Point by point review of NCVHS's rationale for the recommendation. "While we understand the concerns the committee raised, we believe that they are not of great enough concern to postpone these needed updates, and that they can be handled in future versions and instructions."
		Specific to the UDI
July 28, 2023	FDA Jeffrey Shuren, MD, JD Director, Center for Devices and Radiological Health	<ul style="list-style-type: none"> In response to NCVHS' comments specific to stakeholder concerns noted in the Committee's June 14 letter, FDA assured NCVHS that FDA has engaged with stakeholders sufficiently to address unresolved concerns regarding barriers to implementing the use of UDI in the claim transaction, noted by NCVHS. "We are available to answer any questions you may have and look forward to future developments on this matter." "We urge the committee to work expeditiously to resolve open issues with the Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020) and recommend adoption so that UDI information can be captured and exchanged."
Aug 1, 2023	Brigham & Women's Hospital Joel S. Weissman, PhD Dan C. Krupka, PhD	<ul style="list-style-type: none"> Request that NCVHS reconsider its decision to recommend that CMS not move forward with the adoption of the new X12 claim standard. "We are particularly concerned that the decision will indefinitely delay the transmission of unique device identifier (UDI) data from providers to payers thereby indefinitely delaying the establishment of a sorely needed post-market surveillance system for medical implants."
Aug 24, 2023	University of California, San Francisco et al. Sanket Dhruva, MD, MHS	<ul style="list-style-type: none"> Making the case for critical patient, public health, regulatory science, and healthcare delivery reasons to move forward with the update to specifically include the DI portion of the UDI in claims. DI inclusion is beneficial for the entire medical device ecosystem – most importantly to ensure that only safe and effective medical devices are used in clinical care for diagnosis and treatment and to ensure that UDI (and DI) are available to transmit key information that is otherwise not systematically available to patients, clinicians, health systems, regulators, industry, and those engaged in post market safety surveillance for medical devices. JAMA Internal Medicine Viewpoint "Unique Device Identifiers for Medical Devices at 10 Years" published online August 21, 2023

Collaborations/Presentations



Date	Organization	Presenter	Topic
5/23	WEDI	Tammy Banks Jamie Ferguson	NCVHS Standards Subcommittee and ICD-11 Update
8/23	eSolutions Xchange	Tammy Banks	NCVHS Standards Subcommittee Update
11/23	WEDI	Tammy Banks Rich Landen	NCVHS Standards Subcommittee Update
11/23	WEDI	Jamie Ferguson	ICD-11 Update

What's Next on Subcommittee on Standard's Agenda

2024 and
beyond



Subcommittee on Standards 2024+ Workplan



**Discuss Next Steps for the X12
Set 2 Proposal with Full
Committee**



**Compile Lessons Learned from
SDO Conversation & Discuss
with Full Committee**



**Compile planning documents
and draft timeline for the
Modernization 1.0 priority
topics (Pending Full Committee
Approval)**

Work plans
Recommended information gathering
needs.



**Other Emergent Projects, as
assigned by Full Committee**

Current Planning

Modernization 1.0
Initial Areas of
Interest



Developing the Subcommittee on Standards Work Plan: Initial Areas of Interest



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- 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.
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- B. Examine mature and emerging standards and how or if they can co-exist under HIPAA to support current and future business needs and workflows.
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- C. Review relevance of HIPAA in the current healthcare ecosystem.
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- D. Harmonization of Standards and Data Requests
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- E. Other emergent topics, as arise.

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