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:

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
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
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 members state their name, status as a special government employee, and any conflicts of interest for this meeting. No 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 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. First, she described several administrative priorities, including that the U.S. Department of Health and Human Services (HHS) continues to guide its activities according to the goals outlined in the 2022 HHS Strategic Plan: (a) protect and strengthen equitable access to high-quality and affordable health care; (b) safeguard and inform national and global health conditions and outcomes; (c) strengthen social wellbeing, equity, and economic resilience; (d) restore trust and accelerate advancements in science and research for all; and (e) advance strategic management to build trust, transparency, and accountability. HHS has also made considerable progress toward other agency goals, including to expand behavioral health services with a focus on prevention and access to care.

KidneyX Sustainability Challenge

Earlier this month, in collaboration with the American Society for Nephrology, HHS launched the KidneyX Sustainability prize, which is a $7.25 million challenge that aims to improve the sustainability of kidney care. This challenge calls for innovative solutions that reduce the resource demands related to maintaining dialysis—which consumes vast amounts of water and power. HHS will announce the winners in early 2025.

Medicare Price Negotiations

The Biden-Harris Administration recently announced agreements for reduced prices on 10 of the most expensive and frequently used Medicare treatments. These prices, effective January 1, 2026, will save Medicare an estimated $6 billion and reduce out-of-pocket costs for beneficiaries by $1.5 billion.

National Heat Strategy

The Interagency National Integrated Heat Health Information System developed the National Heat Strategy for 2024-2030 to protect communities from the growing threat of extreme heat. The Centers for

Disease Control and Prevention (CDC), the HHS Office of Climate Change and Health Equity, the National Oceanic Atmospheric Administration, and the Federal Emergency Management Agency (FEMA) led the interagency effort with representatives from 29 federal departments and agencies. The Strategy recognizes heat as the leading weather cause of death in the United States and underscores the serious health risks of excess heat to humans, animals, ecosystems, and society. It emphasizes the need for cross-sector partnerships and addresses the compounding environmental challenges presented by heat in tandem with other climate stressors.

National Plan on Aging

The Administration for Community Living released the strategic framework for a national plan on aging, which lays the foundation for creating age-friendly communities that fully support older adults. This framework encourages partnerships across sectors to advance best practices for aging support.

Mental Health Updates

In August 2024, U.S. Surgeon General Dr. Vivek Murthy issued an advisory highlighting the urgent need to prioritize the mental health and wellbeing of parents and caregivers. Approximately 33% of parents report high levels of stress, which can negatively affect the mental health of the parents and their children. This advisory calls for a cultural shift to better support parents and caregivers through policies and programs that promote paid family leave, affordable childcare, and accessible mental health care.

On April 23, 2024, CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA) released the 2024 National Strategy for Suicide Prevention, which outlines 200 actions to prevent suicide, such as integrating mental health and substance use disorder (SUD) care in clinical settings and supporting survivors of suicide loss.

In recognition of September as Suicide Prevention Month, SAMHSA awarded $68 million in grants to address suicide prevention and mental health programs, including state and tribal programs, college programs, and programs focused on youth in schools and juvenile systems. SAMHSA also announced $45.1 million in grants, with $15.3 million dedicated to services for children and youth. Funding will focus on mental health support in schools, services for children and families affected by trauma, and youth with mental health issues. Funding will also support programs focused on homelessness, grief support, and employment for individuals with serious mental illness.

The Administration for Children and Families launched new resources to support the mental health of young children and families and to promote healthy child development and integrate mental health into early education settings.

HHS also unveiled a national strategy aimed at addressing the maternal mental health crisis with recommendations developed by the Task Force on Maternal Mental Health. This strategy calls for a seamless integration of perinatal mental health and substance use care across medical community and social systems that increase equity and access to care, improve coordination, and elevate culturally relevant and trauma-informed approaches. Further, HHS has dedicated more than $500,000 to improve maternal mental health outcomes.

Maternal Health Updates

HHS funding for maternal mental health builds upon the White House's Blueprint for addressing the maternal health crisis, with more than $400 million to expand vital home-visit programs and an additional $118.5 million to prevent pregnancy-related deaths. Much of this funding will be used to enhance voluntary, evidence-based maternal, infant, and early childhood services. In a complementary effort, CDC is investigating public health infrastructure aimed at preventing pregnancy-related deaths; this work will build upon the efforts of maternal mortality review committees. These committees play a crucial role in reviewing pregnancy-related deaths, identifying preventable factors, and making recommendations to improve maternal health outcomes.

HHS has dedicated $105 million through the Healthy Start Initiative to more than 100 community-based organizations across the United States. This funding is targeted at high-need communities where maternal and infant mortality rates are significantly higher than the national average. By offering culturally responsive care, transportation, food assistance, and other social supports, Healthy Start aims to close gaps in health disparities and improve outcomes for mothers and infants in vulnerable communities.

Opioid Crisis Response Updates

On June 25, 2024, HHS Secretary Xavier Becerra renewed the opioid public health emergency (PHE) for another 90 days. As part of its commitment to implementation of evidence-based practices to address the opioid crisis, the Biden-Harris Administration announced more than $1.5 billion in funding opportunities for state, local, tribal, and territorial opioid response programs. This funding will be distributed through SAMHSA to strengthen evidence-based holistic practices, including prevention, harm reduction, treatment and recovery services. HHS aims to build on previous successes, including 500,000 overdose reversals and distribution of 1 million naloxone kits in 2024. SAMHSA's 2023 National Strategy on Drug Use and Health highlighted the ongoing challenges of substance use and mental health across the United States. This report revealed that 22.8% of adults experienced mental health conditions in the past year, and 3.1% of individuals misused opioids. Notably, mental health treatments increased, with more adolescents and adults receiving care, compared to previous years.

Public Health Emergencies

Recently, Secretary Becerra has declared five national health disasters related to PHEs in response to Hurricane Francine. On September 12, HHS deployed disaster management professionals and a health care situational assessment team to Baton Rouge, Louisiana, integrating with FEMA and state officials to address the medical needs of people in affected areas. Teams will ensure that hospitals, nursing homes, and other health facilities can continue to provide care during and after the storm. PHEs have also been declared for Florida, Georgia, and South Carolina because of the health impacts of Hurricane Debby. The Administration for Strategic Preparedness and Response (ASPR) deployed approximately 50 medical providers and disaster management professionals to assist with facility assessments, patient care, and evacuations. HHS renewed the PHE for Hawaii on August 1 in response to the continued impacts of Maui wildfires. ASPR remains on standby to deploy additional resources as needed to support public health and medical needs following the severe weather of Hurricane Beryl, for which a PHE was declared on July 12. ASPR teams have been working closely with state officials to address the combination of severe heat and power outages, which has impacted more than 1 million U.S. residents. HHS continues to provide

resources to ensure that vulnerable populations have access to the care they need during this recovery effort.

Health Care Workforce Training and Support

Several initiatives have recently launched as part of the Biden-Harris Administration's ongoing commitment to strengthen the health care workforce and improve care for vulnerable populations. On July 1, the Administration announced an investment of more than $200 million through the Health Resources and Service Administration (HRSA) to support 42 programs that aim to improve care for older adults, including those with Alzheimer's disease and related dementias. At the forefront of this effort, the Geriatrics Workforce Enhancement Program trains primary care physicians, nurse practitioners, and other health care clinicians to provide age- and dementia-friendly care. HRSA also recently announced a $2.5 million investment in the first licensure portability grant program, which aims to ease barriers to licensure, expand telehealth services, and increase access to mental health and SUD treatment by allowing social workers to practice across state lines.

Earlier this year, HHS, in collaboration with the U.S. Department of Labor, announced two technical assistance programs to help states recruit, train, and retain direct care workers. This workforce is critical in providing home and community-based services for older adults and individuals with disabilities. This initiative includes key data recommendations for future policies that will improve job quality for direct care workers.

Ryan White HIV/AIDS Program

Last month, HRSA announced more than $1.4 billion in funding for the Ryan/White HIV/AIDS Program, ensuring lifesaving HIV medications and care for more than 290,000 low-income individuals living with HIV. HRSA funding supports drug assistance programs in covering costs of copays, insurance premiums, and related health care services. Without such support, the cost of HIV medication could exceed $40,000 annually, making treatment inaccessible to many.

Insurance Navigator Grants

Ahead of the 2024 marketplace open enrollment, the Centers for Medicare & Medicaid Services (CMS) awarded $100 million to 44 navigator grants to help millions of individuals, particularly those in underserved communities, access affordable care and health care coverage through healthcare.gov. Navigators provide free assistance for health care assistance, thus helping to reduce barriers to receiving care for many Americans. This effort is part of a 5-year commitment of up to $500 million to expand navigator services.

Rulemaking Activities

Dr. Lessem described recent rulemaking activities aimed to expand health care coverage, increase access to care, and ensure research integrity. HHS, the Department of Labor, and the Department of the Treasury issued Final Rules aimed at strengthening protections for more than 150 million people with private health coverage. These rules clarify and strengthen requirements for coverage of mental health and SUD treatments under the Mental Health Parity and Addictions Equity Act of 2008.

CMS issued a Final Rule updating Medicaid payments and policies for inpatient and long-term care hospitals. For Fiscal Year 2025, this rule includes a 2.9% increase to payment rates for certain acute care hospitals and a 3% increase for long-term care hospitals. This rule enhances resources for hospitals and strengthens emergency preparedness by implementing streamlined data reporting for future PHEs. In addition, CMS issued three Final Rules to support caregivers, enhance worker compensation, and improve care quality in nursing homes. These rules establish minimum staffing standards for nursing homes, improve Medicaid and Children's Health Insurance Program (CHIP) access, and create transparency in managing care. CMS has proposed rules to reduce mortality and morbidity, particularly in underserved communities, and a rule focused on the Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System, which aims to expand access to care in Indian Health Service (IHS) and tribal facilities, enhance maternal health services, and improve access to care for formally incarcerated individuals.

In addition, in September 2024, the Office of the Assistant Secretary for Health (OASH) and HRSA proposed a rule that would remove burdensome clinical research and institutional review board (IRB) requirements for kidney and liver transplants between HIV-positive donors and recipients, thus expanding access to life-saving transplants.

Finally, the Office of Research Integrity finalized a rule on Public Health Service Policies on Research Misconduct, which updates 2005 regulations in response to advances in technology and the evolving research landscape. Taking effect on January 1, 2025, this Final Rule enhances institutional responsibilities, streamlines misconduct investigation processes, and clarifies institution discretion in handling research integrity issues.

HHS ONC Reorganization

On July 25, HHS announced a major reorganization to streamline and bolster the technology, cybersecurity, and progress in meeting the national artificial intelligence (AI) strategy. The Office of the National Coordinator for Health Information Technology will be renamed as the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC), thus consolidating oversight over HHS' technology, data, and AI efforts. This reorganization will include moving the 405(d) Program from the Assistant Secretary for Administration to ASPR. The new ASTP/ONC office is actively recruiting candidates for open positions, including Chief Technology Officer, Chief Data Officer, and Chief AI Officer.

NCVHS Membership Updates

Dr. Lessem reviewed position transitions within NCVHS. Jacki Monson completed her term as NCVHS Chair, leaving the position open. Ms. Michaelis, the new NCVHS Designated Officers (DFO), is serving as Acting Chair until a new Chair is appointed. Dr. Lessem also thanked Ms. Denise Chrysler and Ms. Debra Strickland for their dedication and contributions to NCVHS as their terms have completed. Dr. Wu Xu will also complete her term early next year. Three new NCVHS members have been nominated and are onboarding.

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 (HIEs) 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 allow participants to share data in accordance with specified agreements, policies, and technical specifications.

A key difference between these newer health information networks and previous point-to-point data sharing is automated data sharing, which occurs because networks now assume some of the responsibility for ensuring compliance with relevant laws, rules, and agreements. Previously, records requested from an institution would be reviewed for compliance before a physical or digital copy would be transferred to the requesting organization; today, the organization receiving the request may not participate directly in the data request, with the data instead being automatically transferred within the network.

National exchanges are working to align policies with Trusted Exchange Framework and Common Agreement™ (TEFCA), a voluntary network for national HIEs; Ms. McGraw noted that TEFCA may replace the need for multiple different national networks, rendering some of the longstanding national networks unnecessary. Many of the current national networks rely on various staff to facilitate necessary data transactions, whereas TEFCA will limit the number of entities that can facilitate data exchanges. Under TEFCA, data will be exchanged by Qualified Health Information Networks (QHINs) under oversight of The Sequoia Project, a Recognized Coordinating Entity. Participants in TEFCA will choose a QHIN to conduct exchanges and transfer data through any of the QHINs in the network.

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

Ms. Myers shared the American Medical Association (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, health information can now be shared on mobile applications that are not covered by Health Insurance Portability and Accountability Act (HIPAA). Ms. Myers emphasized that mobile applications should not receive protected health information (PHI) without a query by the data-sharing institution to assess the application's privacy and security practices. AMA has advocated for ASTP/ONC to implement basic privacy frameworks for mobile applications and data query applications for three items: the use of a relevant standard, a statement on transparency and best practices, and a model notice to patients.

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 in health care for individuals and populations. Healthcare Trust Institute's members include companies and organizations across the U.S. health care system. All members agree that enacting a national privacy standard is needed to continue to enable innovations in health care. In order to implement privacy protections and enhance trust in the health care system, the Institute's work is guided by the following principles:

- Robust privacy and security protections for PHI is essential for trust in the health care system, which is the foundation for the delivery of quality care and patient safety.
- All PHI, whether falling within or outside HIPAA, should be subject to regulation to ensure that data are used in a manner consistent with an individual's reasonable expectations. Uses for other purposes should require an individual's authorization and, where feasible, privacy-enhancing technologies should be implemented.
- Entities collecting and holding PHI should be required to have risk-based physical, administrative, and technical safeguards in place to protect that information from misuse and threats, including cyberattacks. These safeguards should be consistent with nationally recognized frameworks, such as the National Institute for Science and Technology (NIST) Cybersecurity Framework.
- Protections for PHI should be established at the national level to ensure consistency, clarity, and compliance as individuals and data increasingly travel across state lines. Avoiding data masking is also essential to ensure that the vision of national interoperability for health data exchange can be realized, leading to better care coordination and improved health outcomes.
- Principles of data minimization should be central to collection and processing of PHI, including through the use of deidentified data or privacy-enhancing technologies where feasible. To engender consumer and patient trust and public support, recipients of deidentified data should be prohibited from attempting to reidentify the data.
- Individuals should be provided clear and simple privacy notices that explain how any entity collects and processes PHI, as well as the individual's rights and choices with respect to health data. These rights should include the right to request access and corrections.
- HIPAA should remain the framework for the regulation of PHI in the health care industry.
- Regulation of PHI outside of HIPAA regulations should harmonize with the HIPAA framework, using similar concepts and definitions where appropriate, such as treating data deidentified in accordance with HIPAA as deidentified data for all purposes.
- Privacy protections must be enforced through meaningful penalties and a mechanism for individuals to be able to report violations without fear of retaliation.

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

Dr. Calhoun provided the American Health Informatics Association's (AHIMA's) perspective on data exchange processes in the health care sector, focusing on the role of health information professionals in health data access, privacy, and security. AHIMA is a global nonprofit association of health information professionals and a leading authority on health information in the health care industry. AHIMA's overall mission is to empower people to impact health. AHIMA is one of the designated cooperating parties for the *International Classification of Diseases 10th Revision*, *Clinical Modification* (ICD-10-CM), along with CMS, AMA, and the National Center for Health Statistics (NCHS). AHIMA also participates in a variety of coding standardization activities in the United States and internationally, acts as a source of coding education and professional development, and is engaged in standards development and use for

administrative data. AHIMA-certified health information professionals ensure that sensitive health information remains accurate, accessible, protected, and complete at all times.

Health information professionals often play a role in the first step of the data exchange process by compiling and maintaining medical records, processing the release of information and claims, and monitoring and analyzing data for research and reporting. These professionals work within a complex compliance environment in which they interact with various laws from different agencies (e.g., ASTP/ONC, CMS). They may encounter issues related to privacy and consent and may err on the side of denying or delaying requests to comply with every law. This environment is further complicated by a shifting landscape in which data are shared in more ways than ever before and at high speeds, patients have access to more of their data, and new tools and technologies are deployed.

Dr. Calhoun emphasized that improvements to HIPAA are needed because the scope of PHI has expanded and the patchwork of state and federal privacy laws challenges compliance. She encouraged NCVHS to enhance its understanding of how HIPAA interacts with broader privacy laws, determine how data should be treated after leaving HIPAA-covered entities (CEs), and explore opportunities to coordinate data exchange oversight and enforcement.

Discussion

Attendees discussed the types of information entities required to verify and trust the identities of data requesters. Panelists noted that entities use several methods, including requiring a valid ID and stating the data requester's name when requesting data over the phone. Ms. Grande noted that the healthcare.gov marketplace uses robust verification steps that NCVHS may consider as an exemplar of appropriate verification.

In response to a question about the requirements for disclosure from third-party applications, Ms. McGraw acknowledged that the standard operating procedure (SOP) recently released by TEFCA includes a breadth of requirements in relation to disclosure. When asked whether this SOP should become a standard, Ms. McGraw noted that HHS may lack the authority to make that SOP a standard. Ms. Myers noted that more robust standards and an enforcement and penalty system for disclosures would be helpful.

Ms. Grande encouraged NCVHS members to review the Request for Information (RFI) released by Congresswoman Ms. Diana DeGette and Congressman Dr. Larry Bucshon to obtain feedback on the next generation of the 21st Century Cures Act.

Mr. Jamie Ferguson asked panelists to share what they would change, within the confines of HIPAA, to improve outcomes for the health care system. Ms. Myers noted that she would prevent entities from requesting PHI and authorizations long before the patient receives treatment. Ms. Calhoun emphasized that most gaps exist when HIPAA-covered information is shared beyond CEs and that those gaps must be addressed. Ms. McGraw expressed that, although a necessary part of the health care system under HIPAA, many business associates do not conduct data transfers and security practices sufficient to protect PHI, leading to breaches. She emphasized that the gaps associated with business associates, and their expanded roles, should be addressed. Ms. Grande added that law enforcement should not be able to redisclose PHI that they receive.

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 (HIT) strategy to advance national goals for better and safer health care through an interoperable nationwide HIT infrastructure. Specifically, through the HHS HIT Alignment Policy, the HHS Secretary has directed ASTP/ONC to establish and oversee a consistent HHS-wide approach for (a) incorporating standard HIT requirements language in all applicable HHS funding programs, contracts, and policies and (b) providing direct ASTP/ONC assistance to HHS agencies to maximize the use of HHS-approved standards and authorities.

In July 2024, HHS announced the renaming of ONC to ASTP/ONC, thus expanding the office's scope to include oversight over AI strategy and policy. With this reorganization, the former ONC offices focused on technology, policy, and operations will be joined by a new office, the Office of the Chief Technology Officer. This office, led by a Chief AI Officer and Chief Data Officer, will focus on digital services that will provide assistance to operating partners in relation to AI and technology. ASTP/ONC will focus on building a digital foundation to underscore data standards and address HIT gaps, promoting information sharing and interoperability, ensuring responsible use of digital information, and advancing health AI.

ASTP/ONC has launched the U.S. Core Data for Interoperability + (USCDI+) Initiative to support Uniform Data System modernization, developed USCDI Version 3 (required to be supported in electronic health records [EHRs] in 2026), and established TEFCA to simplify health data exchange. New data classes incorporated in Version 3 include health insurance information, health status/assessments, and medications elements, as well as some laboratory and demographic elements. USCDI+ has launched efforts into a variety of areas, including behavioral health, maternal health, and public health. ASTP/ONC established TEFCA through the 21st Century Cures Act, officially enacted in December 2023 with seven QHINs that serve different areas of the health ecosystem. TEFCA's exchange purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange. The permitted purposes outlined in TEFCA are for treatment, payment, health care operations, public health, government benefits determination, and individual access services. A seventh purpose, research, has been discussed and may be added in the future. TEFCA has started to work on the exchange of public health information across participating public health authorities and health care organizations and to explore the incorporation of additional use cases.

Dr. Tripathi then described the current landscape of AI in the United States. One major component is core infrastructure, which is government wide and includes the U.S. AI Safety Institute at NIST, the National AI Research Resource at the National Science Foundation, and the Biden-Harris Administration's secured commitments from leading AI companies to manage risks posed by AI. Other components of the AI landscape are health care products and uses. Future commercial AI-related products will be required to meet longstanding Food and Drug Administration (FDA) regulations related to health care products. ASTP/ONC also implemented the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, which includes a section focused on algorithm transparency and describes what information could comprise a "nutrition label" for AI technologies. Dr. Tripathi then emphasized information related to health care uses: (a) providers, payers, and organizations covered by the Office of Civil Rights (OCR) Affordable Care Act Section 1557

cannot discriminate in any capacity, including when using results of an AI study, and (b) CMS has outlined limits on Medicare Advantage AI usage.

Discussion

In response to a question about evolving AI technology and its relation to the "minimum necessary" standard in HIPAA, Dr. Tripathi noted that ASTP/ONC does not have the authority to change this HIPAA standard; however, this standard is based on judgment and in the future, what is considered "minimum necessary" may evolve to better address AI innovations.

When asked where privacy work will be conducted in the new ASTP/ONC structure, Dr. Tripathi noted that a Chief Privacy Officer reports directly to him and that each office within ASTP/ONC addresses privacy considerations.

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 across the public health, social services, and health care sectors to improve access to care and advance health equity. Currently, the public health, social services, and health care sectors are fragmented and 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, which has enabled organizations to share more data than under previous frameworks to foster whole-person care.

Mr. Mijic highlighted three strategies to overcome siloes in health care: collecting and sharing of social services information using national standards; facilitating consent management for the exchange of health, social services, and public health information; and enabling information matching across data systems to ensure consistent and unified individual identification. He also outlined several critical considerations: reconcile varying state and federal requirements that may be in conflict or not fully aligned; balance privacy of data with access to data for providers and care teams to deliver care and services; and acknowledge lack of infrastructure in public health, behavioral health, and social services to exchange and use data.

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 PHE. Collecting and sharing data are also critical to identifying inequities in the health care system and potential approaches to overcome those inequities. 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 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.

Integrating public health data with health care data has proved challenging because often health care data are not as specific as data collected in public health entities. Dr. Fine emphasized that more tools are needed to help public health entities handle the volume of data being collected. She added that integration efforts should focus of getting the right information to the appropriate entities, staff, and patients to support decision-making while ensuring privacy and compliance with existing legislation at each step of the integration process.

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

Electronic health information from clinical care has been recognized as important for public health preparedness. During the COVID-19 PHE, 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 entities use HIEs and networks, in addition to leveraging state laws, HIPAA CEs, and public health disclosures, to conduct their data reporting and sharing efforts. Tools such as cloud computing can help to better connect health care and public health organizations. To facilitate these connections, legal and regulatory approaches must be enforceable in multiple jurisdictions and health care organizations, and these approaches must overcome different perceptions of federal and state laws. He highlighted several considerations that require more discussion:

- EHR data quality and consistency are important for public health uses (e.g., existing data quality efforts have been limited and standards can be applied more rigorously to improve quality without clinical impact).
- A public health purpose of use designation for public health reporting data should be used broadly and consistently (e.g., consistent enforcement of appropriate data reporting and sharing among HIEs and organizations is needed for entities outside of TEFCA).
- Perception of HIPAA language for disclosures to public health authorities can impede some exchange intermediaries. For example, "[t]he Privacy Rule permits CEs to disclose PHI without authorization to *public health authorities*…for the purpose of preventing or controlling disease, injury, or disability." In cases of disclosure through HIEs, confusion may arise regarding whether intermediaries involved in exchanges qualify as "public health authorities" in this context.
- Perception of conflicting federal regulations can be complex (e.g., although SAMHSA has stated that 42 CFR Part 2 does not block state-required reporting, some public health agencies mistakenly believe that they cannot obtain reports required by state laws if the patient is covered by such regulations).
- Public health agencies have trailed behind clinical care in HIT adoption and understanding of their data rights (e.g., various interpretations by state legal advisors is an ongoing issue).

Discussion

Dr. Loonsk confirmed that a major barrier in public health reporting is insufficient infrastructure to support the collection and sharing of public health data, which the public health sector is working to fix. Ms. Fine encouraged NCVHS to consider the necessary safeguards to protect the increasing body of public health data.

In response to a question, Ms. Fine shared that recent updates to 42 CFR Part 2 were good but not exhaustive to cover all needs 42 CFR Part 2 continues to require consent from the patient in order to transfer data.

Ms. Cathy Donald acknowledged the expected dramatic decrease in public health funding in the upcoming years and asked public health entities to consider how they will continue their progress in leaner financial times.

Dr. Qu Xu emphasized the need to include privacy and TEFCA-specific language into funding opportunities to ensure full compliance with TEFCA and privacy safeguards in public health reporting.

75th Anniversary Celebration Discussion

NCVHS members discussed planning updates for the NCVHS 75th Anniversary celebration in 2025, which will have the theme of "Past, Present, Future." In preparation for the event, NCVHS will develop a booklet to summarize its work over the past 15 years and note future planned efforts. The event will feature short videos (approximately 5 minutes each) from previous NCVHS Chairs and Subcommittee Co-Chairs, who will discuss their time with NCVHS and answer questions, such as:

- What have the impacts of your work been?
- What are you most proud of from your tenure?
- What would you do differently?
- What do you think the greatest impact of the committee's work has been?
- What do you think is the next thing?

Attendees discussed inviting speakers who can share historical insights, successes, and challenges and are well positioned to provide constructive comments that not only support NCVHS but also encourage NCVHS to grow and improve in an evolving HIT landscape—such as senior HHS officials and past NCVHS Full Committee and Subcommittee members and DFOs. Ms. Banks suggested inviting Ms. Linda Kloss, who served on the PCS Subcommittee, to speak during the event, because the topics of privacy, confidentiality, and security have significantly evolved since her term. Other suggested invitees were Ms. Suzie Burke-Bebee Dr. Leslie Francis, Ms. Marjorie Greenberg, Ms. Rebecca Hines, Mr. Rich Landen, Dr. John Lumpkin, Dr. Bill Stead and Dr. Walter Suarez.

Members identified several topics for panels, individual speakers, or discussions: the future of NCVHS and its role in a changing health care system, historical NCVHS successes, the definition of health data, the processes that occur after NCVHS makes recommendations, and celebrating victories. Members suggested forming panels composed of previous members who span different periods of work to provide different perspectives. Members also recommended featuring a memorial segment for NCVHS members and staff who have passed away.

Members suggested that NCVHS staff survey previous NCVHS Full Committee members to assess interest and availability to help identify who may be best positioned to record a video or present in person during the celebration.

—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 Subcommittee members state their name, status as a special government employee, and any conflicts of interest for this meeting. No members disclosed conflicts of interest.

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 ICD-11 Workgroup (WG)'s previous activities to explain how the WG arrived at its current priorities. The WG was chartered at the recommendation of an expert roundtable headed by former NCVHS Chair Bill Stead. Although the original recommendation was issued in 2019, WG formation was delayed by the COVID-19 pandemic. The WG was chartered in 2022 and fully formed in 2023. Its first work product was a global environmental scan of ICD-11 implementations and research; several countries had by that time published studies about their implementations. The WG also issued an RFI to gather input about ICD-11 implementation preparation from domestic stakeholders.

During summer 2023, the WG convened a roundtable meeting of 50 experts in diverse fields to discuss ICD-11 use cases, benefits, concerns, and areas for research. Participants identified areas where *ICD 10th Revision Clinical Modification* (ICD-10-CM) does not meet the needs of the medical community, including for mental, behavioral, and neurodevelopmental health. These unmet needs are key drivers of ICD-11 adoption. To account for national differences in morbidity coding needs, the WG expects that U.S. stakeholders will adopt World Health Organization (WHO) linearization for vital records, mortality, and statistical reporting but a domestic morbidity linearization for the international underlying ICD-11 framework.

During fall 2023, the WG developed a Phase 1 Report based on analysis of responses to its RFI and input from roundtable participants. Later, the WG released a second RFI to determine stakeholders' concerns with and expected benefits of ICD-11 implementation. Responses to the second RFI aligned with previous NCVHS recommendations and encouraged HHS and other stakeholders to start to plan for ICD-11, provide education and communication about ICD-11, and analyze its costs and benefits. The WG is updating its Phase 1 report to include the results of the second RFI.

RFI respondents believed that ICD-11 adoption would improve health care quality and safety, including by capturing more granular data on social determinants of health. Other expected benefits include improvements in reflecting current medical science and practice in research, greater coding precision and flexibility, and lowered software costs. Many commenters believe that automation and AI may drive burden reduction and better timeliness, accuracy, and productivity, including in the coding process. However, commenters also highlighted a lack of understanding of ICD-11. ICD-11 is structurally and syntactically very different from ICD-10, which heightens the need for education and training.

This analysis of responses to the second RFI indicated an array of key use cases for ICD-11. The WG contacted roundtable participants about costs and benefits for each stakeholder group in each use case. The primary concern for every stakeholder group was training and education. Before HHS or other stakeholders can develop training and education or analyze other stakeholder questions, the WG must

identify the structure of a U.S. morbidity linearization. An appropriate U.S. morbidity linearization will depend on the requirements of the stakeholder groups including those in diverse specialty areas.

The WG will determine an appropriate U.S. morbidity linearization by investigating three topics. First, the WG will investigate U.S. stakeholder needs that are not included in ICD-10-CM (e.g., health care quality and safety measures; mental, behavioral, and neurodevelopmental information restructured in ICD-11). Second, the WG will investigate the components of ICD-10-CM that are, and are not, needed in a U.S. ICD-11 morbidity linearization. Initial research by WG members has found that as many as 22,000 of approximately 75,000 codes have never been used for hospital reporting in the past 5 years, which indicates that some codes should not be carried over into ICD-11. As part of its investigation into ICD-10-CM, the WG will seek to understand the rationales for adding codes to ICD-10-CM to understand whether they remain relevant. Finally, the WG will investigate what is needed in a U.S. ICD-11 linearization that is not in the WHO Mortality and Morbidity Statistics (MMS) linearization and what is in the MMS that the United States may not need. For each element of this analysis, the WG will contact researchers, clinicians, payors, and providers to establish requirements for health, equity, safety, and quality. The WG is planning virtual panels to solicit a range of input from different medical specialties and other types of stakeholders. The WG is currently identifying official U.S. representatives and other U.S.-based participants in WHO-Family of International Classifications (FIC) to discuss key questions about U.S. morbidity linearization and comprise the panels. This input will also be included in the updated Phase 1 report.

The WG will also assess the subsidiary question of alternative approaches and guidance for U.S. ICD-11 post-coordination and optional extension codes. An ICD-11 user can achieve coding specificity by adding more pre-coordinated terms or clustering codes together. Clustering would require more consistent guidance on how to implement post-coordination so that the resulting codes could be standardized consistently and in an interoperable manner for EHRs and other systems. Similarly, extension codes offer more specificity and may be necessary for morbidities that are not covered by the U.S. morbidity linearization or post-coordination.

Discussion

Dr. Hodgkins asked whether HHS responded to a WG letter suggesting that the Department appoint a leader for organizing ICD-11 adoption. NCVHS staff responded that the letter was under active discussion in Secretary Becerra's office. Dr. Vicki Mays, a member of the ICD-11 WG, emphasized the importance of appointing such a leader quickly, because WHO is determining licensing terms and requirements for national linearizations and the United States is not represented in those discussions. Members of the ICD-11 WG hope to work closely with an ICD-11 leader to familiarize them with ongoing discussions of domestic stakeholder priorities and to receive updates on WHO licensing and requirements.

Ms. Banks asked how U.S. mortality would be coded if ICD-11 were implemented. Dr. Robert Anderson (NCHS) is conducting a dual coding study for cause-of-death reporting using WHO's ICD-11 MMS subset. All mortality coding is performed in NCHS rather than locally and uses the MMS code set, which is required for international comparisons of cause of death. Information about mortality coding, including use cases and implementation guides from countries that have adopted ICD-11, is available on WHO's website.

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

Recent OCR Rulemaking

OCR administers HIPAA Privacy Rules, including a 2024 rule addressing the notice of privacy provisions required under 42 CFR Part 2. Compliance with the updated privacy provisions is required by February 16, 2026. The updated privacy provisions maintain the former requirements and require CEs to provide individuals with (a) descriptions and examples of the types of uses and disclosures that the new Final Rule prohibits and those for which an attestation is required and (b) a statement of the potential for information to be disclosed.

Mr. Noonan reviewed the timeline for the new HIPAA Privacy Rule to Support Reproductive Health Care Privacy, which strengthens privacy protections for individuals seeking, obtaining, providing, or facilitating reproductive health care. Additional information can be found in OCR's fact sheet, a webinar conducted by Mr. Noonan explaining the new rule in detail, and a message (in English and Spanish). The Privacy Rule was published in the *Federal Register* on April 26 and took effect on June 25. The compliance date is December 23, except for the required notices of privacy practices. The compliance date for these notices is February 16, 2026, to accord with updates to the 42 CFR Part 2 privacy provisions.

The new Privacy Rule strengthens privacy protections by prohibiting CEs from using or disclosing PHI to conduct a criminal, civil, or administrative investigation or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, and it also prohibits identifying any person for either of those purposes.

Mr. Noonan provided two examples of acceptable disclosures under the new Privacy Rule. First, it does not restrict a CE from using or disclosing PHI to a health oversight agency conducting health oversight activities, such as investigating whether health care was appropriately billed in connection with a claim for such services or investigating substandard medical care or patient abuse. Second, it does not prohibit the disclosure of PHI to an inspector general when the PHI is sought to conduct an audit aimed at protecting the integrity of the Medicare or Medicaid programs.

The Privacy Rule applies when at least one of the following conditions exists. First, the Privacy Rule applies if the reproductive health care is lawful in the state where the health care is provided. If a resident of one state traveled to another state to receive health care that is lawful in the state where the health care was provided, the Privacy Rule applies. Second, the Privacy Rule applies if the reproductive health care is protected, required, or authorized by federal law, regardless of the state in which it was provided. For example, contraception is protected by the U.S. Constitution as determined by the *Griswold v. Connecticut* and *Eisenstadt v. Baird* decisions, and the Privacy Rule therefore applies to contraception. Third, the Privacy Rule applies when the reproductive health care was provided by a person other than the person receiving the request for information and the presumption of lawfulness applies. The presumption of lawfulness applies unless the CE has either actual knowledge or a substantial factual basis for believing that the reproductive health care was not lawful. For example, if an individual tells their provider they received care from an unlicensed person and the provider knows this care must be obtained from a licensed provider, the presumption of lawfulness does not apply. During the comment period, OCR received many comments explaining that regulated entities are often not in possession of information about the circumstances surrounding the provision of health care they did not provide. In response, OCR

added the presumption of lawfulness to reduce the Privacy Rule's burden on CEs while maintaining the same levels of protection.

Under the new Privacy Rule, a CE must receive signed attestation that a request for PHI potentially related to reproductive health care is not for a prohibited purpose. The attestation is required when the request for the information is for any of the following purposes: health oversight activities, judicial and administrative proceedings, law enforcement purposes, or disclosures to coroners and medical examiners. Upon receipt of a request and an attestation, the CE must consider all circumstances surrounding the attestation and whether it is reasonable to rely on the attestation. OCR published a model attestation to facilitate the attestation process.

Trends in Large Data Breaches

Mr. Noonan then reviewed recent trends in large health data breaches, those affecting 500 or more individuals. These data indicate an increase in large breaches, particularly those related to third-party hacking and network server security. In 2018 and 2023, 369 large breaches and 744 large breaches were reported, respectively, representing a 102% increase. The number of large breaches reported in 2024 is on track to surpass those in 2023. From 2009 to 2023, 51% of large breaches were caused by hacking, compared to 80% of large breaches in 2024 to date. From 2009 to 2023, theft of physical documents decreased from 18% to 2% of incidents. From 2019 to 2023, large breaches caused by hacking increased by 89% and ransomware events increased by 102%. Hacking, specifically via ransomware, is by far the most likely large breach encountered. Further, large breaches increasingly occur on network servers. From 2009 to 2023, 36% of large breaches occurred on network servers, compared to 66% of large breaches in 2024 to date. The number of email-caused large breaches in 2024 is on track to surpass those in 2023; since 2009, email has consistently been the source of the second highest number of large breaches.

Recent OCR Enforcement Actions

Finally, Mr. Noonan reviewed OCR enforcement actions from August 2023 to August 2024 and common guidance for CEs. Each case was resolved with a settlement agreement, corrective action plan, and either monetary payment or the imposition of a civil money penalty. The case against LA Care Health Plan involved the mis-mailing of health plan identification cards such that individuals received cards other than their own. Ransomware was involved in three cases: Doctors' Management Services, Green Ridge Behavioral Health, and Heritage Valley Health System. The case against St. Jospeh's Medical Center involved inappropriate disclosures to the media, which peaked during the COVID-19 pandemic but have since declined. The case against Lafourche Medical Group involved phishing, and the case against Montefiore Medical Center involved a malicious insider identity theft ring. Five cases involved OCR's Right of Access Initiative, through which OCR has worked to ensure individuals can access their medical records. OCR brought these cases against United Healthcare Insurance, Optum Medical Care of New Jersey, Phoenix Healthcare, Essex Residential Care, and American Medical Response.

To illustrate recent cybersecurity issues in the health care sector, Mr. Noonan discussed the Heritage Valley Health System breach in more detail. OCR received a media report of a data security incident and potential ransomware attack and conducted an investigation. The investigation revealed three violations of security rules. First, OCR found no evidence of a thorough and accurate risk analysis, which is needed to identify potential vulnerabilities in electronic health information. A thorough risk analysis must account for every device with access to an information system and every location in which an entity operates. Good

starting points for risk analysis is network servers or email, where most attacks occur. Second, OCR found that Heritage Valley Health System violated its contingency plan. Such violations are especially problematic in ransomware cases because these attackers often do not return data. To prepare for a wide variety of unforeseen events, entities must create and maintain plans to ensure continued data availability and integrity and enable the organization to return to normal operations as quickly as possible. Third, OCR found violations of access controls, which are intended to limit data access to authorized members. Such violations include passwords that are too easy to guess and lack of multifactor authentication. Heritage Valley Health System settled for $950,000, will implement a corrective action plan, and will undergo 3 years of OCR monitoring. During that time, OCR will provide technical assistance and analyze cybersecurity system documentation to ensure the systems' full compliance with the law.

Discussion

In response to a question, Mr. Noonan explained that OCR defines hacking as an intrusion into a health information system containing PHI that results in an impermissible disclosure of that PHI and does not include negligence or wrongful data use by authorized users. Ransomware involves encrypting and locking down PHI and is one form of hacking.

Dr. Watzlaf thanked Mr. Noonan for his presentation and noted that an NCVHS letter to Secretary Becerra provided guidance on risk analyses and encouraged HHS to strengthen security requirements. Dr. Watzlaf then asked whether mobile phone health data applications are protected under HIPAA. Mr. Noonan affirmed that such applications are direct-to-consumer products and do not meet the definitions of either CEs or business associates. HIPAA therefore does not apply to such applications and will not unless Congress grants OCR new authorities to cover them. Mr. Noonan noted that the Federal Trade Commission (FTC) could regulate any unfair or deceptive trade practices in health data applications, per its mandate. Ms. Doo suggested that the Committee solicit input from Mr. Ryan Mehm (FTC) on this issue, because FTC has provided best practices for developers. Ms. Doo also observed that ASTP/ONC also addresses this topic in its interoperability rules for use of patient access APIs and collaborates with OCR on how to address health care applications.

Dr. Watzlaf shared the concern that 42 CFR Part 2 is impeding the ability to share SUD data for treatment, payment, and health care operations. Mr. Noonan noted that SAMHSA, rather than OCR, administers 42 CFR Part 2 regulations related to SUD, but that changes to 42 CFR Part 2 aligned with the Coronavirus Aid, Relief, and Economic Security Act and included the option to obtain single consent per patient. Ms. Bernstein clarified that a single patient consent is required to transfer data from 42 CFR Part 2 to a HIPAA CE. After such a transfer, the data would be protected by HIPAA regulations, which allow CEs to disclose information without patient consent for payment, treatment, or health care operations.

Dr. Hodgkins observed that corporations' behavior is increasingly responsible for large data breaches, such as the Change HealthCare breach, and asked how OCR could address corporate data mismanagement. Mr. Noonan agreed that many entities in the health care sector have failed to recognize the changing threat landscape and therefore to protect patient data. OCR is drafting a proposed rule to address the shifting technical risk landscape, but Mr. Noonan cautioned that without appropriate risk analyses and access controls, no OCR rulemaking can protect patient data.

CMS Update

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

Mr. Cimmino introduced WEDI representatives 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 CMS burden reduction and HIPAA modernization efforts.

Edward Hafner, Chair, WEDI

Mr. Hafner introduced the Workgroup for Electronic Data Interchange (WEDI), which was formed in 1991 by HHS Secretary Sullivan. WEDI 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. WEDI's partner organizations include health plans, providers, vendors, clearinghouses, government entities, health care associations, standard development organizations, HIE groups, and patient advocacy groups.

Mr. Hafner then introduced a recent survey that was co-created by WEDI's Advice and Payment and Claims workgroups. In January 2023, NCVHS recommended that HHS not adopt Version 008020 to four specified transactions in part because of 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. Of a total of 204 participants, about 80-110 participants responded to each question. About 50% of respondents represented payors, 18% were providers, 11% were clearinghouses, and 23% were vendors. Respondents found measuring the value to be easier than measuring cost, because the cost estimates for each transaction change will depend on more thorough internal analyses. Participants in WEDI's 2024 Summer Forum discussed the results of the survey, after which WEDI held a listening session with CMS to gather opinions on Version 008020 from 100 in-person and 100 virtual attendees.

Merri-Lee Stine, Chair-Elect, WEDI

Ms. Stine detailed the results of WEDI's stakeholder survey. Respondents could choose to rate a feature as highly or moderately beneficial, somewhat or slightly beneficial, or not beneficial, or report that they needed more information and could comment on any statement. Results were calculated as percentages of survey participants rather than respondents to a given statement and were as follows:

- Moving transaction codes from codes lists within the transaction to external code sets: 61% highly or moderately beneficial.
- Predetermination added back to 837 after Version 005010 removed it: 63% highly or moderately beneficial.
- Clearer instructions for real-time adjudication in both 835 and 837: 53% highly or moderately beneficial and 31% somewhat beneficial.
- Updates to the amount allowed in both 835 and 837: 72% highly or moderately beneficial.

- New pharmacy/treatment administration message, non-perfected (RAS segment, formerly CAS segment) that allows for more finite reporting of remarks: 68% highly or moderately beneficial.
- Updated national drug code and prescription information in 837: 51% highly or moderately beneficial.
- More diagnostic codes in 837: 56% highly or moderately beneficial.
- Updates to lengths, elements, and segment repeats: 54% highly or moderately beneficial.
- Segment and element usage changes: 66% highly or moderately beneficial.
- Addition of a claim remittance advice remark code (LQ segment), providing users another place to send information regarding claim adjudication: 64% highly or moderately beneficial.
- New remark code list: 61% highly or moderately beneficial.
- Ability to track devices by their FDA-assigned Unique Device Identifier: 54% highly or moderately beneficial and 20% somewhat or slightly beneficial.
- Ability in 835 to report virtual credit card payments and attach those payments to the claim that was submitted and to the remittance advice received: 42% highly or moderately beneficial and 32% somewhat or slightly beneficial.
- Ability to report invalid procedure codes in 835: 62% highly or moderately beneficial.
- New requirements for patient liability in 835: 63% highly or moderately beneficial.
- New source of payment typology code in 835: 49% highly or moderately beneficial.
- More diagnostic related group segment code types in 835: 62% highly or moderately beneficial.
- Ability to report multiple corrected priority payors in 835: 44% highly or moderately beneficial.
- Updated reversal and correction process in 835: 61% highly or moderately beneficial.
- Updated overpayment recovery process in 835: 70% highly or moderately beneficial.

Ms. Stine highlighted that many respondents understood the proposed features of Version 008020 Remits 835 and Claims 837 transaction sets and viewed them as beneficial, noting in comments that the updates were likely to provide more detailed information for payors and providers. Respondents also noted that Version 008020 will allow submission of information without the need for notes and comments (NTE) segments or other supplemental files and workarounds, which will facilitate automation. However, respondents also noted some concerns in open-ended comments, such as the cost of Technical Report Type 3 (TR3) implementation guides. Implementers of HIPAA transactions have had to pay for TR3s since adoption of Version 005010, and stakeholder concern about TR3 cost persists in new versions.

The next portion of the survey asked participants to compare the cost and value of eight steps of the Version 008020 implementation process as either higher cost and lower value, moderate cost and value, or lower cost and higher value. Respondents were divided, with a slight lean toward higher cost and lower value. Respondents reported in comments that they viewed the costs and value of implementation as high, and that they would not conduct thorough cost-benefit analyses without a federal mandate to adopt Version 008020. Respondents also noted concern that vendors, upon which many stakeholders rely to handle changes to X12, may not be prepared to handle updates.

Ms. Stine observed that implementation costs are high in part because of the scope of the proposed changes, but that costs of change will be high until the next major change to X12 and that implementation of these standards sets the stage for regular updates. Moving to a new version of X12 will keep payor costs low and reduce administrative burden, resulting in more affordability for members. Strong majorities of respondents preferred interim milestones during Version 008020 implementation rather than a single implementation timeline. Overall comments supported the upgrades to reach the

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

Discussion
Mr. Cimmino confirmed that this WEDI update was for informational purposes only, rather than the basis of a request for NCVHS.

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

Data Modernization 1.0

Ms. Banks shared the Subcommittee's current workplan, which is derived from NCVHS's Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange (Data Modernization 1.0) initiative. Data Modernization 1.0 establishes that the HIPAA regulatory process must evolve to meet the current emerging business and clinical needs, including by modernizing the HIPAA transaction standards adoption framework; enhancing privacy and security requirements; and harmonizing clinical, public health, administrative, financial, and other standards. The Data Modernization 1.0 initiative sets forth semantic, syntactical, and structural interoperability requirements, which will ensure privacy and security and the satisfaction of business needs for all stakeholders. The initiative also establishes NCVHS's vision to standardize data capture and improve availability of data across the health care data ecosystem that supports individual health care and wellness, health policy, privacy and security, and health care quality and safety.

To achieve the goals of the Data Modernization 1.0 initiative, the Subcommittee on Standards established four priorities: (a) ensure alignment between HHS and other departments, (b) examine mature and emerging standards to confirm interoperability, (c) review relevance of HIPAA in the current health care ecosystem, and (d) harmonize standards and data requests. The Subcommittee will submit the RFI on the HIPAA exception process to support priority (b) and the RFI on data and standards harmonization efforts to support priority (d).

NCVHS Educational Sessions

Ms. Banks reviewed three educational sessions that occurred in April 2024 and are now available on the NCVHS website. The first session was titled "Standards for SDOH Data Elements: Successful SDOH Approaches and Challenges to Promote Health Equity." The second session, "Value Based Care Models vs Fee-For-Service: Implications for HIPAA Standards," emphasized the need to new and mature standards to operate cohesively. The third session, "Trusted Exchange Framework and Common Agreement (TEFCA) Update," also emphasized the importance of interoperability between new and existing standards, especially as clinical and administrative use cases merge and converge.

Request for Information on HIPAA Exceptions

Ms. Banks introduced an RFI that the Subcommittee plans to submit to the *Federal Register* by December 2024. This RFI seeks guidance on requests for exceptions from HIPAA standards to permit testing of proposed versions of standards to determine whether the new standards improve the current standard by increasing efficiency or effectiveness of data exchange for electronic administrative transactions. Any

organization may request to test a new standard. However, this process has been used only three times since codification in August 2000, in part because HIPAA standard transactions are not numerous.

Ms. Banks reviewed the process for requesting an exception. First, an organization submits its request for exception, which must contain (a) a comparison of the proposed standard to the current adopted standard with explanation of how the proposed modification would be a significant improvement to the current adopted standard; (b) specifications of the proposed standard, including any additional system requirements; (c) an explanation of how the organization intends to test the standard, including the number and types of health plans and health care providers expected to be involved in the test, the geographic areas affected, and the beginning and ending dates of the testing; and (d) written concurrences from trading partners who agree to participate in the test.

After the request, HHS consults with data standards maintenance organizations (DSMOs) to provide the requesting organization with an assessment of whether the proposed standard would be a significant improvement to the current standard and the appropriateness of the proposed length and extent of testing. Then, if approved the HHS Secretary provides the conditions for approval, including the duration of the exception and the trading partners with whom the requesting organization may use the proposed standard. The organization must report on the results of the test within 90 days of completing the test. When complete, the organization may request an extension of the exception, although this extension does not guarantee that the modified standard will be adopted. The organization can then work with the DSMO to submit a request that the modified standard be mandated under HIPAA. HHS expects that a successful test would result in compelling data and facilitate an update to the HIPAA standard through the DSMO.

To produce compelling evidence for a change to the existing HIPAA standards transaction process, the results of the exception process must fulfill 10 requirements. Ms. Banks highlighted that the proposed standard must (a) improve the efficiency and effectiveness of the health care system; (b) meet the needs of the health data standards user community; (c) have low additional development implementation costs relative to the benefits; (d) have timely development, testing, implementation, and updating procedures; (e) have minimum data collection and paperwork burden; and (f) incorporate flexibility to adapt more easily to changes in the health care infrastructure and IT.

Ms. Banks then reviewed the RFI requesting guidance on this exception process, which is divided into questions pertaining to the process instructions, the application process, the process implementation, the overall process, next steps for approved exceptions, and testing standards outside of the exception process. She invited NCVHS members to comment on each section of the RFI.

Discussion: NCVHS Member Suggestions for the RFI

Ms. Michaelis observed that the first question on process instructions, which asks whether a respondent is familiar with the exception process, may not be necessary. Ms. Banks agreed that directing commenters who are unfamiliar with the exception process to specific questions within the RFI may be helpful to these commenters.

Regarding the application process questions, Dr. Watzlaf suggested prompting commenters with more specific questions. The Standards Subcommittee will consider whether more specific questions can be included without leading commenters to predetermined responses. On the same section, Dr. Hodgkins and Mr. James asked whether the question "If there was funding available for completing an exception

process, would that increase participation?" could be expanded to include other supports such as in-kind resources or training. The Subcommittee will broaden this question as indicated.

NCVHS members had no suggestions for the sections on the process implementation, next steps for approved exceptions, or testing standards outside of the exception process.

To clarify the overall process questions, NCVHS members agreed that including definitions of new and modified standards would be helpful. Proposed and adopted standards and operating rules under HIPAA are included in the ASTP ONC Interoperability Standards Advisory. This exception process is for testing a new standard under HIPAA rather than a modification such as the HL7 da Vinci pilot. Transaction standards such as those in X12 or HL7 may serve the same business purpose, but each would still be defined as a new standard because of their technological novelty.

Further Discussion
Members suggested convening a panel to solicit input from the three organizations that have completed the exception process rather than conducting an RFI. The Subcommittee is interested in soliciting input as broadly as possible, especially to hear from organizations that considered, but decided against, requesting an exception and will therefore proceed with the RFI.

Request for Information on Data and Standards Harmonization Efforts

The Subcommittee's second RFI, also to be submitted to the *Federal Register* by December 2024, seeks to identify existing and emerging harmonization efforts among standards development organizations (SDOs), implementers, and terminology organizations. Because standards-specifying organizations such as CDC and FDA do not respond to RFIs, the Subcommittee will hold educational sessions with standards-specifying organizations to solicit their input. Mr. Wagner reviewed the purpose, background, broad input solicitation, and specific questions for implementers, SDOs, and terminology organizations contained in the RFI and asked for NCVHS member feedback.

The purpose of this RFI is to identify existing and emerging harmonization efforts related to health care standards and data to support interoperable data exchange. Prior NCVHS findings suggest that the health care industry needs a comprehensive, well-integrated set of standards that support health information and semantic, syntactical, and structural interoperability. Interoperability must also include data privacy and security across all levels of government and research, administrative, and clinical organizations, as well as the systems that support public and population health. Therefore, this RFI seeks to identify strategies to modernize the standards-driven information infrastructure across the health care ecosystem in partnership with the key federal and industry stakeholders.

NCVHS has identified a broad industry requirement to modernize the standards adoption framework, including enhancing private security and harmonizing clinical, public health, administrative, financial, and other standards. Previous Full Committee information-gathering sessions have identified issues in harmonization between SDOs. Current U.S. harmonization efforts appear to be ad hoc and somewhat inconsistent, although USCDI is an existing activity that supports harmonization efforts. These efforts lack a permanent support structure, which could promote timely and efficient harmonization activities and thereby reduce the burden on implementers.

The Subcommittee requested feedback on this RFI from ASTP/ONC, which suggested the addition of a note explaining the USCDI ONC New Data Element and Class Submission System that supports a predictable, transparent, and collaborative process by which the HIT community can submit new data elements and classes for future versions of USCDI.

Although the Subcommittee originally identified seven key strategic areas on which to solicit input from target organizations, it decided to include only five that are the primary domain of SDOs in this RFI. These areas are information and data elements, terminologies and code sets, security and data privacy, information exchange formats, and methodology used to support harmonization efforts.

Discussion: NCVHS Member Suggestions for the RFI

Members had no suggestions on the purpose, background, broad input solicitation, or specific questions for SDOs or terminology organizations. Ms. Michaelis suggested that the specific questions for implementers should be addressed to nongovernmental organizations such as the American Dental Association, American Heart Association, and American Health Information Management Association in addition to government agencies to encourage broad participation.

Further Discussion

NCVHS members commended the Subcommittee on this RFI and expressed their expectation that responses will contribute to meeting the data harmonization priority established in the Data Modernization 1.0 initiative.

Mr. Banks asked about the length of the comment period. Members agreed that 90 days was the optimal RFI duration to give commenters sufficient time to respond.

Members asked whether Subcommittee members would analyze responses to the RFI themselves. The Subcommittee expects to conduct its own analysis but is currently determining whether it has sufficient resources to hire an outside organization to conduct the analysis instead.

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 U.S. 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, which 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 Full Committee meeting is scheduled for December 3-4, 2025 (virtual).

Closing Remarks & Adjourn—Naomi Michaelis, DFO

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

Naomi Michaelis, MPA

Naomi Michaelis, MPA
Acting Chair, National Committee on Vital and Health Statistics