

Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
Joint Meeting of the Subcommittee on Privacy, Confidentiality and Security and the
Subcommittee on Standards
September 19-20, 2024
Virtual Meeting

MEETING MINUTES

Note: For details on this meeting, please refer to the transcript and slides posted here:

<https://ncvhs.hhs.gov/meetings/full-committee-meeting-17/>

A joint meeting of the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Privacy, Confidentiality and Security and Subcommittee on Standards was convened virtually on September 18-19, 2024. The meeting was open to the public. Present:

Subcommittee Members

Angela M. Alton, MPA, City of Hope
Tammy Feenstra Banks, MBA, FACMPE
Catherine Molchan Donald, MBA, Alabama
Department of Public Health
James Ferguson, Kaiser Permanente
Michael L. Hodgkins, MD, MPH, Home Base
Associates
R. Lenel James, MBA, BCBSA
Steve Wagner, MBA
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA, UPitt

Executive and Lead Staff

Sarah Lessem, PhD, PMP, ASPE, Exec. Director
Naomi Michaelis, MPA, NCHS, Exec. Secretary
and Designated Federal Officer (DFO)
Maya Bernstein, JD, ASPE/OSDP
Lorraine Doo, MPH, CMS
Grace Singson, PharmD, MS, ASPE

NCVHS Staff

Shirley Castillo, MPH, NCHS
Marietta Squire, NCHS

Invited Speakers

Mona Calhoun, PhD, MS, MEd, RHIA, FAHIMA,
American Health Informatics Association
Michael Cimmino, Centers for Medicare &
Medicaid Services
Annie Fine, MD, Council of State and Territorial
Epidemiologists
Edward Hafner, Workgroup for Electronic Data
Interchange (WEDI)
John Loonsk, MD, Johns Hopkins Bloomberg
School of Public Health
Deven McGraw, JD, Citizen Health
Marko Mijic, MPP, California Health & Human
Services Agency
Lisa Myers, JD, American Medical Association
Tina Olson Grande, MHS, Healthcare Trust
Institute
Merri-Lee Stine, WEDI
Micky Tripathi, PhD, MPP, Office of the National
Coordinator for Health Information
Technology

In addition to those individuals who presented virtually during the meeting (listed above), 51 people followed the meeting online on Day 1 and 48 followed on Day 2.

—DAY ONE—

Call to Order and Roll Call—Naomi Michaelis, Executive Secretary and Designated Federal Officer

Ms. Michaelis welcomed NCVHS members, staff, invited speakers, and public attendees.

Ms. Michaelis conducted roll call, requesting that NCVHS Subcommittee members state their name, status as a special government employee, and any conflicts of interest for this meeting. Ms. Michaelis then introduced NCVHS staff members and noted that only one live public comment session would occur during this meeting. Members of the public can provide comments orally or via email to NCVHSmal@cdc.gov and can subscribe to the NCVHS Newsletter to receive email notices from the NCVHS Full Committee.

Agenda Review— Naomi Michaelis, Executive Secretary and Designated Federal Officer

Ms. Michaelis reviewed the Day 1 meeting agenda.

Update: Office of the Assistant Secretary for Planning and Evaluation—Sarah Lessem, ASPE, HHS

Dr. Lessem provided an update from the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The U.S. Department of Health and Human Services (HHS) continues to use the goals outlined in the 2022 HHS Strategic Plan to guide its activities, including efforts to expand behavioral health services with a focus on prevention and access to care, prioritizing mental health and wellbeing of parents and caregivers, and launching the KidneyX Sustainability Prize. In addition, the Biden Administration recently announced agreements for reduced prices on 10 of the most expensive and frequently used Medicare treatments and investments to address the opioid crisis.

Other updates include announcements for the Health Resources and Services Administration (HRSA)'s funding of the Ryan White AIDS Program and programs to improve care for older adults; releases of the National Heat Strategy for 2024-2030, 2024 National Strategy for Suicide Prevention, and a national strategy to address the maternal mental health crisis; and the launch of technical assistance programs to help recruit direct care workers. Recently, HHS has declared several public health emergencies, as well as issued various Final Rules, and renamed the Office of the National Coordinator for Health Information Technology (ONC) as the Office of the Assistant Secretary for Technology Policy (ASTP).

Privacy and Security in Health Data Access: Health Information Exchange Participant Perspectives—moderated by Jamie Ferguson and Angela Alton

Deven McGraw, JD, Chief Regulatory and Privacy Officer, Citizen Health

Ms. McGraw provided a landscape overview of how data exchange is currently promoted and facilitated. Prior to the Health Information Technology for Economic and Clinical Health (HITECH) Act, the health care system primarily conducted health information exchanges through networks at the state and regional levels, and primarily among health care providers and health plans. More recently, an effort has been made to build these networks into national-level exchanges (e.g., Carequality), which now are working to align policies with Trusted Exchange Framework and Common Agreement™ (TEFCA), a voluntary network

for national health information exchanges. A key difference in these health information networks and previous methods for data sharing is the automated manner in which data are shared, which occurs because networks now assume some of the responsibility for ensuring compliance with relevant laws, rules, and agreements.

Lisa Myers, JD, Senior Washington Counsel, Division of Legislative Counsel, American Medical Association

Ms. Myers shared AMA's perspective on privacy and security for health care data. Physicians have long supported patient access to their medical records to enhance patient engagement and outcomes. Ensuring privacy of patient health information is critical, and thus physicians can suffer criminal penalties for providing care when health information is not protected. However, medical information can now be shared on applications that are not covered by Health Insurance Portability and Accountability Act (HIPAA). The American Medical Association (AMA) has advocated for applications to implement basic privacy frameworks and standards and for inclusion of a statement on transparency and best practices for patients to review.

Tina Olson Grande, MHS, President and CEO, Healthcare Trust Institute

Ms. Grande provided an overview of the Healthcare Trust Institute, which is an alliance of health care organizations committed to promoting and implementing effective privacy and security protections for health information as well as enhancing trust in the health care system to enable advancements of treatments, cures, and quality improvement for individuals and populations. The Institute's work is guided by the following principles: (a) robust privacy and security protections for personal health information is essential for trust in the health care system, (b) all personal and health information, regardless of HIPAA coverage, should be subject to regulation, (c) entities collecting health information should be required to have safeguards from misuse and employ data minimization approaches, (d) protections must be established at the national level, and (e) health care entities should provide patients with privacy notices to explain data capture processes.

Mona Calhoun, PhD, MS, MEd, RHIA, FAHIMA, President, American Health Informatics Association, Chair, AHIMA Board of Directors

Dr. Calhoun provided AHIMA's perspective on data exchange processes in the health care sector. AHIMA is a global nonprofit association of health information professionals and a leading authority on health information in the health care industry. Health information professionals are often the first step in the data exchange process by helping to compile and maintain medical records, process the release of information and claims, and monitor and analyze data for research and reporting. Dr. Calhoun emphasized that improvements to HIPAA are needed as the scope of private health information has expanded and the patchwork of state and federal privacy laws creates challenges. She encouraged NCVHS to enhance its understanding of how HIPAA interacts with broader privacy laws, determine how data should be treated once it leaves HIPAA-covered entities, and explore opportunities to coordinate data exchange oversight and enforcement.

ASTP/ONC Briefing—Micky Tripathi, PHD, MPP, Assistant Secretary for Technology Policy, National Coordinator for Health Information Technology, HHS Chief Artificial Intelligence Officer (Acting), Office of the National Coordinator for Health Information Technology

ASTP/ONC is charged with formulating the federal government's health information technology (IT) strategy to advance national goals for better and safer health care through an interoperable nationwide health IT infrastructure. ASTP/ONC has launched the USCDI+ Initiative to support Uniform Data System modernization, developed United States Core Data for Interoperability (USCDI) Version 3 (required to be supported in electronic health records [EHRs] in 2026), and established TEFCA to simplify health data exchange. In July 2024, HHS announced the renaming of ONC to ASTP/ONC, thus expanding the office's scope to include oversight over artificial intelligence (AI) strategy and policy. ASTP will focus on building a digital foundation to underscore data standards and address health IT gaps; promoting information sharing and interoperability; ensuring responsible use of digital information; and advancing health AI.

Privacy and Security in Health Data Access: Public Health, Human Services, and Other Perspectives—moderated by Val Watzlaf and Cathy Donald

Marko Mijic, MPP, Managing Director, Sellers Dorsey, Former Undersecretary, California Health & Human Services Agency

Mr. Mijic presented on approaches to bridge data silos to improve access to care and advance health equity. Currently, the public health, social services, and health care sectors operate in silos, forcing patients and families to navigate these fragmented systems on their own. Mr. Mijic urged NCVHS to consider ways to improve the connections across these sectors through the exchange of data. In California, abiding by California's data exchange framework is mandatory, thus organizations are able to share more data to enable whole-person care. Mr. Mijic highlighted three strategies to overcome siloing in health care: collecting and sharing of social services information using national standards, facilitating consent management for the exchange of information, and enabling information matching across data systems to ensure consistent and unified individual identification.

Annie Fine, MD, Chief Science and Surveillance Officer, Senior Advisor to Data Modernization Initiative, Council of State and Territorial Epidemiologists

Dr. Fine described considerations on data sharing from a public health perspective. Data sharing is critical to health care, both in everyday life and during a public health emergency. Collecting and sharing data are also critical to identify inequities in the health care system. Integrating data across sectors can reduce the burden on public health workers to find and request data from other entities. Public health entities are often accustomed to protecting confidential information, with state and local laws guiding the data protections needed—despite being HIPAA-exempt public health entities. Public health entities are now working to build infrastructure to support the use of health information networks and data exchanges and are determining how TEFCA can work for public health. Dr. Fine emphasized that more tools are needed to help public health entities handle the volume of data being collected.

John Loonsk, MD, Adjunct Professor, Johns Hopkins Bloomberg School of Public Health

Dr. Loonsk provided an overview on data sharing between health care and public health entities. Electronic health information from clinical care has been recognized as important for public health preparedness. With the recent COVID-19 public health emergency, substantial progress was made by

implementing electronic case reporting from EHRs nationally, but work remains to meet all health care needs. The secure exchange of health information across organizations is critical. Public health data reporting uses health information exchanges and networks, in addition to state laws, HIPAA-covered entities, and public health disclosures. Tools such as cloud technologies can help to better connect health care and public health organizations. Dr. Loonsk emphasized that perceptions of HIPAA language for disclosures to public health authorities can impede some exchange intermediaries (e.g., TEFCA qualified health information networks) and that public health agencies have lagged behind clinical care in health IT adoption and understanding their own data rights.

75th Anniversary Celebration Discussion

NCVHS members discussed planning updates for the 75th Anniversary celebration in 2025, which will have the theme of "Past, Present, Future." The event will feature short videos from previous NCVHS Chairs and Subcommittee Co-Chairs and involve the development of a booklet to summarize the work of NCVHS over the past 15 years, as well as note future planned efforts. Attendees discussed inviting live speakers, including senior HHS officials and past NCVHS Full Committee members, Subcommittee members, and Designated Federal Officers, and discussing topics such as the future of NCVHS and its role in a changing health care system, as well as historical successes.

—DAY TWO—

Call to Order and Roll Call—Naomi Michaelis, Executive Secretary and Designated Federal Officer

Ms. Michaelis welcomed NCVHS members, staff, invited speakers, and public attendees.

Ms. Michaelis conducted roll call, requesting that NCVHS Full Committee members state their name, status as a special government employee, and any conflicts of interest for this meeting. Ms. Michaelis then introduced NCVHS staff members and noted that only one live public comment session would occur during this meeting. Members of the public can provide comments orally or via email to NCVHSmail@cdc.gov and can subscribe to the NCVHS Newsletter to receive email notices from the NCVHS Full Committee.

Agenda Review—Naomi Michaelis, Executive Secretary and Designated Federal Officer

Ms. Michaelis reviewed the Day 2 meeting agenda.

Update from the ICD-11 Workgroup—Jamie Ferguson, Chair, ICD-11 Workgroup

Mr. Ferguson presented the timeline of the Workgroup's previous and current activities. He explained that analysis of responses to the second Request for Information (RFI) has revealed alignment with previous NCVHS recommendations, but also new findings that require further exploration. Therefore, the Workgroup is in the process of identifying key use cases and engaging with stakeholder groups to gain additional input—in order to better understand critical dependencies, particularly related to developing a U.S. morbidity linearization. Work in progress and next steps are to identify U.S. participants in the WHO Family of International Classifications and other subject matter experts, plan for additional panel discussions or expert roundtables, and develop a second update report.

Office for Civil Rights Update—Timothy Noonan, Deputy Director for Health Information Policy, Data, and Cybersecurity, HHS Office for Civil Rights

Mr. Noonan reviewed and provided example applications of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy, which strengthens privacy protections for individuals seeking, obtaining, providing, or facilitating reproductive health care and took effect June 25, 2024. Mr. Noonan explained the conditions under which the new Privacy Rule applies. He then reviewed recent trends in health data breaches affecting 500 or more individuals, sharing data that indicate an increase in these breaches and the portion of these breaches related to third-party hacking and to network server security. Finally, Mr. Noonan reviewed recent Office for Civil Rights (OCR) enforcement actions and common OCR guidance for covered entities, such as conducting thorough risk analyses and creating data backup plans.

CMS Update

Michael Cimmino, Director, National Standards Group, CMS/Office of Burden Reduction and Health Informatics

Mr. Cimmino introduced Mr. Hafner and Ms. Stine and emphasized the importance of understanding industry perceptions of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020) in light of the Centers for Medicare & Medicaid Services (CMS) burden reduction and HIPAA modernization efforts.

Edward Hafner, Chair, WEDI

Mr. Hafner introduced WEDI, which collaborates with, seeks input from, and offers education to multistakeholder groups as an HHS advisor with the goal of improving the U.S. health care system. Mr. Hafner then introduced a recent WEDI survey. In January 2023, NCVHS recommended that HHS not adopt Version 008020 to four specified transactions due in part to insufficient industry knowledge and education about the updated transaction versions. Therefore, WEDI conducted a survey to measure industry support for Version 008020 Remits 835 and Claims 837 transaction sets. WEDI conducted the survey from May to June 2024, providing background information on specific changes in the transaction sets and measuring the perceived value and cost of each. Respondents found it easier to measure the value, because the cost estimates for each transaction change will depend on more thorough internal analyses. About half of respondents represented payors, 18% were providers, 11% were clearinghouses, and 23% were vendors.

Merri-Lee Stine, Chair-Elect, WEDI

Ms. Stine detailed the results of WEDI's stakeholder survey and highlighted that many respondents understood the proposed features of Version 008020 Remits 835 and Claims 837 transaction sets and viewed them as highly or moderately beneficial, although respondents also noted some concerns, such as the cost of Technical Report Type 3 (TR3) implementation guides. Ms. Stine explained that without a federal mandate to do so, stakeholders will not adopt Version 008020, and many stakeholders will not conduct their cost-benefit analyses. Respondents also reported that they viewed the costs and value of implementation as high. Ms. Stine observed that implementation costs are high in part because of the scope of the proposed changes, but that (a) this will be the case until the next major change to X12 and (b) implementation of these standards sets the stage for regular updates. Overall comments support the

upgrades to reach a point of regular smaller upgrades, to prevent costly workarounds, and to meet evolving industry needs in a timelier manner.

Update from the Subcommittee on Standards—Tammy Feenstra Banks and Steven Wagner, Co-Chairs, Subcommittee on Standards

Ms. Banks and Mr. Wagner shared the Subcommittee's current workplan, reviewed three educational sessions that occurred in April 2024 and are now available on the NCVHS website, and introduced two RFIs that the Subcommittee plans to submit to the *Federal Register* by December 2024. The first RFI seeks guidance on requests for exceptions from standards to permit testing of proposed modifications. Ms. Banks reviewed this exception process, which has been used only three times since codification in August 2000. The second RFI seeks to identify existing and emerging harmonization efforts among data standards organizations, implementers, and public agencies in seven strategic areas including terminology, code sets, and data privacy. Ms. Banks and Mr. Wagner reviewed the text of both RFIs and solicited input from Full Committee members.

Public Comments

Mr. Stanley Nachimson, ICD-11 subject matter expert for X12, reported that X12 is considering pathways for incorporating ICD-11 in its standards and offered to provide the ICD-11 WG assistance or additional information. He suggested the ICD-11 WG include the impacts to interoperability standards in its research, including any necessary changes to interoperability standards and the timeline for making those changes. He observed that standards organizations' impact analyses and education depend on the US morbidity linearization and the HHS timeline for ICD-11 implementation, and that many organizations will likely not begin preparatory work until HHS proposes or finalizes ICD-11 guidelines. He also observed that ICD codes are procedure codes, as distinct from diagnostic codes, may impact other medical coding sets such as the Current Procedural Terminology (CPT) set.

Ms. Janice Karin, Director of Policy, Technology, and Innovation at the Massachusetts Health Data Consortium, noted that her organization previously considered submitting an exception but declined to do so and would welcome the opportunity through the Subcommittee on Standards' RFI to provide feedback on the current exception process and ways that it could be improved.

Next Steps & Wrap-Up

The next virtual Full Committee meeting is scheduled for (date TBD).

Closing Remarks & Adjourn—Naomi Michaelis, DFO

Ms. Michaelis thanked speakers, panelists, and attendees for their input, feedback, and discussion during this meeting.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

_____/X/_____
_____09/26/2024_____

Chair

Date