Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
December 3, 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-22/

The National Committee on Vital and Health Statistics (NCVHS) was convened virtually on December 3, 2024. The meeting was open to the public. Present:

Committee 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
John Kelly, MHA
Vicki Mays, PhD, MSPH, UCLA
Steve Wagner, MBA
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA, UPitt
Wu Xu, PhD, University of Utah

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
Michael Cimmino, Centers for Medicare & Medicaid Services
Kathleen McGinty, Centers for Medicare & Medicaid Services
Tom Novak, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)

In addition to those individuals who presented virtually during the meeting (listed above), 77 people followed the meeting online.

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 members state their name, status as a special government employee, and any conflicts of interest for this meeting. Ms. Donald noted that she would recuse herself from any discussions related to reproductive health. No other members disclosed conflicts of interest. 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 meeting agenda.

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

Rural Health Care

In October 2024, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) released a report on health care in rural areas, which describes health insurance coverage trends and health care access challenges. This report also describes U.S. Department of Health and Human Services (HHS) programs (e.g., Medicaid, healthcare.gov insurance marketplace) that provide health care coverage for rural Americans and additional investments in rural health care, including in rural hospitals, health care workforce development, and mental health and substance use disorder (SUD) support services. In September 2024, the Health Resources and Services Administration (HRSA) announced nearly $75 million to support health care services in rural areas, including the launch of new opioid use disorder treatment and recovery services, increased maternal health care availability, and support for rural hospitals.

Prescription Drug Affordability

On September 30, 2024, the Centers for Medicare & Medicaid Services (CMS) announced that some Medicare enrollees will receive reduced copays for 54 drugs that are covered under Medicare Part B. These drugs are used by nearly 1 million Medicare enrollees to treat conditions such as cancer, osteoporosis, and pneumonia.

Additionally, under the Inflation Reduction Act, nearly 1.5 million Medicare Part D enrollees have saved nearly $1 billion in prescription copay costs. In 2024, prescription copay costs were capped at $3,500 per year for some Medicare Part D enrollees; in 2025, this cap will be reduced to $2,000 per year and extended to all Medicare Part D enrollees. A recent ASPE study showed that if the $2,000 per year cap had been in place in 2024, 4.6 million Medicare Part D enrollees would have reached this cap by June 30, 2024. Before passage of the Inflation Reduction Act, which included the Medicare Part D annual copay cap, some Medicare enrollees were spending more than $60,000 per year on prescription copays.

Health Care Workforce

A recent ASPE report highlights multiple challenges facing the U.S. health care workforce, including burnout, staffing shortages, lack of racial and ethnic diversity, and increasing administrative burden. This report summarizes information about the supply and geographic

distribution of multiple types of health care workers, including physicians, nurses, direct care workers, behavioral health workers, and oral health care providers. In the next 10 years, direct care workers are expected to become one of the largest subset of health care workers. However, these workers experience low pay, part-time hours, and little or no benefits, which contributes to their high turnover and low job satisfaction. As the U.S. population ages and demand for direct care workers increases, the need to address the challenges faced by direct care workers will become increasingly urgent.

To support and grow the health care workforce, HHS recently launched a new website for people interested in joining the health care workforce or advancing their career within this workforce. To increase the supply and distribution of behavioral health care workers, in particular, HRSA issued two competitive funding opportunities: the Graduate Psychology Education Program and the Behavioral Health Workforce Education and Training Program for Professionals.

Hurricane Recovery Efforts

Public health emergency (PHE) declarations due to the effects of Hurricanes Helene and Milton remain in place for Florida, Alabama, North Carolina, South Carolina, and Tennessee. To assist these areas, the Biden-Harris administration announced $1.8 billion in hurricane recovery assistance funding. This funding covers state disaster recovery efforts (e.g., debris removal), restoration of public infrastructure (e.g., roads, bridges, schools), and provision of many essentials (e.g., food, potable water, baby formula) to affected residents.

HHS is also responding to shortages of intravenous (IV) fluids due to damage by Hurricane Helene to Baxter International Inc.'s facility in North Carolina. HHS efforts to improve the supply of IV fluids include restoring key production sites and protecting existing stocks. As a result, IV fluid stocks in U.S. hospitals have increased by 50% compared to immediately following Hurricane Helene.

Additionally, the U.S. Food and Drug Administration (FDA) quickly conducted scientific and regulatory assessments to allow importation of 23 different IV and peritoneal fluids from five Baxter International facilities in other countries. HHS also invoked the Defense Production Act (DPA) to help Baxter International obtain materials to clean and rebuild its North Carolina facility. The Administration for Strategic Preparedness and Response (ASPR) is currently airlifting IV fluids from Baxter International facilities in other countries to ensure that patients receive these IV fluids as quickly as possible. ASPR continues to explore other potential steps under the DPA to increase the production and availability of IV fluids.

Public Comments

No public comments were received during the meeting.

HHS Health and Human Services Interoperability Introduction—Tom Novak, ASTP/ONC

One major priority of HHS's data strategy is integrating medical data with human services data from various sources, including the following:

- Workforce development and financial well-being services, such as employment-related services, apprenticeship programs, vocational rehabilitation, and work support services for Veterans and people with disabilities
- Aging and senior services, such as housing and home-based support programs, transportation assistance, and home-delivered meals

- Cash and in-kind benefits, including food and nutrition assistance programs, unemployment insurance, and childcare assistance
- Child, family, and community services such as child protective services, youth development programs, and family support programs
- Disability and independent living services, including disability-related support services and community-based behavioral support

HHS began efforts to integrate medical and human services data following passage of the Patient Protection and Affordable Care Act (ACA), which requires greater interoperability between medical and human services data. The goal was to enable a single system that could determine eligibility for multiple government programs (e.g., Medicaid, Supplemental Nutrition Assistance Program (SNAP), housing assistance programs). However, this work has been hindered by multiple challenges, including (a) inconsistent data definitions (e.g., income) between agencies, (b) laws and regulations that prohibit data sharing between agencies, and (c) mistaken concerns that the Health Insurance Portability and Accountability Act (HIPAA) prevents data sharing.

The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) continues to pursue the goal of streamlining health and human services through improved data interoperability. ASTP/ONC seeks to leverage existing data sources from multiple types of organizations, including federal and state government agencies, health care providers, community-based organizations, nonprofit organizations, and standard development organizations (SDOs). ASTP/ONC has three goals for this effort:

- Short Term: Identify and prioritize data sharing opportunities to improve human services delivery.
- Medium Term: Advance human services data exchange and interoperability through HHS levers (e.g., funding mechanisms, existing programs, regulations).
- Long Term: Implement use cases, policies, and tools to drive data interoperability at scale.

Data sharing needs, the health and human services involved, and data sharing barriers can vary between use cases. Mr. Novak provided an example of a family of five in which both parents struggle with SUD and mental health challenges, one child has a disability, and the child welfare system is involved. Other federal, state, and local government programs may also be involved, including Medicaid, SNAP, state SUD treatment services, state disability services, and public school systems. Data sharing is crucial for coordinating care for both the parents and children, referrals to appropriate services, and child welfare monitoring and interventions. Barriers to this data sharing include (a) lack of standardized collection of case data in electronic systems, (b) lack of data-sharing abilities between federal and state programs, (c) multiple applications for different support programs with different requirements and data definitions, and (d) lack of state-level visibility into the full range of services provided to this family.

ASTP/ONC is currently in the first stage of this effort: identifying and prioritizing data sharing opportunities to improve human services delivery. ASTP/ONC recently launched its human services interoperability sprint group that will collaborate with other agencies and interested parties. For example, the Administration for Children and Families recently issued a Request for Information (RFI) on interoperability standards for human services programs. ASTP/ONC is conducting landscape analyses of existing authorities, policy tools, and other resources to improve human services interoperability. ASTP/ONC is also identifying relevant use cases and priorities, which will then be matched against existing authorities and resources to identify potential strategies for driving interoperability. Based on these analyses, ASTP/ONC

will integrate and align efforts across HHS agencies into its Human Services Interoperability Work and Communication Plan.

Discussion

Privacy Act of 1974

Dr. Watzlaf asked whether NCVHS can assist in resolving challenges regarding privacy laws and regulations (e.g., concerns about HIPAA compliance) to improve data interoperability. Mr. Novak responded that the Privacy Act of 1974 often limits the sharing of data between government agencies. The act provides an approach for interagency data sharing, but this approach is cumbersome and requires an established data-sharing strategy between relevant agencies. Mr. Novak suggested that NCVHS could highlight the importance of updating provisions in the Privacy Act of 1974 to simplify interagency data sharing. Ms. Bernstein noted that statutory limitations for specific human services programs (e.g., SNAP) are often the most significant barriers to interagency data sharing, far greater than those barriers resulting from the Privacy Act.

Additionally, human services programs differ in how they define relevant data elements (e.g., household size, income), posing additional challenges for data integration.

State-Level Virtual Gateways for Human Services Programs

Mr. Kelly noted that some states (e.g., Massachusetts) have created virtual gateways that act as a single application point for multiple state-level human services programs, and he asked whether ASTP/ONC has explored using a similar approach for federal human services programs. Mr. Novak responded that despite the success of virtual gateways within specific states, these systems have not been expanded nationwide. Scaling these systems beyond a single state would require funding to integrate different systems (e.g., relevant databases), create a robust user interface that can work across states, and address legal concerns (e.g., HIPAA and Privacy Act compliance) that would arise during this effort. Mr. Kelly asked whether ASTP/ONC could fund pilot programs within specific states to test potential approaches for integrating human services and medical data. Mr. Novak responded that ASTP/ONC does not currently have funding for such pilot projects. He suggested that pilot projects could be funded through different CMS funding mechanisms (e.g., Medicaid Section 1115 demonstration projects).

Linking Human Services and Medical Records

Ms. Banks asked whether the NCVHS Subcommittee on Standards could collaborate with ASTP/ONC on identifying potential approaches and standards to enable data sharing between health care providers and human services programs. Mr. Novak responded that he would be interested in this collaboration. He noted that Care Alliance is exploring approaches to sharing social determinants of health (SDOH) data using Fast Healthcare Interoperability Resources (FHIR) and X12 standards. However, more policy work is needed to enable sharing of these data with human services programs.

Ms. Banks noted that CMS is currently moving toward risk-based care and value-based care (VBC) and that funding these pilot projects may support this transition. However, a roadmap for integrating human services and health care data would likely be necessary to ensure proper allocation of resources and funding.

Linking SDOH Data with Referrals

Dr. Mays noted that California's efforts to improve sharing of SDOH data have revealed challenges to linking these data with referrals to relevant human services that can address SDOH (e.g., housing insecurity). Furthermore, recent research has shown that addressing

different SDOH often requires addressing underlying social vulnerabilities (e.g., larger economic inequalities).

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

Workgroup Background

Mr. Ferguson presented the timeline of the previous activities of the Workgroup on Timely and Strategic Action to Inform ICD-11 Policy (WG) to explain how the WG arrived at its current priorities. NCVHS's early work on ICD-11 featured an Expert Roundtable Meeting in 2019 and recommendation letters to the HHS Secretary in 2019 and 2021. These letters emphasized the need for research to evaluate different approaches to the ICD-11 transition in the United States and to provide timely leadership on strategic outreach and communications to the U.S. health care industry on this transition. The ICD-11 WG was chartered in 2022 to further study issues around ICD-11 implementation and to prepare the Full Committee to make recommendations to the HHS Secretary.

To gather inputs from interested parties, NCVHS issued its first RFI (88 FR 38519) on ICD-11 implementation and held an Expert Roundtable Meeting in summer 2023. Following this meeting, NCVHS issued a second RFI (88 FR 71369) with more detailed questions and a longer comment period than the first RFI. Based on insights from these RFIs, as well as interactions with various ICD-11 subject matter experts, the WG created its most recent ICD-11 Policy Update Report.

Review of ICD-11 Policy Update Report

Mr. Ferguson presented relevant sections of the report to the Full Committee. He noted that 17 organizations responded to the first RFI and that 35 organizations responded to the second RFI. Respondents covered a wide range of interested parties, including health care providers, SDOs, state departments of health, health information technology (IT) experts, medical specialty societies, academic experts, and advocacy organizations for rare diseases and rural health. He highlighted key themes from responses to the second RFI, including the following:

- Benefits and potential opportunities from ICD-11, including improvements in care quality, patient safety, and health equity, as well as potential reductions in administrative burden from artificial intelligence (AI) and automated coding. Respondents disagreed on whether or not AI and automated coding systems are already reducing administrative burden.
- Potential challenges and obstacles to ICD-11 implementation (e.g., costs and resources needed, impacts on reimbursement coding processes).
- Importance of demonstrating both financial and nonfinancial costs and benefits of ICD-11 compared with continuing to use ICD-10-CM.
- Concerns about relinquishing control of code management and updates of importance to the World Health Organization (WHO). Many respondents emphasized the need for coordination with WHO and across federal agencies.
- Potential of ICD-11 to better manage and integrate health care delivery with a focus on SDOH and cultural diversity.
- The need for additional research on ICD-11, including additional mapping of codes between ICD-10-CM and ICD-11.

Mr. Ferguson emphasized that further research on ICD-11 requires additional information on the U.S. ICD-11 morbidity linearization, including how post-coordination and code clustering will be used and which extension codes will be needed to meet U.S.-specific coding

requirements. He also emphasized the importance of establishing ICD-11 governance and maintenance processes within the United States to ensure that U.S.-specific coding needs are met by developing a full Clinical Modification (CM) for ICD-11.

Discussion

Dr. Mays stressed the urgency of research and action on ICD-11 to ensure that the United States can coordinate ICD-11 implementation and development of a U.S. morbidity linearization with WHO. Dr. Mays also emphasized that focusing research and implementation solely on codes that are frequently used for clinical care and reimbursement may overlook other important medical coding uses (e.g., research, identification of potential innovations). For example, in behavioral health and SUD treatment, coding can capture not only diagnoses but also specific signs and symptoms, which can enable researchers to develop effective pharmacological interventions.

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

Review of Subcommittee's 2024 Efforts

A major 2024 priority of the Subcommittee on Standards was development of its scoping document titled "*Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange Working Document*." From this process, the Subcommittee identified four topic areas on which to focus:

- Identify where future NCVHS recommendations might fit into the ASTP/ONC and HHS 2020–2025 strategic plans.
- Examine mature and emerging standards and how they can co-exist to support current and future business needs and their workflows.
- Review relevance of HIPAA in the current health care ecosystem.
- Encourage harmonization of health care standards and data.

To develop this document, the Subcommittee has held regular consultations with the CMS National Standards Group (NSG) and ASTP/ONC. These consultations have been particularly relevant for the first goal regarding strategic plans.

The Subcommittee held multiple education sessions in 2024:

- VBC models vs. fee-for-service: implications for HIPAA administrative transaction standards
- SDOH data elements, health equity measures, essential human needs, and social services
- Introduction to the Trusted Exchange Framework and Common Agreement (TEFCA)
- HIPAA exception process overview

The Subcommittee also developed content for 2025 education sessions on health care data harmonization.

The Subcommittee recently developed two RFIs. The RFI on "HIPAA Exceptions Process to Test a Proposed Modification of a HIPAA Standard" seeks to gather information on the HIPAA exceptions process and provide feedback to inform recommendations to the HHS Secretary on the exceptions process. This RFI encourages responses from HIPAA covered entities (CEs), SDOs, and other interested parties. The RFI's questions cover five focus areas: (a) instruction/guidance regarding the exceptions process, (b) application process for

exceptions, (c) exception process and trading partners, (d) impacts of exception process, and (e) potential next steps and changes once exception testing is completed. The RFI also seeks input on other topics, such as exception standard testing.

The RFI on "Harmonization of Standards and Data for Healthcare Interoperability" seeks to gather information to help modernize the health care data ecosystem's standards-driven infrastructure. Feedback will inform a Subcommittee report or recommendations to the HHS Secretary. This RFI encourages responses from SDOs, health care terminology organizations, entities that specify health care data standards, and health care standards implementers. The RFI's questions cover six focus areas: (a) harmonization of standards and data for interoperability, (b) data elements, (c) medical terminologies and code sets, (d) security and data privacy, (e) information exchange formats, and (f) methodologies for data harmonization. The RFI also encourages respondents to describe their efforts to harmonize health care data standards as well as challenges and opportunities in implementing new or updated standards.

Both RFIs have been submitted for processing and publication in the *Federal Register*. Interested parties can sign up for the NCVHS listserv on the NCVHS website to receive email notifications when these RFIs are released.

Proposed Transaction Standards and Operating Rules

The Council for Affordable Quality Healthcare, Inc. (CAQH) Committee on Operating Rules for Information Exchange (CORE) recently proposed multiple updated and new operating rules:

New / Updated	Proposed Rule	Corresponding Currently Mandated Rule (for updated rules)
Updated	CORE Payment & Remittance Electronic Funds Transfer (EFT) Enrollment Data Rule vPR.2.0	CAQH CORE Payment & Remittance EFT Enrollment Data Rule Version PR.1.0
Updated	CORE Required Maximum EFT Enrollment Data Set Companion Document	
Updated	Core Payment & Remittance Electronic Remittance Advice (ERA) Enrollment Data Rule vPR.2.0	CAQH CORE Payment & Remittance ERA Enrollment Data Rule Version PR.1.0
Updated	CORE Required Maximum ERA Enrollment Data Set Companion Document	
New	CORE Health Care Claim (837) Infrastructure Rule vHC.2.0	Not applicable
New	CORE Health Care Claims (837) Data Content Rule, vHC.1.0	
New	CORE Claim Acknowledgement Data (277CA) Content Rule vCA.1.0	
New	CORE-required Error Code Combinations for CORE-defined Business Scenarios	

CAQH CORE has stated that the updated electronic funds transfer (EFT) and electronic remittance advice (ERA) will provide multiple benefits, including the following:

- Improved machine readability
- Greater transparency of EFT fees
- Ability of health care providers to opt in or out of non-EFT payments

- Updates to EFT and ERA datasets
- Ability to enroll health care providers in bulk and standardize data element groups
- Timely notifications and confirmations for health care provider enrollment
- Improved guidance on alternative payment methods

CAQH CORE has also stated that its new 837 claim submission and claim acknowledgment rules will standardize telehealth reporting processes and coordination of benefits requirements and will increase the capacity of diagnostic codes per 837 claim from 12 to 14.

For any proposed operating rules, NCVHS obtains feedback from a wide array of interested parties in the health care industry on multiple aspects, including potential benefits and costs resulting from the proposed rules, necessity (or lack thereof) of implementing these new rules, and how the proposed rules support the objectives of HIPAA and the ACA. Based on these inputs, NCVHS makes recommendations to the HHS Secretary regarding adoption of the proposed rules.

CAQH CORE will present on these proposed operating rules to the Subcommittee in December 2024. The Subcommittee will consult with the Workgroup for Electronic Data Interchange (WEDI) and CMS regarding these rules, and will hold a meeting with other interested parties (e.g., health care providers, payers) in April 2025 to gather additional feedback.

Discussion

Mr. James suggested notifying interested parties about CAQH CORE's presentation in December to enable them to prepare for the feedback session in April 2025. He also asked about the length of CAQH CORE's presentation. Ms. Banks responded that the Subcommittee did not specify a length because it does not want to force CAQH CORE to condense a large amount of information into a short presentation.

Update from the Subcommittee on Privacy, Confidentiality, and Security Update—Val Watzlaf, Chair, Subcommittee on Privacy, Confidentiality, and Security

Dr. Watzlaf reviewed the Subcommittee on Privacy, Confidentiality, and Security's past activities, which serve as a foundation for the Subcommittee's ongoing work. In 2019, NCVHS released its *Beyond HIPAA* framework, which lays out foundational privacy protections. The Subcommittee drafted two recommendation letters in 2022 and a third in 2023, which were approved by the Full Committee and delivered to HHS Secretary Becerra. The first letter covered best practices for collecting, using, protecting, and sharing personally identifiable information during a PHE. The second focused on strengthening cybersecurity in the health care sector, and the third provided a risk analysis and recommendations for strengthening the Security Rule. Also in 2022, the Subcommittee released an environmental scan conducted by Cason Schmit (Texas A&M University) that reviews health care privacy and legislative developments related to security protections across the states. In June 2023, the Subcommittee provided comments to the Office of Civil Rights (OCR) on a proposed update to the HIPAA Privacy Rule to support reproductive health privacy. HHS cited the Subcommittee's recommendations in the Final Rule.

Privacy and Security in Health Data Access

In a presentation to the Full Committee in April 2024, Tim Noonan (OCR) described OCR's beliefs that an individual's right to access their personal health information (PHI) is essential to their ability to make informed medical decisions and that this right is a cornerstone of the HIPAA Privacy Rule. Past OCR support for this right includes rulemaking, guidance, technical

assistance, outreach, and training. However, a large volume of complaints delivered to OCR still pertain to individuals' ability to access their PHI, including issues with timeliness or excessive cost. The Subcommittee developed a project proposal to investigate the source of these issues. In September 2024, the Subcommittee invited panelists to discuss their concerns about privacy and security in health data access.

Panelists reported on the lack of regulation regarding health data applications and the need for a national campaign to educate health care providers, application developers, and members of the public about the privacy and security risks associated with health data applications not covered by HIPAA. Panelists expressed frustration with the patchwork of state laws that govern PHI sharing and voiced support for creating a national privacy law that standardizes the PHI sharing process. Panelists reported concerns about business associates who use PHI in a network environment, which may share data with non-CEs and therefore fail to protect data privacy and security. Panelists also reported that members of the public increasingly believe that data privacy is impossible to maintain; they expressed uncertainty about what steps would bolster faith in privacy protection. Panelists noted that reidentification decreases trust between consumers and data holders. They reported a need for infrastructure to facilitate data sharing between public health, social services, and other entities; many data infrastructure issues surfaced during the COVID-19 pandemic. Finally, the panelists expressed a need to clarify the HIPAA Privacy Rule in terms of sharing PHI with public health authorities. Despite being updated, 42 CFR Part 2 regulations can hinder the sharing of SUD data because they require consent for treatment payment and health care operations.

The Subcommittee will hold future panels to address its remaining questions on privacy and security in health data access and to solicit the perspectives of engaged partners including federal agencies, patients, and providers. The remaining questions include how CEs can confirm identity validity and purpose of use assertions, what standards third parties should meet to ensure protection of PHI, and how the identity and authorization of any requester can be verified without impeding timely access to medical records. The Subcommittee will ask representatives of federal agencies the appropriate auditing and enforcement provisions for (a) violations of timely access to medical records or (b) misuse of consent, authorization, or identity when PHI is disclosed. The Subcommittee will also investigate the challenges that both patients and providers face when patients request PHI and appropriate education for patients about privacy and security risk.

Based on past and planned panels, in the second quarter (Q2) of 2025, the Subcommittee will draft a letter of recommendation for Full Committee consideration.

Potential Future Workstreams

Dr. Watzlaf discussed several topics that the Subcommittee will explore further before deciding whether to develop recommendations for consideration by the Full Committee.

<u>HIPAA Security Rule</u>
In December 2024, OCR will issue an update to the HIPAA Security Rule that aims to improve cybersecurity in the health care sector by strengthening requirements for HIPAA CEs to safeguard electronic PHI and to prevent, detect, contain, mitigate, and recover from cybersecurity threats. The Subcommittee will read the proposed rule and decide whether a response is warranted. If so, the Subcommittee will draft a formal response letter in April 2025 for Full Committee consideration in May or June 2025. However, this timeline may be compressed based on the comment period provided; the Full Committee may need to convene ad hoc meetings to seek input and consider a draft response letter depending on

the comment period. This exploratory work has already started and will continue through Q2 2025.

Civil Monetary Penalties under HIPAA
In April 2022, OCR issued an RFI that focused on (a) defining compensable harm and (b) identifying best practices for sharing a percentage of civil monetary penalties and monetary settlements with harmed individuals. The RFI included the following questions:

- What constitutes compensable harm with respect to violations of the HIPAA rules?
- Should potential or future harm be compensable?
- Should OCR allow individuals to include actual and perceived harm?
- Should harm be presumed in certain circumstances?
- Should HHS recognize as harm the release of information about a person other than the individual who is the subject of the information (e.g., a family member whose information was included in the individual's record as family health history) for purposes of sharing part of a civil monetary penalty or monetary settlements?
- Should there be a minimum total settlement or penalty amount before HHS sets aside funds for distribution?
- How should harmed individuals be identified?
- How should harmed individuals be notified that they may be eligible for distributions?
- What goals should HHS prioritize when selecting a distribution model?
- What additional factors or information should HHS consider in developing a proposed methodology to share a percentage of civil monetary penalties and monetary settlements with harmed individuals?

The Subcommittee will decipher and categorize the RFI responses to determine whether to pursue this topic. This exploratory work is slated to start in Q3 2025.

Accounting of Disclosures
Accounting of disclosures is an area of interest for OCR and an outstanding requirement of the 2011 Health Information Technology for Economic and Clinical Health Act. In 2018, OCR published an RFI with questions that centered on several key themes related to care coordination, one of which was accounting of disclosures. OCR received more than 1,300 responses. Many respondents that addressed the topic raised concerns about industry burden. In addition, in 2021 OCR issued a Notice of Public Rulemaking (NPRM) that aimed to strengthen HIPAA by removing barriers to and otherwise supporting coordinated care and individual engagement. The Subcommittee will review comments from the 2018 RFI and the 2021 NPRM and may hold further discussions with OCR and briefings with industry representatives to gather more information. This exploratory work is slated to begin in Q3 2025.

Privacy and Security of Telehealth
The Subcommittee is interested in how health information is transmitted, protected, and kept secure in telehealth environments. To explore this topic, the Subcommittee may conduct an environmental scan, invite OCR to brief NCVHS at a future public meeting, or hold panel briefings. This exploratory work is slated to begin in Q4 2025.

Discussion

Ms. Bernstein and Dr. Watzlaf discussed past Subcommittee comments on OCR rulemaking. When OCR issued an NPRM for the HIPAA Reproductive Health Privacy law, the comment period was 60 days. The Full Committee submitted comments to OCR within the specified time limit, which OCR cited throughout its rulemaking. Ms. Bernstein added that, in that case, OCR directly invited the Full Committee to comment, which is unusual but indicates

that OCR highly values the expertise of the Full Committee, and by extension the Subcommittee.

Mr. Kelly asked whether any HHS rulemaking considers the potential privacy and security benefits if the health care sector adopts digital identity management, which may help ensure the accurate matching of identity and health records and improve security and ease for patients in health data access. Dr. Hodgkins observed that CLEAR is one of five digital identity management companies that have met the requirements of the National Institute of Standards and Technology SP 800-63 rev.3 Class of Approval at Identity Assurance Level 2. Mr. Kelly explained that another company, ID.me, offers digital identity management that has been adopted for government use—including by CMS Medicare and the Social Security Administration—and may therefore offer insight about secure digital identity management for government agencies. Dr. Watzlaf agreed that receiving input from both CLEAR and ID.me would be valuable.

Dr. Mays suggested that NCVHS could write recommendations to HHS that strengthen security standards for health data applications. HHS could require health data applications that are funded by HHS to meet privacy and security requirements. Dr. Mays noted that these applications already must meet ethical standards and suggested that privacy and security standards could be administered similarly. Ms. Bernstein observed that HIPAA applies to health data applications provided by CEs, whereas the Federal Trade Commission (FTC) has authority over health data applications that are not provided by CEs. FTC targets unfair and deceptive trade practices but does not require security standards across industries. HHS could provide guidance or recommendations but may not have authorities to require a warning or standards or security. Dr. Mays and Ms. Bernstein agreed that NCVHS could engage in fruitful partnerships with FTC and the Federal Communications Commission (FCC) and its Federal Advisory Committees. These partnerships may aid all parties in understanding which agencies have the authority to set and enforce privacy protections and whether new authorities must be established.

Mr. Kelly observed that CMS and ASTP/ONC have different sets of rules for patient access application programming interfaces, both of which address interoperability for patients, payors, and providers. Mr. Kelly praised the implementation of these two sets of rules and suggested that the Subcommittee investigate the best practices of each, which could form the basis of a unified health data access rule. Further, Mr. Kelly suggested that a single operating body should administer the unified rule.

National Standards Group (NSG) Update—Michael Cimmino and Kathleen McGinty, National Standards Group, CMS Office of Burden Reduction and Health Informatics

NSG is focused on modernizing and streamlining the HIPAA standards development and adoption process to ensure that it keeps pace with industry needs and technological innovation. The adoption of HIPAA standards has resulted in efficiencies and cost savings, especially in claims payment and eligibility transactions. However, the development and adoption of new and updated standards has not been predictable or consistent in recent years.

To promote predictable and consistent HIPAA standards development and adoption processes, NSG aims to ensure that the required standards setting organization (SSO) consultation, Designated Standards Maintenance Organizations (DSMO) coordination, and public stakeholder engagement occur during the HIPAA standards development and adoption processes. NSG hopes that improved consensus building across SSOs, DSMOs, subject matter experts (SMEs), and the public during standards development will improve the resulting standard and streamline the processes by reducing duplicative reviews and

evaluations. Further, ensuring predictable and consistent HIPAA standards and development processes will enable NSG to align adoption of HIPAA standards with SSO releases and NCHS recommendations.

Mr. Cimmino and Ms. McGinty reviewed the key topics that NSG has investigated over the past year to understand the HIPAA standards development and adoption processes. NSG has focused on (a) reviewing the law to identify the statutorily designated process for standards development and adoption, (b) identifying specific opportunities to streamline the HIPAA standards development and adoption process, and (c) clarifying requirements for participation in the standards development and adoption process.

NSG utilized three main strategies to address these topics. One strategy was collaborating with NCVHS on an RFI that addresses requests for exception from HIPAA standards to test new standards versions. Both Mr. Cimmino and Ms. McGinty emphasized the importance of this RFI and the role that the responses will play in deepening NSG's understanding of HIPAA standards testing, which is a crucial part of the standards development and adoption processes. A second strategy involved seeking guidance broadly, including from advisory bodies (e.g., NCVHS and WEDI), other organizations such as the DSMO Steering Committee and individual DSMOs, and other engaged partners. The third strategy involved reviewing prior changes to HIPAA standards development and adoption and their impact on the industry partners that engage with these processes. NSG's analysis identified opportunities for increased consultation between SSOs, DSMOs, WEDI, and SMEs across the health care industry. NSG believes that increased consultation with these entities will result in stronger HIPAA standards and a streamlined HIPAA standards development process by reducing duplicative reviews later in the process.

During the NSG review of the HIPAA standards development and adoption processes, NCVHS recommended that NSG develop guidance for industry partners on measuring the readiness of a standard for adoption. In 2025, NSG hopes to publish guidance on this issue, which the SSOs can use when evaluating their own standards.

NSG hopes to act early in 2025 to ensure consultation and coordination across SSOs, DSMOs, and SMEs, which will highlight and improve consensus among these entities during standards development. NSG also hopes to foster robust public engagement to ensure that a proposed HIPAA standard is ready for adoption when it is submitted to SSOs. NSG will collaborate with WEDI, HHS agencies, DSMOs, and SSOs to conduct a coordinated public outreach and education strategy and increase awareness of the HIPAA standards development and adoption processes among industry partners.

Discussion

Ms. Banks thanked the speakers and emphasized the importance of responding to the RFI regarding requests for exception from HIPAA standards to test new standards versions. She also asked the speakers to comment on operating rules for non-HIPAA-mandated standards; Mr. Cimmino indicated that he would follow up with Ms. Banks later on this topic.

Ms. Banks also asked whether NSG plans to release an RFI or a proposed rule for comment for the CAQH CORE operating rules in Version 5010 of the X12 standards for HIPAA transactions. Mr. Cimmino indicated that he cannot comment on the timing of forthcoming rules but that NSG would establish comment periods that enable NCVHS participation.

NCVHS Workplan Development—Tammy Feenstra Banks, Steven Wagner, and Val Watzlaf, NCVHS Full Committee

Standards Subcommittee—Tammy Feenstra Banks and Steven Wagner

Ms. Banks and Mr. Wagner reviewed the three areas of focus for the Standards Subcommittee in 2025: two RFIs and a planned recommendation letter regarding CAQH CORE. One RFI pertains to requests for exception from HIPAA standards to test new standards versions, and the other pertains to data and standards harmonizations efforts. Both RFIs have been submitted to the *Federal Register*, and the Subcommittee anticipates that they will be published by mid-January. The RFIs will have 90-day comment periods. During Q1 2025, the Subcommittee will establish a structure for processing responses to the RFIs. During Q2 and Q3 2025, the Subcommittee will analyze the responses to the RFIs and compile and categorize the information. Also during Q3 2025, the Subcommittee will draft letters of recommendation for submission to the Full Committee for approval in Q4 2025.

The Subcommittee is currently reviewing CAQH CORE rules. During Q1 2025, the Subcommittee will organize a panel for a hearing on the rules, which is scheduled for April 21, 2025. The Subcommittee plans to draft and then finalize for NCVHS consideration a recommendations letter in Q2 and Q3, respectively, based on the information gathered from the panel.

Subcommittee on Privacy, Confidentiality, and Security—Val Watzlaf

Dr. Watzlaf reviewed the Privacy, Confidentiality, and Security Subcommittee's planned areas of focus for 2025. The Subcommittee will hold panel briefings in early 2025 to gather information about privacy and security in health data access. This information, together with information from panels convened in September 2024 on the same topic, will shape a final letter of recommendation that the Subcommittee will submit to the Full Committee for consideration in Q3 2025. The Subcommittee will also review OCR's December 2024 proposal for an update to the HIPAA Security Rule and determine by January 2025 whether comments on the proposed rule are warranted. Dr. Watzlaf reiterated that the Subcommittee will adjust the timeline to ensure that NCVHS comments are submitted within OCR's designated comment period.

Other potential future workstreams for the Subcommittee pertain to civil monetary penalties, accounting of disclosures, and the privacy and security concerns associated with telehealth. The Subcommittee will determine whether these topics should be addressed via recommendations. Based on feedback from other NCVHS members, the Subcommittee may instead decide to focus on other topics such as the privacy and security challenges associated with health data applications. In this case, the Subcommittee will invite representatives of FTC and FCC to discuss this topic. Dr. Watzlaf encouraged NCVHS members to continue to provide comments and questions about proposed Subcommittee workstreams.

ICD-11 WG—Jamie Ferguson

The ICD-11 WG will focus on identifying an appropriate U.S. morbidity linearization for ICD-11 by investigating three areas: (a) novel morbidity coding requirements for ICD-11 that are not included in ICD-10 or ICD-10-CM, (b) morbidity codes in ICD-10 and ICD-10-CM that are not necessary for ICD-11, and (c) the ICD-11 for Mortality and Morbidity Statistics. The WG will consider releasing an RFI and using other information-gathering mechanisms to investigate these areas. Then, the WG will turn its attention to ICD-11 post-coordination and

extension codes as well as considerations for ICD-11 adoption and implementation. The WG will update NCVHS during the next Full Committee meeting.

Discussion—NCVHS Full Committee

Full Committee members discussed their priorities for 2025. They agreed that the Full Committee should address any priorities established by an incoming HHS Secretary, pursuant to the NCVHS mandate, while continuing work on already identified important topic areas. While NCVHS members identified many significant and potentially fruitful efforts to undertake, they recognized that staff and member resources limit the number of topic areas that can be fully addressed.

Discussion: Beyond HIPAA
Health data collected and maintained by non-HIPAA CEs are an important and expanding area of interest for NCVHS members. Therefore, NCVHS members decided that the key presentations during the next Full Committee meeting should focus on data policies that fall outside of HIPAA. Members agreed that this topic aligns well with the meeting's theme: past, present, and future of NCVHS. In January 2025, Ms. Banks, Dr. Watzlaf, and Mr. Kelly will collaborate on plans for that meeting, including by reviewing prior NCVHS recommendations pertaining to privacy protections outside of HIPAA. NCVHS staff will invite other Committee members to participate in this planning discussion.

Ms. Bernstein suggested that a prior NCVHS letter that recommended that all health data regardless of its provenance should have a baseline level of privacy protections may be relevant to these discussions. Ms. Banks and Mr. Wagner observed that the Standards Subcommittee's RFI about harmonization will provide some insight into data standardization outside of HIPAA authority. NCVHS members also discussed the possibility of restarting an ad hoc workgroup to address privacy, security, and standards concerns outside of HIPAA's domain. However, because similar prior efforts failed to produce recommendations and because the Committee's time and budget are limited, Full Committee members decided to not pursue this ad hoc workgroup.

Dr. Mays and Mr. Kelly highlighted the privacy and security concerns posed by wearable devices (e.g., glucose monitors and watches), which can extend access to care by collecting health information and sharing that information with physicians and patients. However, the companies offering wearable devices are often not HIPAA CEs or business associates and may not have rigorous privacy and security standards. Mr. Kelly emphasized that companies gather vast quantities of health data via wearable devices. Dr. Mays also observed that, by mining health data and selling insights gleaned from those data back to consumers, companies offering wearable devices may undermine consumer trust.

Discussion: Modernizing HIPAA
NCVHS members agreed on the importance of modernizing HIPAA standards to keep pace with technology innovations. Mr. Kelly highlighted that technology vendors were once regulated as business associates under HIPAA provisions but that this regulation has since eroded because HIPAA standards have not been updated as technology vendors have evolved beyond HIPAA-defined categories.

Further Discussion
Dr. Mays emphasized the importance of ensuring that telehealth services are secure and suggested that the Subcommittee on Privacy, Confidentiality, and Security prioritize this potential workstream. She highlighted the rapid expansion of telehealth services during the COVID-19 pandemic and the unresolved data privacy challenges associated with interstate telehealth delivery.

Dr. Mays and Mr. Kelly also observed that HHS and many interested partners in the health care sector have advanced their understanding of SDOH, and voiced support for NCVHS' exploring both health care services data and SDOH data to understand drivers of health outcomes and quality of life. Dr. Mays suggested that Full Committee members could improve both health care and public health by strengthening their work on SDOH.

Next Steps & Wrap-Up

The next Full Committee meeting is scheduled for March 18-19, 2025, and will be a hybrid meeting.

Closing Remarks & Adjourn—Naomi Michaelis, DFO

Ms. Michaelis thanked speakers, panelists, and attendees for their input, feedback, and discussion during this meeting. In recognition of her departure from NCVHS, Ms. Banks and Ms. Michaelis thanked Dr. Xu for her work on the Committee.