**Department of Health and Human Services**
**NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS**
**April 11-12, 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-16/

The National Committee on Vital and Health Statistics (NCVHS) was convened both in person and virtually on April 11-12, 2024. The meeting was open to the public. Present:

**Committee Members**
Jacki Monson, JD, Chair, Sutter Health
Angela Alton, MPA, City of Hope
Tammy Banks, MBA, FACMPE
Denise Chrysler, JD, Network for Public Health Law
Catherine Donald, MBA, Alabama Department of Public Health
James Ferguson, Kaiser Permanente
Michael Hodgkins, MD, MPH, Home Base Associates
R. Lenel James, MBA, BCBSA
Richard Landen, MPH, MBA
Debra Strickland, MS, Conduent
Steve Wagner, MBA
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA, UPitt
Wu Xu, PhD, University of Utah

**Executive and Lead Staff**
Sharon Arnold, PhD, ASPE, Exec. Staff Director
Rebecca Hines, MHS, NCHS, Exec. Secretary
Sarah Lessem, PhD, PMP, ASPE

**NCVHS Staff**
Maya Bernstein, JD, ASPE/OSDP
Shirley Castillo, MPH, NCHS
Lorraine Doo, MPH, CMS
Naomi Michaelis, MPA, NCHS

**Invited Speakers**
Garrett Adams, Epic Systems
Vanessa Candelora, POCP
Aneesh Chopra, MPP, CareJourney
Michael Cimmino, MPH, CMS
Todd Couts, MS, CMS
Gniesha Dinwiddie, PhD, NIMD, NIH
Jennifer Goldsack, MChem, MBA, MA, DiMe
Steve Gravely, JD, MHA, DURSA
Rachel Harrington, PhD, NCQA
JaWanna Henry, MPH, MCHES, ONC
Jonathan Jungck, Palantir Technologies
Meagan Khau, MHA, CMS
Preana Laddha, MS, Epic Systems
Farzad Mostashari, MD, ScM, Aledade
Tim Noonan, JD, OCR
Von Nguyen, MD, MPH, Google
Somava Saha, MS, MS, WIN Network
Julia Skapik, MD, MPH, FAMIA, NACHC
Erin Weber, MS, CAQH
Chantal Worzala, PhD, Alazro Consulting
Marianne Yeager, MBA, The Sequoia Project

In addition to those individuals who presented virtually during the meeting (listed above), 218 people followed the meeting online on Day 1 and 219 followed on Day 2.

ACTIONS

1. The Committee approved two recommendations, based on the ICD-11 Workgroup's findings, to the Department of Health and Human Services (HHS) Secretary on designating a federal agency to coordinate U.S. ICD-11 morbidity coding and appointing a federal representative to the World Health Organization (WHO).

**—DAY ONE—**

**Call to Order and Roll Call—Rebecca Hines, Executive Secretary and Designated Federal Officer**

Ms. Hines welcomed NCVHS members, staff, invited speakers, and public attendees. She reminded members that during its previous meeting, the Full Committee approved the Privacy, Confidentiality, and Security (PCS) Subcommittee's recommendations to HHS Secretary Xavier Becerra on strengthening the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule. Following that meeting, the NCVHS International Classification of Diseases, 11th Revision (ICD-11) Workgroup on Timely and Strategic Action to Inform ICD-11 Policy published its Phase I Findings report, which summarizes the workgroup's activities from spring 2023 to fall 2023.

Ms. Hines conducted roll call, requesting that NCVHS Full Committee members state their name, status as a special government employee, and any conflicts of interest for this meeting. Ms. Donald noted that she would recuse herself from any discussions related to reproductive health, and Mr. Ferguson noted that he would recuse himself from any discussions related to Kaiser Permanente's comments on ICD-11. No other Full Committee members disclosed conflicts of interest. Ms. Hines 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—Jacki Monson, Chair**

Ms. Monson reviewed the Day 1 meeting agenda.

**Update: Office of the Assistant Secretary for Planning and Evaluation—Sharon Arnold and Sarah Lessem**

***Personnel Updates***

Dr. Arnold expressed her appreciation for Ms. Hines' efforts on behalf of the Full Committee and wished her well in her upcoming retirement. In addition, Dr. Arnold announced her own departure from the Full Committee to dedicate more time to her role with the new White House Council on Supply Chain Resilience. Dr. Arnold introduced Dr. Lessem, who will serve as the new NCVHS Executive Director. Dr. Lessem is a Senior Data Scientist in the Office of the Assistant Secretary for Planning and Evaluation (ASPE). She previously led the evaluation of a COVID-19 prevention campaign while at Fors Marsh and the data support contract for the new National Center for Health Statistics (NCHS) Rapid Surveys System—which combines two probability-based, online survey panels to facilitate quick data collection for federal statistics—while at RTI International. In addition, Dr. Lessem was a qualitative researcher in the Division of Research and Methodology and later coordinated the National Health Interview Survey (NHIS) redesign in the NCHS Division of Health Statistics.

### *HHS Highlights Within Recent Months*

Dr. Arnold shared that Congress passed a continuing resolution (CR) to fund HHS through December 30, 2024.

Toward the end of 2023, HHS unveiled its 2023 HHS Data Strategy to demonstrate its dedication to leveraging data as a strategic asset to foster innovation and enhance outcomes in health and human services. The strategy is a culmination of coordinated efforts across multiple agencies within HHS, reflecting a unified approach toward harnessing the power of data to drive meaningful impact. It envisions data that are readily available, easily accessible, timely, equitable, meaningfully usable, and safeguarded. It aligns with President Biden's Unity Agenda and addresses five key priorities aimed at enhancing data infrastructure and capabilities across HHS: (1) cultivate data talent, (2) foster data sharing, (3) integrate administrative data into program operations, (4) enable whole-person care delivery by connecting human services data, and (5) responsibly leverage artificial intelligence (AI). The strategy highlights two anchor use cases that represent the highest priority areas where cross-department data action can significantly advance critical mission objectives: the Cancer Moonshot and Preparedness and Incident Response.

In March 2024, through the Office of the National Coordinator for Health Information Technology (ONC), HHS released a draft 2024–2030 Federal Health Information Technology (IT) Strategic Plan for public comment by May 28, 2024. This Strategic Plan outlines federal health IT (HIT) goals and objectives that aim to

- improve access to health data, deliver a more equitable health care experience, and modernize the nation's public health data infrastructure;
- emphasize the policy and technology components necessary to support the diverse data needs of all HIT users;
- align with recent HHS initiatives—such as the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule and the HHS Health Care Sector Cybersecurity concept paper;
- ensure that all populations benefit from HIT, which is integral to how health care is delivered, managed, and tracked across populations and communities; and
- address emerging technologies and their impact on health care delivery.

In December 2023, HHS released the HHS HealthCare Sector Cybersecurity concept paper, which aligns with President Biden's National Cybersecurity Strategy and outlines HHS' four key pillars for action: (1) publish new voluntary health care–specific cybersecurity performance goals, (2) work with Congress to develop supports and incentives for domestic hospitals to improve cybersecurity, (3) increase accountability within the health care sector, and (4) enhance coordination for a one-stop shop within HHS for health care sector cybersecurity. Because of recent, sizable security concerns, HHS encourages all providers, technology vendors, and members of the health care ecosystem to urgently bolster cybersecurity measures to protect sensitive health information.

### *Trusted Exchange Framework and Common Agreement*

The Trusted Exchange Framework and Common Agreement℠ (TEFCA) became operational in late 2023. TEFCA governs the nationwide health data exchange, which currently consists of seven Qualified Health Information Networks™ (QHINs).

### *COVID-19 Updates*

The Centers for Disease Control and Prevention (CDC) recommends that all individuals aged 6 months and older receive the updated COVID-19 vaccine boosters, because vaccination remains pivotal in mitigating infection and mortality risk for COVID-19 variants JN.1 and XBB. CDC data from February 2024 highlighted the efficacy of these vaccines; however, recent data indicate that only 14 percent of children, 22 percent of adults, and 42 percent of older adults have received the updated booster. Adults received boosters primarily at retail pharmacies or physicians' offices; approximately 29.8 million doses and 2.3 million doses were administered at these locations, respectively, as of March 2024.

On March 8, 2024, the U.S. government suspended its COVIDtests.gov program, which distributed more than 870 million COVID-19 tests to American households. However, the government will continue to ensure low- or no-cost access to these tests for uninsured individuals and underserved communities through existing outreach programs.

In November 2023, HHS established a Federal Advisory Committee to inform government-wide research, innovation, and action aimed at mitigating the impacts of long COVID on public health. NHIS data reveal that in 2022, 6.9 percent of adults have experienced long COVID, and 3.4 percent of adults had long COVID at the time of the interview. In addition, data collected in 2023 through the NCHS Rapid Surveys System show that 68 percent of U.S. adults were aware of long COVID, indicating the need for additional public education to increase that awareness.

### *Other Infectious Diseases*

In March 2024, CDC issued updated guidelines and fundamental prevention strategies to reduce the risks of contracting respiratory viruses, stressing the importance of cleaner air and remaining current on COVID-19 and flu vaccinations. In recent months, seasonal influenza, COVID-19, and respiratory syncytial virus rates have gradually declined nationwide.

Although the COVID-19 public health emergency (PHE) is waning, HHS remains dedicated to protecting individuals, families, and communities against both infectious and noncommunicable diseases. On February 6, 2024, HHS and 16 other federal agencies unveiled the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in People in accordance with the 2019 Kay Hagan Tick Act. Vector-borne diseases result from pathogens—transmitted by vectors such as mosquitos, ticks, and lice—that cause widespread illness and mortality across the globe.

HHS also established the National Syphilis and Congenital Syphilis Syndemic Federal Task Force to utilize federal resources, curb rising rates of syphilis, promote health equity, engage with affected communities, and allocate resources to support individuals who are most impacted by syphilis. In addition, the Food and Drug Administration (FDA) exercised enforcement discretion to enable temporary importation and use of Extencilline—an antibiotic used in France that the FDA has not approved for use in the United States—to ensure treatment availability amid the ongoing Bicillin® L-A drug shortage.

On December 1, 2024, in honor of World AIDS Day, the Health Resources and Services Administration unveiled the most recent Ryan White HIV/AIDS program data, which reveal that 9 out of 10 people with HIV who receive medical care through the program are virally suppressed.

### *Opioid Crisis Updates*

In December 2023, HHS partnered with the U.S. General Services Administration to update guidelines for safety station programs in federal facilities—the first update in 15 years. These guidelines strongly advise federal facilities to convert automatic external defibrillator stations into comprehensive safety stations for effective emergency response. These updated stations should include opioid reversal agents (e.g., naloxone) to address opioid-related emergencies and hemorrhagic control strategies (e.g., STOP THE BLEED®) for bleeding incidents.

Effective March 27, 2024, HHS Secretary Becerra renewed the opioid crisis PHE declaration for another 90 days. This renewal enables the Secretary to take crucial actions—such as modifying telemedicine practices, making temporary personnel appointments, and waiving the Paperwork Reduction Act requirements—to facilitate HHS' response to the ongoing crisis.

### *National Disaster Public Health Emergencies*

HHS continues to support communities impacted by natural disasters. Since the previous Full Committee meeting, Secretary Becerra had declared PHEs for Georgia and Florida in response to Hurricane Idalia (expired). In February 2024, he renewed the PHE declaration for Hawaii in response to the Maui wildfires.

### *Behavioral Health Care Updates*

The HHS Roadmap for Behavioral Health Integration highlights significant achievements in HHS' approach to expand access to behavioral health services by integrating these services with primary care and other community sites. Two successful examples from the Centers for Medicare & Medicaid Service (CMS) include policy guidance, which encourages direct reimbursement for interpersonal consultation in Medicaid, and the Children's Health Insurance Program (CHIP), which improves integration of mental health and substance use disorder (SUD) treatment in various health care settings.

HHS has also implemented various initiatives to enhance the behavioral health workforce and effectively address SUD. Examples include a National Institutes of Health (NIH) study on substance use stigma in mental health care settings and a Substance Abuse and Mental Health Services Administration (SAMHSA) initiative to integrate SUD content into early academic training for health care professionals.

HHS is actively involved in strengthening the implementation and enforcement of behavioral health parity. HHS, along with the Departments of Labor and the Treasury, proposed critical rules to ensure equitable access to mental health and SUD care. HHS has also targeted outreach efforts toward high-risk populations—including youth, individuals experiencing homelessness, and individuals involved with the justice system—to engage them in tailored and integrated behavioral health care.

Further, HHS drives innovations in care integration and technology adoption to bridge technology gaps and promote data integration to enhance the quality and efficiency of behavioral health service delivery. Example innovations include CMS' announcement of a new state-based payment model for integrated services and SAMHSA's investment in advancing HIT in behavioral health care settings.

### *Maternal Health*

CMS recently introduced the Transforming Maternal Health Model—a 10-year initiative that aims to revolutionize maternal health care delivery, prioritize personalized care, and increase access to maternal health providers for pregnant and postpartum people with Medicaid and CHIP coverage. Through this

model, the United States will implement evidence-based practices to monitor high-risk pregnancies and address health-related social needs to foster healthier outcomes for mothers and infants.

***Recent Rulemaking Updates***

Administration for Children and Families
On February 29, 2024, the Office of Child Care announced the Improving Child Care Access, Affordability, and Stability in the Child Care and Development Fund (CCDF) Final Rule, which updates the Child Care and Development Fund and includes policies that lower child care costs for families, improve payments to child care providers, increase child care options for families, and make enrollment easier and faster for families.

In November 2023, the Office of Head Start released a Notice of Proposed Rulemaking (NPRM) to stabilize the Head Start workforce and improve the quality of comprehensive services for young children. Proposed policies include significant increases to compensation and benefits for Head Start staff, integration of mental health services into Head Start programming more broadly, and other quality improvements to help Head Start programs effectively and equitably meet the evolving needs of the communities that they serve.

Centers for Medicare & Medicaid Services
In January 2024, CMS finalized the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F), which aims to improve electronic exchange of health information and prior authorization processes for medical items and services between payers and providers, reduce the administrative burden on the health care workforce, empower clinicians to focus on patient care, and prevent avoidable delays in patient care.

Office of National Coordinator for Health Information Technology
In December 2023, ONC announced the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, which aims to advance patient access, interoperability, and standards. Key aspects of the Final Rule are discontinuing year-themed editions of the ONC certificate criteria for HIT, establishing transparency requirements for AI and other predictive algorithms, and revising information blocking requirements to encourage secure, efficient, standards-based exchange of electronic health information (EHI).

***ASPE Highlights Within Recent Months***

ASPE published a Data Point containing its analysis of data from NHIS for the third quarter (Q3) of 2023. Data revealed that the national uninsured rate remained at approximately 7.7 percent, which affects an estimated 25.6 million individuals. Data also revealed that the uninsurance rate has trended downward since 2020 and that changes between quarters of 2023 were not significant; in Q3 2023, 11.4 percent of adults (aged 18-64 years) and 3.4 percent of children (under age 18 years) were uninsured, which reflected a decrease from Q1 2020. Lastly, data showed that public coverage slightly increased, while private coverage slightly decreased, for both adults and children in Q3 2023 compared to Q1 2023.

In addition, ASPE published an Issue Brief on Medicare Enrollees and the Part D Drug Benefit: Improving Financial Protection through the Low-Income Subsidy (LIS). Research indicated that the 2022 Inflation Reduction Act—which expanded the LIS program—would have benefited nearly 461,000 partial LIS enrollees if it had been established in 2020. Moreover, the program's enhanced support could benefit an additional 2.9 million individuals eligible for LIS with Part D coverage, as well as 661,000 Medicare enrollees who lack drug coverage.

ASPE published a report on Child and Caregiver Outcomes Using Linked Data, which discusses the need to bolster data infrastructure and accessibility for research that focuses on parents with children in the child welfare system who require treatment for SUD—including opioid use disorders—or behavioral health issues. The report recommends the creation of a multistate dataset for secondary analysis, a road map for data sharing, a linkage between Medicaid and child welfare agencies, and the analysis of treatment outcomes under Medicaid for patients, parents, and children in the child welfare system to highlight the impact of services on treatment success.

### *HHS Appointments*

On January 8, 2024, President Biden renominated Dr. Rebecca Haffajee to serve as the Assistant Secretary for Planning and Evaluation; however, this appointment is not yet confirmed. Also on January 8, 2024, Secretary Becerra appointed Ms. Stacy Sanders as the Chief Competition Officer—a newly created role at HHS—whose role focuses on lowering health care and prescription drug costs by increasing competition. Ms. Sanders will spearhead efforts to promote competition in health care markets by working closely with the Federal Trade Commission and Department of Justice to address market competition through data sharing, reciprocal training programs, and development of policy initiatives.

### *Changes to Race and Ethnicity Data Collection*

On March 28, 2024, the Chief Statistician of the United States published revisions for the Statistical Policy Directive No. 15 (SPD 15), which provides standards for maintaining, collecting, and presenting federal data on race and ethnicity and was last revised in 1997. The current revisions reflect recommendations from the Office of Management and Budget (OMB) Federal Interagency Technical Working Group on Race and Ethnicity Standards. The Working Group—which consists of federal government career staff from 12 principal statistical agencies, 22 Chief Financial Officers Act agencies, and the Equal Employment Opportunity Commission—conducted research on statistical information, collected more than 20,000 public comments, and held nearly 100 listening sessions to develop recommendations for more accurate and useful race and ethnicity data collection across the federal government. Significant changes to the SPD 15 include

- collecting data using a single combined race and ethnicity question that allows multiple responses;
- adding Middle Eastern or North African (MENA) as a minimum reporting category that is separate and distinct from the White category;
- requiring the collection of more detail beyond the minimum race and ethnicity reporting category, unless the agency receives an exemption from OMB's Office of Information and Regulatory Affairs, because the potential benefits of detailed data would not justify the additional burden to the agency and the public or would create additional risk to privacy and confidentiality; and
- updating terminology.

Effective immediately, agencies have 18 months to develop plans for full implementation of these revisions within 5 years. In addition, ASPE will convene staff across HHS to contribute to plans to implement SPD 15 and coordinate promotion of the revised standards.

***Recruitment***

Dr. Lessem announced that Ms. Chrysler and Ms. Strickland are leaving the Full Committee and expressed appreciation for their dedicated service. As a result, NCVHS will accept nominations of qualified individuals who possess relevant experience and can contribute to the collaborative efforts of the Full Committee and HHS. NCVHS is committed to fostering diversity across various dimensions, including race, gender, ethnicity, sexual orientation, gender identity, disability status, geographic representation, professional backgrounds, and sectors within the health and health care industry. NCVHS has published information about this process online.

***Discussion***

Mr. James asked for additional details on the Cancer Moonshot initiative, which was reignited under President Biden's leadership after its launch during the Obama administration. Dr. Lessem noted that this initiative has remained a priority; it garnered additional funding and focus with the creation of the Advanced Research Projects Agency for Health (ARPA-H).

**HIPAA: Administrative Simplification—Michael Cimmino, Director, National Standards Group, Office of Burden Reduction and Health Informatics, CMS**

Mr. Cimmino noted that the National Standards Group (NSG) is charged with enforcing compliance with health care transaction standards under the HIPAA Administrative Simplification provisions. From 2023 through the first half of 2024, NSG has focused most of its efforts on expanding its presence in the health care industry, holding listening sessions and forums with stakeholders to learn of key issues, and providing guidance that were responsive to stakeholders' concerns. One notable effort is NSG's Guidance on National Provider Identifier (NPI) Enumeration, which authorizes health plans to require health care providers to enumerate subparts based on differences (e.g., address, specialty type). NSG also released an Enforcement Discretion for Referral Certification and Authorization Transaction Standard at 45 CFR § 162.1302 that discusses prior authorization and the use of the X12 278 transaction set; NSG will release a frequently asked questions (FAQ) document to clarify questions and policy issues raised during stakeholder discussions. In addition, Mr. Cimmino's team has actively disseminated education materials to help address misperceptions of the exceptions process. His team is interested in the reasons behind underutilization of exceptions and plans to hold discussions in 2024 to learn more from the industry.

***Regulatory Efforts***

During the remainder of 2024, NSG plans to focus on finalizing its proposed rules on Modifications to NCPDP Retail Pharmacy Standards (CMS-0056-P) and Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures Final Rule (CMS-0053-P); establishing an Interim Final Rule on NCVHS' recent recommendations for federal adoption of the operating rules from the Council for Affordable Quality Healthcare's Committee on Operating Rules for Information Exchange; and continuing to explore strategies and regulatory actions related to X12 Standard Version 8020 for Claims and Remittance Advice transactions.

***Enforcement Efforts***

NSG's enforcement purview includes noncompliance with adopted standards for any electronic transactions, nonadherence to the adopted operating rules, and misuse of code sets and unique identifiers. To enforce proper compliance, NSG offers two tools: the Administrative Simplification Enforcement and Testing (ASETT) tool and the compliance review process.

First, ASETT helps to identify noncompliance through NSG's complaint process. Individuals who suspect noncompliance or believe that they are required to conduct transactions that are noncompliant with the standards can submit complaints through ASETT. NSG is working to streamline this process to expedite adjudication of complaints and will seek industry feedback during the upcoming BD conference in May. Second, NSG's compliance review process focuses on health plans and clearinghouses to identify noncompliant, HIPAA-covered entities (CEs) and determine whether a corrective action is warranted. This process helps entities identify vulnerabilities in their compliance, areas of improvement, and consistent policies and procedures to prevent future noncompliance. Currently, NSG is working to increase its annual sample size for these reviews to reach a larger volume of CEs. Additional information on NSG's enforcement efforts are available online.

Mr. Cimmino noted that NSG continually strives for impact and has made recent improvements to shorten the time frame for adjudicating complaints. NSG is also working to improve transparency in its processes and its ability to impose substantial consequences for repeated noncompliance. Mr. Cimmino also noted that individuals who experience compliance issues because of a recent health care breach should contact NSG for assistance, especially if these issues impact their ability to implement a corrective action plan.

***National Plan and Provider Enumeration System (NPPES) Updates***

NSG recently made changes to the NPPES database, specifically on the NPI application and on options for publicly displayed data. These changes were announced in the *Federal Register* (89 FR 15581), which outlined the addition of two new options for gender—"X" for unspecified (i.e., neither male nor female) and "U" for undisclosed (i.e., do not wish to disclose gender)—and the acceptance of Post Office Boxes as a health care practice location to address the safety concerns of providers who solely practice out of their homes.

***Future Priorities and Work***

NSG has held many discussions with the industry to improve the standards development and adoption process, which is currently slow and unpredictable, as part of its HIPAA modernization efforts. NSG plans to facilitate consistency in the adoption of standards by modifying the steps of this process, which could result in 50 percent time savings. NSG is also working on identifying approaches to better evaluate standards prior to their adoption and on understanding strategies to better gauge the return on investment through an improved cost-benefit analysis.

In addition, NSG's recent enforcement discretion on the 278 transaction is a unique circumstance that resulted from the combination of the exceptions process and Medicare regulatory provisions. NSG plans to seek stakeholder feedback as entities work to implement a Fast Health Interoperability Resources (FHIR)-based prior authorization process. Mr. Cimmino acknowledged the need for such a standard to undergo the evaluation process consistent with statutory provisions and looks forward to the outcome or recommendation that results from this process. In the meantime, NSG will work toward establishing clarified guidance in the upcoming FAQ document release.

Lastly, Mr. Cimmino expressed his appreciation for NCVHS' input on ICD-11. He noted that future NCVHS recommendations and industry feedback on any additional work required, such as a cost-benefit analysis, will help inform the adoption or implementation of ICD-11 under HIPAA. NSG recognizes—through feedback from payers, providers, and federal partners who experienced ICD-10 implementation—that transitions require a careful, thoughtful, and resource-intensive evaluation of the need, timing, and

priorities. Mr. Cimmino concluded his presentation by noting that additional resources are available online and that specific questions may be sent via email to AdministrativeSimplification@cms.gov.

***Discussion***

Ms. Banks noted her optimism for Mr. Cimmino's work in expediting the review of future standards and looks forward to the FAQ release. She asked whether Mr. Cimmino could share additional details on the scope of the 278 exception. Mr. Cimmino replied that NSG hopes to address this scope in the FAQ.

**Workgroup on Timely and Strategic Action to Inform ICD-11 Policy—Jamie Ferguson and Workgroup Members**

***Overview***

ICD-11 Background

In 2019, the World Health Organization (WHO) adopted ICD-11, and in 2022, ICD-11 went into effect globally. ICD-11 includes three components for use in the United States: (1) mortality reporting, which is a United Nations treaty obligation and requirement for WHO membership; (2) morbidity reporting for U.S. health care and public health; and (3) morbidity coding using a HIPAA-mandated medical code set for U.S. health care billing and payment (e.g., reimbursement, risk adjustment, quality and safety reporting). Mr. Ferguson reminded members that the ICD-11 Workgroup focuses its efforts on morbidity, not mortality.

Early NCVHS Activities for ICD-11

In 2019, NCVHS held an Expert Roundtable Meeting and delivered two recommendation letters to the HHS Secretary. 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. In 2021, NCVHS issued an additional letter of recommendation that primarily reinforced statements in first letter urging HHS to begin ICD-11 implementation efforts in the United States.

NCVHS identified goals for U.S. implementation of ICD-11 morbidity reporting and coding to prevent a recurrence of the issues from the lengthy and costly U.S. transition from ICD-9 to ICD-10. These goals address the need for more research to inform the transition to ICD-11, which is both structurally and conceptually different from previous versions because of its ability to be continually updated; identify necessary work to avoid full clinical modification (CM), reduce costs, and increase the flexibility and international comparability of U.S. statistics and reporting; and identify key topics and messages to communicate to the industry to foster stakeholder engagement and preparation for this transition.

Timeline of Phase I Activities

In December 2022, NCVHS established the ICD-11 Workgroup. In early 2023, NCVHS invited members to join the Workgroup and engaged with the National Library of Medicine to conduct an environmental scan of all research related to ICD-11. This scan, which aimed to inform U.S. adoption efforts for morbidity reporting and coding, highlighted implementation efforts in the health systems of approximately 12 countries. In June 2023, the Workgroup issued a Request for Information (RFI) (88 FR 38519) for the August 2023 Expert Roundtable Meeting. Following this meeting, it released a meeting summary and then a Phase I Findings Report.

***Interim Update on Phase II***

In October 2023, the Workgroup entered Phase II and issued a second RFI (88 FR 71369) to collect additional information on the use of ICD-11 for morbidity coding in the United States. The Workgroup is currently analyzing this second set of RFI responses. In addition, the Workgroup added new members to ensure that all ICD-11 stakeholders are represented on the Workgroup.

***Learnings from Both Requests for Information***

First RFI Analysis

The August 2023 Expert Roundtable Meeting welcomed approximately 50 subject matter experts across academia, clinical practice, public and private sectors, and federal agencies. Dr. Patrick Romano (ICD-11 Workgroup member) noted that participants discussed the first set of RFI responses, which shared the following themes:

- ICD-11 presents opportunities supporting modernization, potential for burden reduction, and automation to support transformation to a 21st century digital health care data infrastructure.
- Coordinated governance and funding are necessary. Coordinated governance needs include strategies for (1) the process of developing and maintaining linearization within the United States for morbidity purposes and (2) coordinating with other countries through WHO to ensure that U.S. linearization is consistent with the basic architecture of ICD-11 and with other internationally adopted linearizations. In addition, coordination across federal agencies and health care entities is critical for the successful implementation of ICD-11.
- ICD-11 maintenance processes must be well understood and managed for the United States. These processes are likely different from the ICD-10-CM maintenance processes.
- Additional ICD-11 content analysis is necessary to assess U.S. implementation approaches. This analysis will help identify coverage gaps in current stem codes that appear in ICD-11's main linearization—Mortality and Morbidity Statistics (MMS)—and help stakeholders envision a non-MMS linearization if necessary.
- Stakeholder understanding of technical implementation methods and costs is lacking and must be improved. WHO offers improved tooling through ICD-11, which improves user interfaces for those who input information into electronic health records (EHRs). Any resulting AI tools will need to be evaluated for usability, accuracy, and implementation feasibility throughout the health care systems.
- The role of ICD-11 in clinical documentation use cases, and other new uses beyond existing ICD-10-CM use cases, should be analyzed more comprehensively. Dr. Romano's particular research focuses on the quality and safety use case, although other cases (e.g., payment, clinical research) could help inform stakeholders of ICD-11's value and impact.
- Education and workforce challenges and changes could be profound.

Alignment of NCVHS Recommendations and RFI Responses

Ms. Donald noted that the second set of RFI responses aligned with NCVHS' recommendations to HHS on the U.S. implementation of ICD-11. These responses highlighted the need to conduct additional research to evaluate the impact of different approaches to ICD-11, including by analyzing costs and benefits; conduct outreach and encourage stakeholders to commence planning for the ICD-11 transition; and provide education on ICD-11 and its application in EHRs.

The second set also aligned with the first set of RFI responses. Both sets of responses emphasized the need for governance and funding on all aspects of ICD-11 adoption, implementation, and maintenance;

evaluation of U.S. ICD-11 governance options to best manage U.S. ICD-11 and coordinate with the WHO Family of International Classifications (FIC) Network; and additional national ICD-11 research, which requires coordination and federal funding, to optimize value and reduce costs related to implementation. In addition, both sets of responses highlighted a strong interest and willingness from stakeholders to engage in ICD-11 planning; the need for additional research on the benefits, costs, and impacts of ICD-11; increased attention on AI and automation in ICD-11 implementation for potential burden reductions and quality improvements; and the need for strategies for pilot testing, education, and communications for the ICD-11 transition.

Second RFI Analysis

In addition to these alignments, the second set of RFI responses presented new themes, benefits, and challenges associated with the U.S. transition to ICD-11. Ms. Sue Bowman shared the following key themes:

- If a U.S. CM of ICD-11 is not developed, ICD-11 governance and maintenance processes must be established to ensure that U.S. needs are met. Respondents expressed concerns about relinquishing control of reimbursement coding to WHO and WHO's adequacy to meet U.S. needs (e.g., timely responsiveness). In addition, U.S.-specific rules and coding guidance must be developed, and users must be trained. Respondents lack sufficient knowledge and understanding of ICD-11 to evaluate whether ICD-11 can reflect U.S. cultural issues and question its ability to meet specific U.S. data needs.
- To gain the support of key stakeholders in health care payment processes for a transition to ICD-11, demonstration of a financial return on investment will be very important. Realistic cost and burden estimates, as well as solid evidence of benefits, will be needed.
- ICD-11 presents a range of new challenges; ICD-10 and ICD-11 have different structures, which creates knowledge gaps (e.g., in understanding implementation post-coordination) and raises fundamental issues related to change management, technical, human resources, cost, and other questions.

In addition, Ms. Mary Stanfill highlighted the following key benefits:

- Approximately 37 percent of RFI respondents identified benefits of a transition to ICD-11, 9 percent saw no benefits, and 54 percent either do not know yet or did not address benefits. These benefits vary by stakeholder; those using ICD-10-CM for billing and payment may not need ICD-11, whereas those using ICD-10-CM for health equity, social, or community health needs may benefit from using ICD-11.
- Some benefits are conditional, depending on use cases and specific implementation options. ICD-11 automation in EHRs could reduce provider burden, improve timeliness of documentation, improve public health reporting, increase coding accuracy, improve coding productivity, and reduce labor costs. Using ICD-11 to increase diagnostic granularity, alongside clustering to identify relationships, could improve value-based and accountable care methods, as well as measurements of quality, safety, and equity in health care.
- Other benefits are indisputable: ICD-11 remains current with medical science and practice; improves statistical analysis, international comparability research, and surveillance; enables greater precision, flexibility, and timeliness; and reduces software and other related costs.

Lastly, Mr. Ferguson noted the following key challenges:

- The overall financial system impact of ICD-11 granularity and precision in coding is unknown. The effects of ICD-11 on fee-for-service (FFS) payments and risk adjustment have not been adequately studied.
- Potential licensing issues remain to be resolved with WHO. U.S. licensing needs for mappings, linearizations, and derivative works must be considered.
- Semantic standardization concerns: consistent U.S. rules will be needed for syntax, post-coordination, use of Foundation Uniform Resource Identifiers, and others; and the role and relationship of ICD-11 with SNOMED Clinical Terms (SNOMED-CT), Current Procedural Terminology (CPT®), and other regulatory standards are undefined.
- The role of AI in ICD-11 implementation requires more investigation. Respondents indicated wide variation in implementation of AI; vision and plans for AI; differences in level of understanding, knowledge, and experience with AI; and opposing views on the associated cost and burden of AI.

***Next Steps***

During Fiscal Year (FY) 2024, the Workgroup plans to continue its second RFI analysis to generate a Phase II Report. The Workgroup will identify additional new findings, analyses, and discussion points to inform future NCVHS recommendations on the potential adoption, implementation, and maintenance of ICD-11 as a U.S. morbidity code set.

During FY25, the Workgroup will enter Phase III and continue its research on the needs for ICD-11 implementation. Planned Phase III activities include hearings, RFIs, or other necessary events to improve stakeholders' understanding of ICD-11 and to obtain public input on a plethora of related topics, which include workforce development, communications, industry outreach, technical standards issues and technology implementation issues, relationships to other coding and terminology systems, uses of ICD-11 for U.S. interoperability and population health, issues of governance and U.S. licensing of ICD-11 artifacts and derivative works with WHO-FIC and accredited U.S. standards developing organizations. The Workgroup also plans to develop strategic options and identify new findings for Full Committee consideration.

***Current Issues for Consideration***

<u>ICD-11 Workgroup Consideration</u>
Mr. Ferguson noted that the Workgroup's Phase II efforts are focused on addressing the following issues:

- **Scope of Analysis of the ICD-11 Transition:** What topics are in scope for this analysis and what are not in scope? Examples of possible topics include new application programming interfaces (APIs) for ICD-11 access, electronic medical record integration, value set mapping and conversion of health care quality and patient safety measures, dual coding, and use of AI to implement ICD-11. The Workgroup must determine these boundaries to ensure that its analysis is in scope for its recommendations to the Full Committee.
- **Transition Planning:** Transition planning is necessary for the coordination of content and maintenance of ICD-11 from current processes for ICD-10-CM, especially with WHO-FIC on international content and nationally for U.S.-specific extension codes.
- **Transition Timeline:** The Workgroup must determine strategies to optimize planning and minimize burdens (e.g., dual coding) to shorten the transition phase while ensuring the quality of this transition.
- **U.S. Linearization**: The United States needs a linearization for morbidity and reimbursement-related processes that differs from the current MMS linearization that is used for mortality and

statistical reports. The Workgroup must determine how this new linearization must be created and maintained, as well as how it relates to U.S.-specific extension codes. In particular, FFS reimbursement may not work well under this linearization so this topic must be discussed further.

Full Committee Consideration

Mr. Ferguson reminded the Full Committee that both sets of RFI responses highlighted the need for central governance to coordinate the implementation and use of ICD-11 across federal agencies and the private sector. He reiterated that HHS must designate a lead federal office or agency with the overall coordination and funding responsibilities for the ICD-11 morbidity coding transition in the United States. Mr. Ferguson also emphasized a heightened urgency to address central governance and U.S linearization. This new urgency is derived from multinational efforts of other countries that have started to negotiate with WHO about licensing their country-specific morbidity linearizations, which could materially disadvantage the United States' future uses of ICD-11.

Workgroup Finding for Full Committee Consideration

Mr. Ferguson presented the Full Committee with the following Workgroup finding to facilitate discussion: *It is imperative that HHS designate one office or agency to be responsible for overall coordination of ICD-11 morbidity coding in the U.S. This office or agency should further be charged with, and allocated sufficient resources for, federal government coordination of all ICD-11 morbidity coding research, funding, rulemaking, and resources relevant to adoption, implementation, and maintenance of ICD-11 as a U.S. regulatory code set.*

***Discussion***

Ms. Hines encouraged all members to focus on the needs and goals that the Full Committee's recommendation should present to HHS, rather than on the mechanisms to achieve these goals.

ICD-11 Workgroup and Full Committee Members Only

Ms. Hines asked for clarification between country-specific linearization and country-specific CM. Mr. Ferguson explained that a linearization is a subset of ICD-11 that is derived from the foundation and underlying ontology of the international version of ICD-11 and presents its users with an ICD-11 code set that works with optional, country-specific extension codes. Linearization also ensures compatibility with international tooling and reporting. In contrast, a CM is a customized version of ICD-11 that is specific to a country.

Ms. Banks commended the Workgroup on its substantial efforts. She asked for clarification on WHO's involvement during CM and linearization and whether ICD-12 is forthcoming. Mr. Ferguson confirmed that CM efforts do not involve WHO, whereas linearization efforts occur with WHO. Regarding ICD-12, Mr. Ferguson noted that ICD-11 has a structural foundation that is based on ontology that is continuously updated. This new structure would enable the United States to maintain U.S.-specific updates to the international edition of ICD-11 and reduces the nation's burden of costs and resources.

Dr. Hodgkins noted the nuances of a cost-benefit analysis, which differs at the system and stakeholder levels, and that the cost or benefit depends on the individual stakeholder. He also commented on the use of AI automation, noting that AI implementation involves varying levels of sophistication at an organizational level and that successful AI utilization to facilitate the automation of ICD-11 implementation will have to be conducted through a centralized model or activity that is based on a U.S.-specific linearization.

Dr. Hodgkins then asked for clarity on the potential impacts of different nations adopting different ICD-11 linearizations and code extensions on U.S. adoption and international comparability of data. Mr. Ferguson responded that the impact will depend on the degree to which other countries utilize unique extensions that fundamentally and conceptually differ from U.S. extensions. He added that country-specific linearizations will have minor impact on international comparability of data; if linearizations differ, whether entirely or by exposing differing levels of granularity, then comparisons will be made at hierarchical code positions that enable these comparisons.

Mr. James noted that the Workgroup's summary highlighted the challenges of ICD-11 implementation for all stakeholders and the urgency of starting this transition, sharing that state public health departments will need to obtain approval from state legislatures before updating their systems and workflows.

Dr. Romano expanded on Mr. Ferguson's earlier points and explained that the ICD-11 foundation contains nearly 100,000 clinical concepts, of which only a fraction are included in the MMS linearization. He added that an alternative linearization for morbidity would contain a larger fraction of the foundation's concepts for stem code utilization. Dr. Romano also noted his experience serving on the WHO-FIC Quality and Safety Working Group and described WHO's concerns about international compatibility. He noted that active engagement with the appropriate U.S. governance structure for international conversations will enable the United States to partake in the creation of multinational extension codes. In addition, he explained that cluster coding begins with a stem code and ends with extension codes that are indicative of laterality, pathology, causal mechanisms, or other factors. The Full Committee and Workgroup must consider the implications of using longer codes (e.g., at least 20 characters) in information systems, which currently utilize ICD-10-CM codes with a fixed width of 7 characters.

Dr. Vickie Mays (ICD-11 Workgroup member) emphasized the need for centralized coordination of ICD-11 morbidity coding and suggested that the designated coordinator engage a council of agencies to facilitate communication. Mr. Ferguson replied that the designated agency would coordinate a council or committee that represents all stakeholders—including the public and private sectors—to collaboratively address a range of issues (e.g., HIT, informatics) and lead the morbidity negotiations with WHO.

Dr. Mays also asked whether this centralized coordination should include coordination of ICD-11 implementation for mortality. Mr. Ferguson noted that Dr. Robert Anderson (of NCHS) is the coordinator for mortality reporting, which uses MMS linearization. Dr. Anderson explained that combining morbidity and mortality under the same coordinating entity is problematic, because their respective implementation processes are substantially different; the addition of mortality oversight would encumber the morbidity process. In addition, NCVHS is not subject to the regulatory process for the implementation of mortality coding, and NCHS executes all mortality coding for the United States. However, Dr. Anderson supports communication on progress between the morbidity and mortality coordinating groups.

Ms. Banks inquired whether the Workgroup's finding should include "in collaboration (or coordination) with ICD-11 mortality," upon which she would make a motion to approve this statement. Mr. Ferguson reminded the Full Committee that the statement of the Workgroup's finding is a report to the committee, not a recommendation itself, and that the Full Committee must use this Workgroup finding to develop a recommendation to HHS. He added that if this statement were a Full Committee recommendation, the recommendation could include a rationale that offered a mechanism for coordination.

Ms. Bowman noted that implementation and linearization efforts are different issues; the lead offices to coordinate either aspect may be different. Ms. Bowman also shared that CDC has an ICD-10-CM classification team that leads the U.S. morbidity efforts with WHO and suggested that this team be heavily

involved in the U.S. linearization effort for ICD-11 morbidity because of its vast expertise on U.S. specific codes and ICD-10-CM maintenance.

Dr. Geoffrey Reed (ICD-11 Workgroup member) noted his experience leading the development of the mental and behavioral disorders classification for ICD-11 and WHO's detailed diagnostic manual during his previous 10-year tenure at WHO. He emphasized the absence of U.S. representation at WHO and WHO-FIC and stressed that the United States must participate in discussions with WHO on country-specific needs for ICD-11 linearization. Ms. Stanfill agreed with Dr. Reed's assessment of the urgency for U.S. representation for morbidity at WHO-FIC.

Dr. Hodgkins expressed that coordination should not be separated into implementation and linearization, because linearization is a central piece of ICD-11 implementation. However, he acknowledged Dr. Reed's comments on the lack of U.S. representation on linearization at WHO and questioned whether the United States would designate a lead agency for overall coordination in a timely manner. In addition, Dr. Hodgkins pondered whether the ICD-10-CM classification team would be biased toward an ICD-11-CM if involved in the linearization process.

Mr. Ferguson shared that the August 2023 Expert Roundtable Meeting highlighted the widely divergent opinions among experts on which agency should lead coordinating efforts. He reiterated that the Workgroup's finding does not designate a lead office or agency, and that HHS must select this lead if the Full Committee makes this recommendation to HHS.

Dr. Kin Wah Fung noted that ICD-11 is capable of effectively replacing ICD-10-CM through full leverage of linearization, without a need for a CM, and that U.S. linearization is advantageous.

Dr. Watzlaf expressed concern about the limited progress since 2018 and requested that the Full Committee move forward by accepting the statement of the Workgroup's finding as already written. Dr. Mays countered and expressed that the specificity of this statement has implications for the public; the public should not independently contact WHO and should participate in the coordinating council instead. She explained that this specificity is essential to inform the government of the necessary requirements and resources to facilitate quick action. In response, Mr. Ferguson reiterated that the rationale for the recommendation, not the recommendation itself, would highlight the essential need for a coordinating body.

Full Committee Members Only

Mr. Ferguson noted that the language in the statement of the Workgroup's finding would be retained, but with a new provision that the Full Committee will work with the ICD-11 Workgroup to develop a rationale statement upon approval of the recommendation. This provision will emphasize the critical importance of a coordinating council and collaboration with the mortality group. In addition, Dr. Watzlaf clarified that the Full Committee would be able to offer input to the coordinating council.

Ms. Banks requested the addition of a second recommendation to emphasize the urgency of appointing a U.S. representative to the appropriate WHO committee. Ms. Hines requested proposed language for the second recommendation.

Mr. Ferguson inquired about the sufficiency of adding "immediately" or "now" to the first recommendation to eliminate the need for a second recommendation. Ms. Banks noted that a second recommendation would enable a quicker appointment to WHO, compared to creation of a coordinating entity, without adding complexity to the first recommendation.

Ms. Monson clarified that the Full Committee would modify the first recommendation from "designate one office or agency" to "designate one office or agency immediately" and to add a second recommendation to emphasize the urgency to appoint a specific individual to participate in WHO discussions.

Ms. Banks suggested that the second recommendation stress that the United States immediately appoint a federal representative to advocate for U.S. interests during WHO discussions.

Dr. Hodgkins expressed concern about a disconnect between the first and second recommendations related to the need to select both a specific individual representative and an agency for overall responsibility and asked whether the second recommendation should be a part of the rationale for the first recommendation instead. Mr. Ferguson clarified that Dr. Hodgkins suggested that the rationale include U.S. appointment of an individual on a temporary or permanent basis, immediately, while the agency is being determined.

Ms. Donald noted her support for a second recommendation to highlight the urgency and need for U.S. representation. She also noted that the specification about mortality in the recommendations will confuse the public because the general public likely does not understand this difference. Dr. Watzlaf also noted her support for two recommendations to highlight the importance of both a U.S. representative and a coordinating entity.

In response, Dr. Hodgkins suggested that the second recommendation clearly note that the appointment of a U.S. representative would be on an interim basis and that the coordinating entity would be responsible for appointing a permanent representative. Mr. Ferguson disagreed with addition of "interim basis." Ms. Banks noted that a position previously existed, but was not refilled, and asked whether refilling this position would be more expeditious than creating a new role. Mr. Ferguson noted that the recommendations should focus on the goal and not the methods. Ms. Banks requested that the rationale development include a note for appropriate coordination with mortality implementation work.

***Vote***

Ms. Hines presented the following two updated recommendations for approval:

- **Recommendation 1:** It is imperative that HHS designate one office or agency immediately to be responsible for overall coordination of ICD-11 morbidity coding in the U.S. This office or agency should further be charged with, and allocated sufficient resources for, federal government coordination of all ICD-11 morbidity coding research, funding, rulemaking, and resources relevant to adoption, implementation, and maintenance of ICD-11 as a U.S. regulatory code set.
- **Recommendation 2:** While HHS is in the process of organizing a coordinating office or agency, it is imperative that the Department appoint a federal representative to represent the U.S. to WHO for morbidity coding coordination now.

Ms. Banks made a motion to approve these two recommendations, which was seconded by Mr. Wagner. Ms. Monson called for a vote of the NCVHS Full Committee members; all 12 members voted in favor, and the recommendations were approved.

**NCVHS 2024 Report to Congress—Jacki Monson, Chair, and NCVHS Members**

***Overview***

Ms. Monson provided a brief overview of the purpose of the NCVHS Report to Congress. This report advises the HHS Secretary and Congress on the status of implementation of Part C of Title XI of the Social Security Act; assists and advises the Secretary in complying with the requirements imposed by that provision; studies the issues related to the adoption of uniform data standards for patient medical record information and the electronic interchange of this information; and reports to the Secretary any recommendations and legislative proposals on these data standards and electronic exchange. This report should also address the following topics as deemed appropriate by the Full Committee:

- The extent to which entities required to comply with Part C of the Act are cooperating in implementing the standards adopted under such part;
- The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards;
- Whether the federal and state governments are receiving information of sufficient quality to meet their responsibilities under such part;
- Any problems that exist with respect to implementation of such part; and
- The extent to which timetables under such part are being met.

The 13th Report to Congress covered years 2017-2018 and was published in March 2019. The 14th Report covered years 2019-2020 and was published in 2021. The current report covers years 2021-2023 and will likely be finalized and approved by June.

***Review and Discussion***

Ms. Monson asked members to suggest changes to the overall approach, additions, deletions, and specific line edits, adding that they need not focus on grammatical errors during this session. She concluded her overview by introducing and acknowledging the efforts of Ms. Denise Love and Ms. Patricia Mactaggart for the current report. Ms. Love led the review and live editing of the draft report. Participants provided the following feedback.

<u>Executive Summary</u>
The Full Committee did not review the executive summary during this session. However, Ms. Monson noted that the executive summary draft is too long.

<u>Introduction</u>
Dr. Hodgkins noted that the document focused on AI when discussing emerging technologies. He asked whether this category should include additional evolving, emerging technologies—such as mobile health solutions, blockchain technology, and FHIR—and noted that the cybersecurity section referenced zero-sum algorithms, which could be folded into the emerging technologies section. Ms. Monson replied that the Full Committee determine the scope of this category. She added that this document was difficult to organize, and therefore multiple sections make recurring references.

In addition, Ms. Mactaggart explained that the document has two health care innovations sections and that emerging technologies is not limited to AI; FHIR is under the standards section and can be moved if necessary. She also explained that Table 1 in the Introduction framed these innovations as two groups: "AI" and "other." Dr. Hodgkins suggested that the latter be changed to "innovations, technology, and

other." Ms. Monson added that the document may benefit from a specifically-focused section (i.e., "digital innovations") that other relevant sections (e.g., standards, privacy and security) can reference.

Ms. Love then reviewed Table 1, which outlines advances in HIT and data policy, standards, and models drivers and dependencies. She explained that the "Emerging Health IT: Health IT and Digital Innovations" section lists the innovations and summarizes their potential opportunities and associated risks. She also explained that the report extensively utilizes footnotes to embed pertinent information.

Furthermore, Mr. James explained that regulations and advancing technologies are abundant in the health care industry and that stakeholders are struggling to implement current technology. He cautioned that this report, which informs standards for the next 2 years, must focus on emerging technologies that align with current industry efforts without projecting future advancements. These projections could cause the audience to stop reading based on budget concerns. In response, Dr. Hodgkins suggested expansion of the title of Section III, Part C under the Executive Summary in the Table of Contents ("Emerging Technologies – Artificial Intelligence Future Considerations") to include "Health IT and Digital Innovations."

Evolving Health Care Context
Participants had no specific feedback for this section.

Progress: HIPAA Standard Transaction and Medical Code Set Standards and Operating Rules
Ms. Banks encouraged the Full Committee to highlight the digital health enforcement of HIPAA standards. She emphasized that enforcement is critical and that this section should include a visualization (e.g., chart, graph) and statement that highlights the impact and efforts related to enforcement. Ms. Banks will help Ms. Love draft specific language to highlight related needs.

Progress: Transition to ICD-11
Participants had no specific feedback for this section.

Progress: Privacy, Security, and Breach Notification
Mr. Ferguson requested that the report emphasize previous discussions on ensuring greater compliance with the existing HIPAA Security Rule.

Ms. Monson requested replacement of the words "poor" and "lack" with "do not meet the minimum cybersecurity hygiene," as well as a statement that enforcing the HIPAA Security Rule could benefit cybersecurity practices. She also noted that the report should explain that AI is both a benefit and a challenge, because AI-based cyberattacks are a new and serious risk to protected health information (PHI) and patient safety. With this new risk, entities that do not already meet the minimum cybersecurity hygiene requirements could leverage AI to devise defensive strategies against cyberattacks.

Ms. Monson requested that the report highlight two recent actions by the Office of Civil Rights (OCR): (1) the opening of an investigation of Change Healthcare and (2) the labeling inappropriate access to medical records as an insider threat to cybersecurity. Mr. Ferguson added that the change in the nature of threats—such as cybercrime, organized crime over nation-state attacks, and the prevalence of ransomware—should also be included.

Ms. Maya Bernstein shared that the use of numbers in Table 11 is challenging to interpret quickly. Ms. Love replied that this table was originally a set of pie graphs, but the smallest entity affected by reported breaches ("Health Care Clearinghouse," with less than 1 percent) could not be displayed. Ms. Monson

acknowledged Ms. Bernstein's comment that pie charts are helpful in visualizing patterns. Ms. Bernstein suggested that adding numbers from previous reports to Table 11 may help to show the trend over time.

Dr. Hodgkins asked whether Table 11 should repeat the existing footnote on the recent Change Healthcare breach. He explained that this footnote would prevent misinterpretation of the small percentage for "Health Care Clearinghouse." Ms. Monson further explained that the breached data resided in a clearinghouse, and Ms. Love agreed that health care clearinghouses are a new target of attacks. Ms. Hines noted that NCVHS staff or contract logistics support could help format the document's tables throughout the next few weeks.

Ms. Monson noted that the HIPAA Security Rule is outdated if emerging trends are not being sufficiently met and that the financial margins in health care are small, which limits health care entities' investments in cybersecurity.

Ms. Monson shared a chat message sent via Zoom that suggested that the report contain both text and visuals to help people who are visually impaired.

Ms. Monson suggested replacing Table 12, which includes details—extracted from OCR's portal—on individual breaches that occurred in 2023, with trend data of these details (e.g., types of incidents, frequency, impact). Ms. Love noted that an alternative to the table is to provide a hyperlink to the OCR reports. Mr. Ferguson and Ms. Hines agreed that showing trends from the past 5 years would be useful for the reader. Ms. Monson will help Ms. Love refine the trend data.

Emerging Trends and Challenges: Interoperability

Ms. Hines revisited Mr. James's previous comment on the untenable pace of the innovation and implementation of emerging technologies. Mr. James agreed that this section aims to increase awareness of the breadth of innovation that is available to health care and does not require immediate implementation of these innovations.

Ms. Monson shared a chat message that asked whether the document should specifically include FHIR adoption under this interoperability section. Mr. James noted that FHIR should be covered in standards to help readers understand that the FHIR standard is available for use. In addition, Mr. Ferguson noted the importance of outlining the risks and benefits of implementing API-based ecosystems. He explained that the FHIR standard is used in APIs and will soon replace X12.

Emerging Trends and Challenges: Cybersecurity

Mr. Ferguson and Ms. Hines will send Ms. Love, via email, specific language about future-oriented cybersecurity. Mr. Ferguson noted that this language calls for increased enforcement of the HIPAA Security Rule through reviews, assessments, audits, and additional assistance for smaller entities that have fewer resources, as well as CEs and business associates. He explained that the majority of large breaches are due to third-party risk and that many CEs neither utilize risk assessments nor audit business associates to manage risk.

Ms. Monson suggested the addition of another footnote discussing the MOVEit data breaches, which began late in May 2023 and are ongoing.

Emerging Trends and Challenges: Emerging Technologies – Artificial Intelligence

Ms. Love noted that she will revisit Ms. Monson's comment on including cybersecurity hygiene requirements beyond the Security Rule in its current form.

**Standards for SDOH Data Elements: Successful SDOH approaches and challenges to promote health equity—moderated by Jamie Ferguson and Lenel James**

***Somava Saha, MD, MS, Executive Lead, Well Being in the Nation (WIN) Network***

In January 2017, the NCVHS Population Health Subcommittee released the fourth version of the NCVHS Measurement Framework for Community Health and Well-Being. During that timeframe, Dr. Saha led the 100 Million Healthier Lives movement, which implemented multiple initiatives that tasked communities and health systems with collecting various measures. Dr. Saha noted that Cambridge Health Alliance had 542 measures—540 physical health indicators and 2 behavioral health indicators—that did not measure social determinants of health (SDOH).

Dr. Saha led a process to develop such measures, which prioritized needs that were defined by communities, such as overall well-being. The measures were validated measures using the National Quality Forum criteria and a "grassroots-to-grasstops" approach. Dr. Saha highlighted the importance of measuring trust, everyday discrimination on health outcomes, loneliness, and social connection. She noted that this effort provided a range of stakeholders—including grassroots communities (e.g., farmers, barbers), health and hospital systems, and federal agencies—with validated core measures for use and established the WIN Network—a strategic network to advance intergenerational well-being and equity.

The WIN Network's measure process exists to (1) connect the grassroots to the grasstops in an unprecedented and living collaboration (e.g., the Food is Medicine initiative) to define, measure, and improve communities' values; (2) provide communities access to standard measures and data to drive their own improvement and accountability; and (3) create enabling tools and supports to transform the nation and the world. This process is ongoing and provides a living library of measures. Currently, the WIN Network is updating this library with measures of racial justice and intergenerational well-being and equity.

The WIN Network offers the following core measures for short- and long-term use across sectors: people's perception of their well-being; life expectancy; healthy communities index (e.g., *US News and World Reports*, County Health Rankings and Roadmaps); child poverty; differences in subjective well-being; years of potential life gained; income inequality and graduation rates; and differences by demographic variables. The WIN Network also developed a Vital Conditions framework based on social needs that communities noted were valuable, such as belonging and civic muscle.

To conclude, Dr. Saha noted that CDC and the Federal Emergency Management Agency requested that the WIN Network develop Thriving.us—a springboard for equitable recovery and resilience—and shared examples of real-time data availability that include measures that correlate to outcomes (e.g., morbidity, mortality, cost) for communities.

***Meagan Khau, MHA, Director, Data Analytics & Research Group (DARG), Office of Minority Health (OMH), CMS***

CMS OMH—one of eight offices of minority health within HHS—coordinates health equity data collection and leads data improvement initiatives, including two frameworks that focus on collecting standardized information. In fall 2022, CMS OMH released a Data White Paper to identify gaps in CMS' health equity data collection and define CMS' current and future initiatives to improve this collection.

Ms. Khau highlighted two Executive Orders (EOs)—EO 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government) and EO 14031 (Advancing Equity, Justice, and Opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders)—that focus on the need to collect disaggregated data and assess equity. To address these needs, CMS collected race and ethnicity data using the 2011 HHS Data Standards, replacing the OMB 1997 standards, when possible.

Ms. Khau described the challenge posed by use of disaggregated data in the context of EHR interoperability to target interventions for specific populations. To refine race and ethnicity data collection, CMS led various initiatives. As of January 2023, CMS required participants of all Center for Medicare and Medicaid Innovation (CMMI) models to report race and ethnicity data using the United States Core Data for Interoperability (USCDI) standards. From October 2022 to October 2023, CMS began data collection in four post-acute care settings. More recently, CMS has started to collect race and ethnicity data on Medicare enrollment forms (Parts C and D), but these data are limited. Lastly, CMS utilizes various survey instruments to collect self-reported data.

Ms. Khau reviewed the recent revisions to the OMB SPD 15, which expands write-in responses for data collection. She noted that these write-in responses may introduce challenges related to small sample sizes that cannot be released for data analytics and could therefore detriment smaller, underserved communities. Ms. Khau also shared that CMS' Marketplace application collects demographic data on sexual orientation and gender identity, which are important to collect and must be stratified to identify specific groups for targeted intervention.

CMS OMH is involved in various initiatives to collect SDOH data. For example, CMS OMH submitted a new SDOH data element to the USCDI standards. It began data collection for SDOH in the post-acute care settings. It added two SDOH measures—screening for social determinants of health and screen-positive rate for social determinants of health—that went into effect in FY23 and will be applied to End State Renal Disease Quality Incentive Program, Inpatient Psychiatric Facility Quality Reporting Program, and Prospective Payment System-exempt Cancer Hospital Quality Reporting Program.

To conclude, Ms. Khau shared the following opportunities for CMS data usage: (1) Tribal Data Learning Community Program, a new 1-year pilot program that provides Tribal Epidemiology Centers with data resources to facilitate meaningful research efforts; (2) Health Equity Data Access Program Grant, which provides access to CMS data through the CMS Virtual Research Data Center; and (2) Minority Research Grant Program, which supports researchers at minority-serving institutions.

***Vanessa Candelora, Senior Consultant, Gravity Project Program Manager, Point-of-Care Partners (POCP)***

The Gravity Project (i.e., Gravity) is a multi-stakeholder, collaborative initiative to develop consensus-driven data standards to support the collection, use, and exchange of data to address SDOH and support the integration of health and human services in the HHS Strategic Approach to Addressing SDOH to Advance Health Equity. In its seventh year, Gravity has successfully introduced a nationally recognized set of open data standards-based terminologies to support care across 19 social domains.

Ms. Candelora explained that Gravity utilizes a trusted, evidence-based curation process to develop open-source, consensus-driven standards and integrates subject matter expertise and lived experiences into existing coding and standards for widespread implementation and adoption across EHRs, among other systems. She highlighted the following achievements, resulting from this trusted process, and noted that adoption is a key factor for success:

- Most national SDOH quality measures programs and regulations reference Gravity's value sets as the base for compliance.
- Gravity develops data standards set forth by the CMS Framework for Health Equity.
- Gravity data elements have been incorporated into USCDI since USCDI Version 2.
- Gravity was named in the White House U.S. Playbook to Address Social Determinants of Health (November 2023) and ONC's HTI-1 Final Rule.
- Gravity created evidence-based value sets that the National Committee for Quality Assurance (NCQA) references in its Social Determinants of Health Equity Measurement Approach.

In addition, Ms. Candelora noted that Gravity data use principles for equitable health and social care to promote trust and accountability among care providers, patients, communities, and institutions. These principles aim to improve personal health outcomes and population health equity; ensure accountability and personal control; design appropriate solutions; and prevent, reduce, and remediate harm.

Ms. Candelora also noted that Gravity utilized a tiered model approach to pilot its adoption in various organizations nationwide. She hopes that the success of these pilots will encourage other states and entities to leverage Gravity data terminology and FHIR standards to enable national interoperability of these standards.

Lastly, Ms. Candelora shared that Gravity can be leveraged for additional opportunities to address needs at individual, group (e.g., family, household), population, and community levels; tackle challenges in data representation for families, households, and tribal connections; reduce burden and improve sustainability for community-based organizations; evaluate inequities to facilitate structural solutions; expand data support for use cases to center whole-person care; and increase capacity for intelligent social care navigation.

***Prerana Laddha, MS, Director of Social Care and Behavioral Health, Epic Systems Corporation***

The Electronic Health Record Association (EHRA) is a trade association composed of 29 EHR companies that serve a vast majority of hospitals, post-acute, specialty-specific, and ambulatory health care facilities nationwide. It aims to improve the quality and efficiency of patient care through the adoption and use of innovative, interoperable, and secure HIT. The EHRA SDOH and Health Equity Task Force aims to identify, prioritize, and address the barriers to delivering equitable, socially informed care. In addition, EHRA is committed to exploring strategies to leverage technology to effectively address health care disparities.

Ms. Laddha noted a significant increase in the number of health systems documenting and addressing SDOH for patients. However, documentation of these data elements in EHRs present challenges. First, clinical visits rarely afford time to complete and document assessments of SDOH. To minimize this burden, technology can be leveraged to integrate these assessments into existing clinical workflows; improve data accessibility across care settings to promote timely interventions; encourage patients and families to self-report social needs prior to their visit; and extract SDOH information from clinical notes using AI.

Second, existing standards and policies lack a consensus on which social domains are a screening priority. Ms. Laddha provided the following examples: CMS recommends, in its 2023 Inpatient Prospective Payment System Final Rule, screening for five domains; Healthy People 2030 lists five broad domains of risk; the Future of Nursing 2020–2030 lists 11 domains of risk; and the Gravity Project, to classify and encode a broad list, includes 19 current and 3 upcoming domains. Ms. Laddha noted that solutions to

address this discrepancy include standardization of domains for uniform screening across care settings and feasible timelines for EHRs to implement new regulations for this screening.

Third, providers hesitate to screen patients without being readily aware of solutions to offer those who have social needs. To address hesitation, technology can facilitate the education and dissemination of SDOH interventions, which include educational material, connections to community partners, referrals to social work services, and creation of care plans. Additional strategies include initiatives that fund and engage community partners on an ongoing basis, standard taxonomy of services to define the appropriate level of interventions, and standards for closed loop referrals (i.e., electronic exchange of data) with community-based organizations.

Ms. Laddha also emphasized the importance of interoperability of SDOH across different systems (e.g., different EHR systems) to reduce duplicative screening efforts. Although data standards are available (e.g., USCDI, Gravity) for these assessments, the following barriers to interoperability exist: (1) regulatory programs at the national or state level might suggest using screeners for Logical Observation Identifiers Names and Codes (LOINC) codes that are not readily available; (2) different verbiage across screeners deviate from LOINC code mappings; and (3) the mapping of screeners to domains is not standardized. To address these barriers, EHRs should utilize a standardized code set (e.g., ICD-10-CM Z codes, LOINC codes) to represent domains screened and domain risk in a standardized way (e.g., "housing insecurity is present") and should use optional coded values to indicate the measurement or instrument used for assessment.

Further, Ms. Laddha noted that technology for research and analytics elicit meaningful data to evaluate screening and positivity rates to reveal geographic trends in specific domains (e.g., housing and transportation). These data may also elucidate the impact of SDOH on outcomes and can be augmented with public data sets (e.g., Area Deprivation Index, Social Vulnerability Index) to identify vulnerable populations to inform strategic initiatives and targeted interventions. In addition, data stratification (e.g., race, ethnicity, language) may inform efforts to promote health equity.

To conclude, Ms. Laddha noted that standardized capture of SDOH data will enhance analytics and accelerate initiatives to address health disparities.

***Rachel Harrington, PhD, Senior Research Scientist, Health Equity, National Committee for Quality Assurance (NCQA)***

NCQA is a national organization that develops measures and standards, implements programs, and conducts supporting research to ensure access to high-quality, equitable care.

Dr. Harrington shared a study that analyzed unmet social needs by payer type and found that unmet social needs are not limited to specific populations. She then provided an overview of the transformation of health care expectations over the past several years, highlighting the following efforts by CMS:

- **Medicare:** The Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 expands the ability to offer SDOH-focused supplemental benefits to address unmet social needs.
- **Medicare:** As of 2022, Medicare Part C plans offered meals (68 percent of plans), transportation (39 percent), nutrition (30 percent), and in-home support (11 percent).
- **Medicaid:** As of 2021, 33 states operated with a level of SDOH-related requirements.

- **Medicaid:** 24 states require a screening for social needs; only 11 of these states require the use of a uniform screening tool.
- **Medicaid:** The inconsistency of standardized requirements fosters a heterogeneity in policy and data environments—a common theme of Section 1115 Medicaid waivers.

Dr. Harrington noted that to ensure that these resources and services deliver care that is high quality, equitable, and impacting outcomes, the CMS Universal Foundation includes a statement on measures for social needs screening and intervention.

To improve quality measurements, NCQA incentivizes the collection and management of data using best practice terminology (e.g., accreditation or structural standards, quality measures of data completeness, score organizational quality on data maturity) and leverages standardized terminology to redefine high-quality care targets (e.g., measures of social needs, revised measure population definitions, stratification using standardized terminology).

Dr. Harrington shared an example of NCQA's efforts to construct a measure of Social Needs Screening and Intervention (SNS-E), which includes Healthcare Effectiveness Data and Information Set (HEDIS) indicators for screening and intervention and uses clinical data systems for measurement. She then explained the operationalization of HEDIS SNS-E screening and intervention indicators with specific instruments and standardized terminology to highlight the measure's ability to obtain nuanced data.

Dr. Harrington noted that a recent set of NCQA's qualitative interviews with health plan organizations nationwide shared the following themes:

- **Process and Workflow:** Screening is documented through case management by health plans, not by clinicians; follow-up is being done but not captured.
- **Facilitators:** An increase in the number of policymakers, states, and quality organizations that leverage standardized data and mapping will facilitate easier implementation of infrastructure for standardized data collection and exchange.
- **Barriers:** Mapping to LOINC, especially from multiple data sources, and pulling EHR data, especially SNOMED codes, is difficult; requirements built around specific tools are not reflected in current data standards.
- **Feedback for Consideration:** The measure should be updated to include ICD-10-CM Z codes.

Dr. Harrington concluded by briefly highlighting NCQA's efforts to build infrastructure for standardized data collection and exchange, as well as its engagement in cross-sector partnerships to address health-related social needs.

***Julia Skapik, MD, MPH, FAMIA, Chief Medical Information Officer, National Association of Community Health Centers (NACHC)***

Dr. Skapik began her presentation by disclosing that she is the volunteer Board Chair of the Health Level 7 International (HL7), which is an international HIT standards development organization (SDO).

Dr. Skapik noted that the Community Health Center (CHC) Movement began during the Civil Rights Movement, which highlighted the disparate health care access for underserved communities. Designed to improve access and provide culturally competent health care, CHCs are centered on five essential tenets:

1. They must be located in high-need areas.

2. They must provide comprehensive health and wraparound services, including enabling services (i.e., social interventions).
3. They must be open to all residents, regardless of insurance or ability to pay, with a sliding scale fee based on income.
4. They must be patient-centered, nonprofit, and governed by community boards, to assure responsiveness to local needs.
5. They must follow performance and accountability requirements regarding their administrative, clinical, and financial operations.

Currently, the United States has 1,487 CHCs, which served over 31.5 million patients during the previous year. However, NACHC estimates that more than three times this patient volume still need health care. Dr. Skapik also noted that a high concentration of people with social needs seek care at CHCs.

Dr. Skapik remarked that numerous barriers prevent the successful use of standards. First, EHRs were built on proprietary systems, not open-source standards, and therefore utilize closed-source terminology to represent clinical data. Second, data extracted from EHRs present the following challenges:

- Limited validation of EHR
- Low data quality
- High prevalence of missing data; variance in documentation, including the structure of the content, the locations within the record, and the extent to which data are hidden in free text
- Lack of harmonization (in federal, state, city, payer, registry, and local requirements) that lead to data inconsistency and is a barrier to success
- No sophisticated dashboarding or data extraction tools
- Lack of interoperability in data reuse

Dr. Skapik explained that FHIR is designed for ease of data extraction; exchange through API; use of services; ease of use for programmers, even those without HIT expertise; and open-source use (i.e., free to use). Further, all certified EHR products are required to use the HL7 FHIR API. Whereas HL7 provides this open API, this API version does not incorporate the USCDI version that requires SDOH data exchange.

Dr. Skapik reviewed the USCDI Draft Version 5 summary. She noted that although this version includes data elements in multiple data classes that are relevant to social- and health-related outcomes, people have expressed concerns about the lack of clarity and guidance on which data elements should be implemented, mapped, and exchanged to facilitate interoperability.

Dr. Skapik also reviewed the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE)—a national standardized patient risk assessment tool designed to engage patients in assessing and addressing social drivers of health. PRAPARE serves as an important tool for harmonization and normalization of high-quality, patient-level data because it is actionable, standardized and widely used; evidence-based and stakeholder-driven; designed to accelerate systemic change; and patient-centered.

Furthermore, Dr. Skapik briefly reviewed ICD-10-CM Z codes, noting that Z codes facilitate SDOH data extraction from EHRs; that workflows to record Z codes do not exist; and that Z codes do not provide a sufficient level of granularity to address social needs. To address these needs, health care systems must adopt an equity-first approach that requires assessments on social needs and care gaps and utilize dashboarding tools for SDOH data visualization.

Dr. Skapik concluded by noting that strategies to target the following opportunities could support meeting social needs: standardization of data elements and templates; SDOH interoperability, reconciliation, and follow-up utilizing automated workflows; EHR support for care teams; and integration of patient-generated health data into EHRs using APIs.

***Gniesha Dinwiddie, PhD, Health Scientist Administrator, National Institute on Minority Health and Health Disparities (NIMD), National Institutes of Health (NIH)***

Dr. Dinwiddie explained that NIH investments in SDOH research totaled approximately $3.4 billion for 5,885 projects in FY21, $4 billion for 7,540 projects in FY22, and $4.7 billion for 7,709 projects in FY23. In addition, She highlighted the following projects and NIH-wide initiatives that exemplify novel advancements in SDOH.

The *All of Us* Research Program aims to collect longitudinal data from more than 1 million people and focuses on participants as partners by requiring patient consent for release of EHR records into the program's data repository. This repository includes multiple data types, such as EHR data; survey responses to questions on health care access and quality, behavioral health, and SDOH; baseline physical measurements; biospecimens (e.g., blood, saliva); and genomic data. It also serves as a national, open resource for all researchers and ensures security and privacy safeguards for all participant data. Dr. Dinwiddie noted that in November 2021, the program's SDOH survey included 81 questions across 11 domains and captured a diverse sample; approximately 80 percent of respondents were underrepresented in biomedical research. However, this survey had missing data on important health equity measures, including race, ethnicity, age, and socioeconomic status. To improve data collection, the program relaunched this survey, which received fewer responses.

The PhenX toolkit represents a catalog of recommended measurement protocols across many domains to facilitate cross-study analysis, increase the impact of individual studies, and facilitate consistent data collection across studies. In May 2020, the PhenX toolkit launched an SDOH Core Collection, composed of 16 recommended protocols, for NIH-funded researchers to use for data collection. This core collection also includes 23 protocols and 14 protocols to measure SDOH at the individual level and structural level, respectively. She added that various SDOH measures from this toolkit will soon be converted into common data elements (CDEs) at NIH.

The National COVID Cohort Collaborative (N3C) Data Enclave is a patient-centric database composed of EHRs from patients that have been tested for COVID-19 across 45 health systems nationwide.

The funding opportunities for Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities (PAR-23-112) received immense support at NIH, which pledged to provide $125 million over 5 years. In FY22, this initiative awarded 38 grants. This initiative funds research projects focused on evaluating the impacts of structural interventions that have implications for health disparities. It has addressed institutional racism, neighborhood community contexts, and other important domains of influence that are instrumental to SDOH.

The ComPASS program aims to (1) catalyze, deploy, and evaluate Community-Led, Health Equity Structural Interventions (CHESIs) that leverage partnerships across multiple sectors to reduce health disparities and (2) develop a new health equity research model for community-led, multisectoral structural intervention research across NIH and other federal agencies. This program funds 10-year projects through three initiatives: CHESIs; the ComPASS Coordination Center (CCC) at Drexel University, which coordinates

the training and capacity to support CHESIs during their intervention projects; and Health Equity Research Hubs, which focus on providing additional infrastructure and training to supplement the CCC's efforts.

To conclude, Dr. Dinwiddie noted that most of these initiatives require the collection of CDEs. She add that NIH launched a CDE repository in 2015. Maintained by the National Library of Medicine, the repository provides access to structured human and machine-readable definitions of data elements and facilitates data interoperability. It contains 18 different collections of CDEs, and 3 collections focus on SDOH: (1) Science Collaborative for Health Disparities and Artificial Intelligence Bias Reduction, which is a cloud-based platform for population science; (2) PhenX toolkit, which primarily uses LOINC codes; and (3) Rapid Acceleration of Diagnostics (RADx®) Underserved Populations, which encourages data collection using CDEs for the RADx Data Hub.

***Discussion***

WIN Network

Mr. Ferguson asked whether the WIN Network uses preexisting, high-quality data, and if not, how it obtains additional data for developers of SDOH measures. Dr. Saha replied that the WIN Network researches the availability of standard, well-collected, and well-sampled data to ensure accessibility of these data to communities. It also employs two strategies that facilitate self-collection of data and returns data from a survey collection of priority measures to communities to drive community responses.

Disability and SDOH

Mr. James asked how disability-related information is captured as a SDOH. Ms. Candelora replied that Gravity captures a level of specificity that then determines the intervention provided. Ms. Khau added that CMS OMH is exploring strategies to better support disabled populations.

Potential Strategies for SDOH Data Collection

Mr. Ferguson asked whether panelists had insight into potential strategies to impose consistent data standard requirements. Ms. Candelora shared that the private sector focuses on developing a minimum viable product that can serve as a national standard and that this minimum viable product is based on shared features between variable standards (e.g., community- or state-specific). Ms. Khau added that a baseline set of standards—similar to OMB's standards on race and ethnicity—that includes disability and other demographic elements would be helpful. In addition, Dr. Saha noted that a measurement system that assesses people's values in real time would be useful to the federal government in its efforts to improve population and community health.

Dr. Hodgkins noted that the underlying structure of the U.S. health care system does not facilitate the nation's ability to address social issues and asked whether panelists had strategies to meaningfully leverage SDOH data collection. Dr. Saha replied that NCVHS designed its Measurement Framework for Community Health and Well-being around structural determinants of health to include measures of societal, environmental, and community-based infrastructure to inform policy changes. She added that the Pathways to Population Health Equity Framework, which aims to help the public health system address structural and root causes of inequities, utilizes the same domains as those in the NCVHS and WIN Network frameworks. Dr. Skapik noted the importance of using key performance indicators for equity to understand unmet needs, volumes, and failures of care coordination and inform efforts to restructure ongoing health care investments. Dr. Dinwiddie added that health care systems must determine whether SDOH measures are appropriate for particular communities, in addition to assessing methods to capture these measurements, and reiterated the importance of ComPASS's focus on structural interventions at the community level.

Ms. Banks asked panelists to share potential strategies to ensure the collection of high-quality, primary data that are comparable and that SDOH research occurs at the community level. Dr. Skapik noted that primary data points must come directly from the patient and suggested the use of AI alongside other sophisticated tools to reconcile and validate data. Ms. Laddha agreed that patients are the primary source for data and emphasized the importance of consistency of domains assessed across health care systems.

Panelists' Suggestions for NCVHS

Dr. Watzlaf asked panelists for suggestions on how the Full Committee could help advance efforts related to SDOH and health equity. Ms. Khau requested guidelines for agencies to follow for efficient, consistent data collection and for additional support from experts who understand SDOH programs, data, and health equity. In addition, Dr. Harrington requested a solution designed to meet public health needs alongside the health care system; solutions that are designed solely for health care systems are ineffective for team-based care models (e.g., community organizations, Promotoras). Moreover, Dr. Skapik requested establishment of a task force on data governance and harmonization of SDOH.

Data Harmonization and Mapping

Mr. Wagner noted his experience working on harmonization standards and shared that diverse perspectives are important for proper definition and harmonization of data elements. He asked about panelists' awareness of organizations that work on and support the harmonization of data. Ms. Candelora noted that the Gravity Project fosters an open consensus-based process with stakeholders across all sectors to identify gaps in existing standards and to recommend additional standards for SDOH data. Whereas the Gravity Project is focused on the documentation, use, and exchange of SDOH data specifically, many SDOs are involved in work groups and collaborative accelerator projects that are focused on different areas of data standardization.

Mr. Ferguson asked whether panelists have started to map their data elements and measures into ICD-11. Dr. Skapik remarked that separate mappings is not best practice; people should automate mapping and build intentional value sets that withstand time. In addition, Ms. Khau noted that CMS OMH has not mapped data and is currently exploring ICD-10-CM Z codes for SDOH.

Ms. Donald noted that organizations can reference the NCHS model for standards setting and data collection. In response, Dr. Saha commented that the WIN Network currently partners with NCHS.

### Value Based Care Models vs Fee-for-Service: Implications for HIPAA Standards—moderated by Deb Strickland

***Farzad Mostashari, MD, ScM, Co-Founder and Chief Executive Officer, Aledade***

Compared to traditional FFS models, value-based care (VBC) models seek to better align incentives between payers and health care providers. Under traditional FFS models, reimbursements are often based on factors (e.g., price negotiations between payers and providers) that are unrelated to patient health outcomes. This misalignment in incentives between payers and providers often limits data sharing to those data required for claims. VBC models seek to align incentives between payers and providers by basing reimbursement levels on care quality and cost savings and exchanging additional data to determine care quality and cost savings compared to relevant population benchmarks.

Aledade, which is the largest network of independent primary care providers (PCPs), partners with these PCPs to help them shift from FFS to VBC models. Aledade partners with CMS and more than 200

commercial payers, including national (e.g., Humana), regional (e.g., Highmark), and local (e.g., Arkansas BlueCross BlueShield) organizations.

Aledade conceptualizes VBC models across its "Core 4" components: (1) Access & Quality (particularly for primary care), (2) Point of Care services, (3) Care Compass, and (4) Care Transitions (e.g., between PCPs and specialists). Based on these four components, Aledade has identified five key data needs for VBC models:

1. **Attribution** (i.e., identifying relevant patient populations served by each health care provider) is crucial for identifying relevant benchmarks and attributing patient outcomes to relevant health care providers. Attribution lists must be updated regularly (e.g., monthly or quarterly) and should include relevant patient details (e.g., demographic data, risk score/categorization) to identify relevant risk-adjusted benchmarks.
2. **Quality reporting** is crucial for identifying potential gaps in primary care. Relevant quality metrics include HEDIS Care Gaps reports and medication adherence lists.
3. **Risk adjustment** requires proper patient attribution and is necessary to identify relevant risk-adjusted benchmarks for different patient populations. Under Aledade's VBC models, this risk adjustment also impacts reimbursement amounts (i.e., higher reimbursement for higher risk populations).
4. **Revenue/funding data** for attributed patients, including relevant premiums and funding.
5. **Claims and non-claims expenses** for all paid professional and institutional medical claims for all attributed members. Claims are included regardless of status (e.g., reversed, denied, adjusted).

Fulfilling these data needs requires further alignment of health care data standards, particularly harmonization of administrative and clinical data. Data exchange also requires the flexibility to test, update, and advance the use of FHIR-based transactions (e.g., prior authorizations, claims attachments) to identify new efficiencies in data exchange.

***Todd Couts, MS, Deputy Director, Business Services Group, CMMI, CMS***

CMMI was created under Section 3021 of the Affordable Care Act (ACA) to "test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care." To fulfill this mission, CMMI conducts model tests in which potential policy changes are pilot-tested in Medicare or Medicaid to determine whether those policies reward health care providers for novel approaches to cost-efficient and high-quality health care. Participation is voluntary and includes a real subset of health care providers and Medicare/Medicaid beneficiaries. Model tests also have a limited duration (typically 5 years). Model tests can lead to permanent changes in Medicare or Medicaid under three scenarios: (1) care quality improves and costs are not impacted, (2) care quality remains the same and costs are reduced, and (3) care quality improves and costs are reduced.

Since 2010, CMMI has launched 50 model tests across three model groups:

1. **Seamless Care Models Groups**, which includes tests for accountable care organizations (ACOs), special populations models (e.g., kidney care), Medicare Advantage models, and prescription drug models.
2. **Patient Care Models Group**, which includes primary care, hospital-based, and episode-based payment models.
3. **State & Population Health Models Group**, which includes population health models, state and local models, and multi-payer models.

Compared to traditional Medicare and Medicaid FFS models, CMMI model tests have several unique features. First, CMMI interacts with health care entities beyond traditional health care providers (e.g., non-provider ACOs) to gain access to necessary data. Second, participating health care providers join model tests voluntarily, which often results in significant heterogeneity among participating providers. Third, CMMI makes payments to providers that are not claims-based (i.e., not based on specific diagnoses or procedures).

CMMI model projects also use additional types of data compared to traditional Medicare and Medicaid FFS, with relevant data including quality measures, clinical metrics, and SDOH data. Because of its unique data needs, CMMI often uses custom data exchange formats and processes rather than X12 administrative standards. CMMI recently began using FHIR-based data exchanges through multiple mechanisms, including APIs with ACOs, FHIR-based data collection with the Enhanced Oncology Model, and a FHIR Questionnaire capability for obtaining data from EHRs. However, the majority of CMMI data exchanges continue to use custom formats and processes.

For VBC model tests, CMMI uses the following sequential approach for data exchanges:

1. Entities (e.g., health care providers, ACOs) apply to participate in model tests.
2. Once CMMI approves the entity's application, both CMMI and that entity sign a participation agreement. CMMI then sends attribution data and relevant financial and quality benchmarks to this entity.
3. While participating in the model test, the entity shares many types of data beyond what is typically required for Medicare or Medicaid FFS. Data shared can include provider rosters, quality measures, clinical data, demographic data, and SDOH data. At the same time, CMMI sends multiple types of data to the entity, including claims data, participant (i.e., entity) feedback report, and reconciliation reports. CMMI also facilitates the availability of additional data to the entity, including multi-payer data and patient admission, discharge, and transfer data.
4. Based on data exchanged, CMMI pays the entity adjusted FFS claims-based payments (amount depends on the specific model test) as well as non-claims-based payments such as capitation, population-based, shared savings, and incentive payments.

***Aneesh Chopra, MPP, Co-Founder & President, CareJourney, Author, Innovative State***

The revised OMB Circular A-119 enables government agencies (e.g., CMS) to use voluntary consensus standards developed by nongovernmental organizations to address HIT gaps, and then subsequently adopt those standards through agency rulemaking processes. This process was recently used as part of the Creating Access to Real-Time Information Now Through Consumer-Directed Exchange (CARIN) program, in which participating health plans collaborated to develop a standardized approach for patient access to their medical records through mobile applications. This effort resulted in a FHIR API standard for enabling this data access, which was later adopted by CMS as part of its Final Interoperability Rule.

Voluntary consensus standards offer similar opportunities for addressing current HIT challenges, as described in examples below.

SDOH Data Standards

For health care providers, obtaining a list of patients currently experiencing specific SDOH (e.g., food insecurity) can be challenging because ICD-10-CM Z codes are only used in approximately 0.1 percent of claims. Multiple EHR vendors (e.g., Epic, Cerner) collaborated to modify existing USCDI codes for

indicating relevant SDOH, and these vendors also developed an API for linking their EHR systems with FindHelp.org, which provides resources for patients with food insecurity and other social needs.

Clinical Data for Cancer Stage
Current mandated standards do not provide a consistent manner for reporting cancer stage even though stage influences reimbursement amounts in VBC plans. EHR vendors collaborated to develop a voluntary standard that incorporates cancer stage data based on Enhanced Oncology Model data elements for consistent reporting of cancer stage.

Trusted Exchange Framework and Common Agreement (TEFCA) for Population Health
Current TEFCA exchange networks are focused on specific treatments, which prevents payers from participating in these networks for population health as part of VBC plans. In January 2023, the TEFCA Recognized Coordinating Entity (RCE) proposed a use case for payers to participate in TEFCA exchanges using a FHIR API. ONC is expected to make an approval decision regarding this use case in May or June 2024.

Bundled Pricing Data
Negotiated bundled pricing for complex procedures (e.g., hip replacement surgeries) is currently challenging because of a lack of standards for bundled pricing. Multiple EHR vendors are collaborating to develop a FHIR-based approach for sharing bundled pricing data, including all relevant fees (e.g., operation costs, operating room services), and easily develop bundled explanation of benefits.

Patient Opt-Ins for VBC
Processes for patients to opt in to VBC and select their PCP currently varies significantly between payers and EHRs. As part of the Biden Administration's Cancer Moonshot Program, CMS and EHR vendors are collaborating to develop a consistent method for enabling up to 150 million patients to opt in to VBC and select their PCP.

***Erin Weber, MS, Chief Policy and Research Officer, CAQH***

Ms. Weber provided an overview of CAQH, which is a coalition of more than 100 health care organizations that coordinate on HIT rulemaking and include health plans, providers, state Medicaid programs, vendors, and clearinghouses.

Many CAQH members have collaborated to identify potential approaches for reducing the administrative burden in VBC models. Based on this collaboration, members have identified seven opportunities for streamlining VBC payment:

1. Data quality and uniformity
2. Data interoperability between different VBC stakeholders
3. Accurate patient risk stratification
4. Consistent methodology for provider attribution
5. Reduction in burden of care quality measurement and reporting
6. Health equity by design, including consistent collection and reporting of SDOH data
7. Consistent approaches to address the increasing complexity of VBC plans and their administration

Based on these needs, the CAQH Committee on Operating Rules for Information (CORE) has proposed five sets of operating rules:

1. **CORE Patient Attribution Operating Rules**: Point-of-care and monthly exchange of member attribution data for population health models.
2. **CORE Health Equity Operating Rules**: Standardized collection and exchange of member socio-demographic data.
3. **CORE Health Care Claims Operating Rules**: Standard pathways for the submission of additional diagnoses at a single patient encounter.
4. **CORE Connectivity Rule vC4.0.0**: Real-time exchange through web-based APIs using SOAP and REST connectivity protocols.
5. **Standardization of VBC Terminology:** Consensus-built definitions for common VBC concepts for industry use and reference.

CAQH efforts have also identified how dependent VBC models are on revenue cycle transactions (e.g., X12 834, 270/217 transactions). Thus, these transactions, data sources, and corresponding data definitions need to be harmonized across different health care stakeholders to reduce the administrative burden associated with VBC.

Ms. Weber concluded her presentation by emphasizing three points:

1. Optimizing revenue cycle transactions like those covered under HIPAA to support VBC is critical.
2. Embracing the flexibility of APIs, including FHIR APIs, will help to achieve that next level. However, widespread adoption of VBC will require the health care industry to align around common data definitions and concepts for data exchange.
3. Industry must come together through voluntary coalitions to ensure that technical and data content requirements are moving at the same pace as the uptake of accountable care programs.

***Discussion***

Mr. James asked whether any CMMI model tests have focused on approaches for collecting SDOH data in a format usable for VBC. Mr. Couts responded that two current model tests (Primary Care First and ACO Reach) are examining approaches for improving collection of demographic and SDOH data. In Primary Care First, 98 percent of ACOs submitted improved demographic and SDOH data, but quality varied between types of data. In particular, sexual orientation and gender identity data had many inconsistencies and blank values, potentially because of errors by health care providers and patients electing not to disclose this information. ACO Reach just completed its first data collection and is currently analyzing data collected.

Mr. Hames asked whether CMMI model tests provide funding to enable community health clinics to invest in upgrades to infrastructure and training to update health care workflows. Mr. Couts responded that model tests can provide this funding, and multiple state and local model tests currently fund these improvements.

Ms. Strickland asked how payers can indicate that they are ACOs in X12 271 transactions. Dr. Mostashari replied that ACOs previously sought to develop an approach for indicating ACO status in 271 transactions approximately 10 years ago. He argued that the inability to indicate ACO status remains a policy gap for CMS. Mr. Chopra added that ACOs also require a consistent ability to include supplemental benefits (e.g., medically tailored meals) in 271 transactions. APIs offer an opportunity for an easy approach to exchange data for supplemental benefits.

**Public Comment—Rebecca Hines, Executive Secretary and Designated Federal Officer**

Ms. Hines opened the floor for public comments, noting that written comments may be submitted to NCVHSmail@cdc.gov, and reiterated that Day 2 would not have an oral public comment session. No public members who attended in-person provided comments.

Ms. Hines shared the following question that was asked through Zoom: Where can we learn more about the supplemental benefits for SDOH Services API that was just mentioned? She replied that those interested may visit the HL7 website on Sync for Social Needs.

Mr. Stanley Nachimson, an online participant, provided the following comment through Zoom: Mr. Ferguson and the members of this committee raised quite a number of very important issues and questions and needs for further analysis in order for us to move forward on ICD-11. Given that vast number and their tremendous questions, do we have a sense of how long all of these analyses might take and any idea when the industry might even begin to expect a recommendation and the movement to ICD-11? Mr. Ferguson replied that the timeline is unknown. He noted that the ICD-11 Workgroup began outlining findings for the current phase of work, in this fiscal year, to inform the Full Committee's recommendations. He added that the timeline will likely be clearer through Phase 3 efforts in the next fiscal year.

**Standards Subcommittee Report Out—Tammy Feenstra Banks and Steven Wagner, Subcommittee Co-Chairs**

Ms. Banks reminded the Full Committee that it received two different sets of X12 transactions to review in the previous year and that the Committee received the following two letters since the last NCVHS Full Committee meeting:

1. From Diana Fuller (State of Michigan Medicaid)on November 29, 2023: Supports the health care industry moving to X12 Version 8020 for all currently mandated HIPAA transactions.
2. From Jane Pleasants (Executive Director of SMI®, a nonprofit, community of health care supply chain organizations): Reconsider decision regarding adoption of the updated X12 standard, specifically with regard to inclusion of the UDI-DI in claims transactions.

She expressed appreciation for these comments but reminded the Full Committee that the Committee reviews transactions from a national implementation perspective only.

The previous NCVHS Full Committee meeting featured a session with ONC and SDOs—including X12, HL7, and the National Council for Prescription Drug Program (NCPDP)—to enhance the Full Committee's understanding of approaches used by SDOs and certification bodies to evaluate and assess the readiness of new and updated standards prior to release for national implementation or certification. Ms. Banks noted that the following questions were raised; she discussed answers to these questions in the sections below.

***Does ONC or the SDO assess and report on backward, cross-compatibility or specific anticipated issues with the version update?***

Ms. Banks noted that the SDOs, HL7, and NCPDP assess for backward and cross-compatibility and that X12 assesses these for individual standards. In contrast, ONC examines forward compatibility in particular cases and assesses directionality of compatibility based on how standards are referenced.

***How does ONC or the SDO assess and report on backward compatibility or specific anticipated issues with version updates?***

Ms. Banks provided the following explanations. ONC considers the compatibility of standards relative to whether there are "breaking" changes that would affect the industry efforts to update infrastructure and standard performance as it relates to its HIT Certification standard selection. HL7 provides documents related to backward compatibility, provides summaries of changes made to each version of a standard, and creates a maturity-level framework that is applied to each artifact in the specification. NCPDP provides its members with documents that are easy to read and understand—referred to as Crosswalks—with a side-by-side comparison of the transaction, message types, and guidance; and X12 provides a list of changes supported in the implementation guide to serve as a reference.

***How does ONC or the SDO assess whether current systems can support the functionality and the impact?***

Ms. Banks shared the following: ONC certification for EHRs is voluntary, and testing is completed prior to implementation in real-world settings; HL7 completes testing prior to release and release four stages of standards development up through normative; NCPDP does not require a specific level of test for all new or revised standards and relies on members, stakeholders, and implementers through data request and harmonization efforts instead; and X12 does not require a specific level of testing for all new or revised standards and have initiated a proof-of-concept for the versions that were released for NCVHS review.

***Does ONC or the SDO assess cost and value of changes within a new, updated standard?***

Ms. Banks noted that HL7, NCPDP, and X12 do not utilize peer-to-peer validated studies for cost-benefit analyses, whereas ONC utilizes a peer-reviewed national study to assess benefits. She added that HL7 compiles implementer case studies, including a few academic studies on FHIR, and that NCPDP collects data on the cost and harm incurred when a standard does not move forward. She also noted that ONC assesses cost (e.g., the need to purchase licenses, obtain a form of membership to access the standards) and other factors to include in its Interoperability Standards Advisory report. In addition, Ms. Banks briefly reviewed the HL7 Cambria Grove Innovator Fellowship—now discontinued—and noted that in June 2022, HL7 presented on its value metrics framework that helps characterize various benefits of a specification, which has sufficiency, security, and financial savings.

***Does ONC or the SDO assess potential risks and impacts across existing standards? What is the status of plans for the future of ICD-11 implementation?***

Ms. Banks noted that ONC defers to NSG at CMS to assess potential risks and impacts across existing standards. She explained that HL7 has a collaborative agreement (i.e., contract) with WHO to develop guidance and works directly with code set developers to ensure use in standards. Ms. Banks added that NCPDP is focused on National Drug Code review and monitoring of the status of FDA's proposed rule and is seeking education on ICD-11. X12 is also seeking education on ICD-11, as well as confirmation that ICD-11 will not have a U.S. CM.

***Does ONC or the SDO perform reporting or testing prior to proposing new and/or updated standards for national implementation or certification?***

Ms. Banks noted that ONC performs real-world testing as new certification rules are published and that HL7 performs detailed testing, including specification testing and software validation. In contrast, NCPDP and X12 do not require a specific level of testing for their standards.

***Areas of Consideration for NCVHS***

Ms. Banks noted that these comments from the presenters highlighted the following areas of consideration for NCVHS:

- When considering different types of standards, examine the industry availability of testing infrastructure.
- Consider the cost of obtaining the standard (e.g., license, membership) and other factors.
- Consider the cost of not moving forward or promulgating a Final Rule in a timely manner, including the cost of missed opportunities and use of nonstandard proprietary solutions.
- Define the meaning of backward compatibility. Cross-compatibility is a better term for testing across different standards with different versions.
- In terms of cost-benefit analysis, provide SDOs detailed information about what is required so that they can improve information collection. Unlike HHS, SDOs are not required to collect information.
- Ms. Banks asked the Committee if any of the above comments to be added to the Subcommittees Project Plans. All were added with the exception of the cost-benefit analysis, since a recommendation has been previously forwarded to the Secretary on this topic.

***Discussion***

Mr. James suggested that NCVHS create an inventory of testing tools available from several vendors. Creating this inventory could help entrepreneurs and venture funders to realize that tools are important to create and test. Ms. Strickland agreed and emphasized the importance of testing approaches to move the health care industry forward.

Dr. Watzlaf asked for clarification on whether HL7 could be used as best practice, because HL7 is the only SDO with a testing infrastructure. Mr. James responded that the HL7 tool was built specifically for FHIR, which is the health care version of APIs that is governed by HIPAA and data privacy regulations. He added that vendors and other industries may assume that the health care industry is not interested in engaging in complex, high-quality, and high-volume data exchange.

Mr. Ferguson highlighted the need to assess licensing cost during cost-benefit analyses of testing and implementation approaches. He noted that unlike other U.S. SDOs, HL7 offers free-to-use licensing that includes testing.

Ms. Strickland noted that widespread conversations on testing will help address questions on mixed version compatibility. Mr. Ferguson noted that backward compatibility and cross-compatibility are two different issues that should be addressed. He added that backward compatibility within a family of standards from a single SDO will still be important to analyze and that NCVHS could adopt from the existing definitions of backward compatibility.

**Closing Remarks and Adjourn—Jacki Monson, Chair, and NCVHS Members**

Ms. Monson thanked all participants for their time and support. She also highlighted the need to continue discussions on SDOH during the NCVHS Workplan Development on Day 2 and adjourned Day 1 of this meeting.

**—DAY TWO—**

**Call to Order and Roll Call—Rebecca Hines, Executive Secretary and Designated Federal Officer**

Ms. Hines conducted roll call, requesting that NCVHS Full Committee members state any conflicts of interest for this meeting. Ms. Donald and Mr. Ferguson reminded participants of their conflicts of interest related to discussions on reproductive health and Kaiser Permanente's comments on ICD-11, respectively. Dr. Hodgkins and Mr. Ferguson noted their possible conflicts of interest related to involvement with The Sequoia Project.

**Welcome Remarks/Agenda Review—Jacki Monson, Chair**

Ms. Monson reviewed the Day 2 agenda.

**TEFCA (Trusted Exchange Framework and Common Agreement) Update—moderated by Michael Hodgkins**

***JaWanna Henry, MPH, MCHES, Interoperability Systems Branch Chief, Office of the National Coordinator for Health Information Technology (ONC)***

The 2016 21st Century Cures Act established TEFCA through Section 4003, which states that the National Coordinator will convene public and private stakeholders to develop or support a trusted exchange framework for policies and practices and for a common agreement for exchange between HINs. The three goals of TEFCA are to (1) establish a universal policy and technical floor for nationwide interoperability; (2) simplify connectivity for organizations to securely exchange information to improve patient care, enhance welfare of populations, and generate health care value; and (3) enable individuals to gather their own health care information. Since 2016, ONC has released multiple drafts of TEFCA, selected The Sequoia Project as the RCE, initiated ONC and RCE stakeholder engagement, and released the first Common Agreement. In 2023, ONC began receiving and accepting applications for testing. In 2024, RCE and ONC released a draft second version of the Common Agreement, which focuses on the implementation of FHIR standards.

Ms. Henry described the current state of sharing EHI through networks. About 85 percent of hospitals in the United States reported electronically querying patient data through various methods (e.g., HINs). Only 64 percent of hospitals reported using national networks to exchange information across HIT systems in 2021. Hospitals have reported challenges in exchanging data across different EHR vendor platforms, developing customized interfaces, and matching correct patients across systems. Challenges reported by hospitals also include costs, cumbersome onboarding processes for reporting, and hospitals noting that many public health agencies lack the capacity to electronically receive information.

ONC recently developed a Report to Congress focused on the significant progress made connecting HINs with health information exchanges (HIEs) nationwide. In this report, ONC noted limitations in connecting HINs and HIEs that TEFCA aims to address by simplifying network participation by establishing a single connection to access EHI on a national scale. The report describes how an initial group of Qualified Health Information Networks (QHINs) were designated and began sharing health information through TEFCA. ONC has since designated additional QHINs and anticipates building momentum to include more organizations, creating a pathway for modern health information sharing, advancing common standards and modern HIT capabilities, and establishing expected business practices for sharing EHI.

Currently, TEFCA is fully operational with several entities designated as QHINs. Once designated, these QHINs can immediately begin supporting the exchange of data under TEFCA. Many stakeholder group scan benefit from the information sharing under TEFCA, including technology developers (who can

provide a scalable policy and technical foundation for innovation), state government and public health authorities (who can get timelier data, reduce costs, and support interoperability), individuals (who can gather their own health information more easily), providers and systems (who can improve care coordination and population health through more connection points), and health plans (who can access and share data needed for care management). Additional benefits include increasing secure access to EHI capabilities nationwide, ensuring that a core set of data will be available and standardized among networks through the Common Agreement, decreasing costs, and providing HINs and HIT developers with a common set of privacy and security requirements to protect patient information.

Overall, TEFCA provides the following resources to QHINs:

- Shared governance structure for all QHINs
- Structured onboarding process to ensure Common Agreement adherence; common protocols for authenticating and authorizing users
- Shared directory service
- Guidance on responses to data requests under the Common Agreement
- Guidance on how QHINs are prohibited from requiring broad exclusivity arrangements and imposing discriminatory limits on organizations
- Guidance on compliance with relevant privacy and security rules
- Security incident notification process

Most participating organizations will be HIPAA CEs, but non-CEs will be required to protect individually identifiable information in the same manner as CEs. QHINs will initially support secure EHI sharing for the following purposes: individual access services (IAS), treatment, payment, health care operations, public health, and government benefits determination.

In December 2023, ONC and The Sequoia Project released the FHIR Roadmap for TEFCA Exchange Version 2; this version updates the previous roadmap and continues the momentum already established by providing more details and guidance for the future of FHIR in TEFCA. TEFCA marks a new era for network-to-network interoperability in the United States, combining the richness of API-based exchange and the foundation of TEFCA's shared infrastructure and trust services. TEFCA will reduce administrative burden while expanding the use of FHIR and advancing interoperability for public health and state and local HIEs.

***Mariann Yeager, MBA, CEO, The Sequoia Project (the TEFCA RCE)***

As the TEFCA RCE, The Sequoia Project collaborates with ONC to develop baseline policy and technical requirements; evaluates and designates applicant QHINs; maintains the RCE directory services; establishes and oversees representative government processes; and engages with and solicits feedback from stakeholders.

Each QHIN voluntarily signs the Common Agreement with the RCE in order to receive services that connect to TEFCA exchanges. QHINs then have access to TEFCA standard operating procedures (SOPs). For example, the Exchange Purposes (XP) SOP delineates when and how information can be requested or shared through TEFCA. As another example, the XP Implementation SOP provides additional details related to use cases. Overall, these SOPs create the flexibility for TEFCA to evolve and expand over time and will be created through a defined change management process.

Another component of TEFCA is the QHIN technical framework (QTF), which outlines technical, functional, privacy, and security requirements to exchange data. In addition, the Sequoia Project maintains the

directory services to support information between and among TEFCA-designated entities; this key component of TEFCA enables access to the electronic endpoints and other information about entities that participate in TEFCA. The directory information is kept up to date to ensure information flows to the correct destination regardless of network changes. The Sequoia Project's governing approach begins with the signing of the Common Agreement, which establishes a governing council that reviews amendments to the Common Agreement, QTF, and SOPs, while also serving as a resource for oversight and dispute resolution.

Next steps for TEFCA processes involve updating technical and policy documents to support greater use of FHIR, better support for use cases beyond treatment, static terms of participation to ease onboarding, and the ability to participate with multiple QHINs.

***Chantal Worzala, PhD, Principal at Alazro Consulting, LLC***

The Sequoia Project is currently finalizing various documents, including Common Agreement Version 2, which will include enhancements and updates to require support of HL7 FHIR-based transactions. Other documents under revision include the QTF Version 2 and associated SOPs, as well as XP implementation SOPs and the FHIR Roadmap for TEFCA exchange Version 2. The FHIR Roadmap describes four stages to leverage FHIR in exchanges: (1) FHIR content support, (2) QHIN-facilitated FHIR exchange, (3) QHIN-to-QHIN exchange, and (4) end-to-end FHIR exchanges.

The XP implementation SOP identifies reasons for which information could be requested through QHIN-to-QHIN exchanges. Currently, only six XPs are authorized under the Common Agreement: treatment, payment, health care operations, public health, government benefits determination, and IAS. The XP SOP specifies that treatment and IAS require responses, and eventually the remaining XPs will also require responses in the future.

Dr. Worzala presented a public health use case for TEFCA in which a participant public health authority is performing a case investigation. First, that authority would request medical records from one QHIN, who then initiates queries to all other QHINs, which execute their query methodology to request medical records from their participants. Each participant hospital within a QHIN will then identify relevant documents, share them across QHINs, resulting in the initial QHIN to share the desired medical records to the public health authority. Exchanges in public health provide common data sharing structures to alleviate the need for multiple one-off sharing agreements. A draft public health SOP is in development and describes three major exchange modalities: QHIN message delivery, QHIN query, and facilitated FHIR exchanges.

***Steve Gravely, JD, MHA, Founder, Gravely Group, Principal Author of the Data Use and Reciprocal Support Agreement (DURSA)***

Protecting the privacy of health data is a key underlying principle of TEFCA. TEFCA's approach to data privacy involves a rigorous QHIN designation process in which QHINs must demonstrate the ability to protect the privacy and security of information exchanged through TEFCA. TEFCA recognizes that the health care ecosystem is diverse, with both CEs and non-CEs. Non-CEs must show compliance with specific sections of the HIPAA Privacy Rule as a matter of contract for all individually identifiable information. This approach establishes a consistent set of obligations across the diverse set of QHINs, participants, and sub-participants, and promotes trust among all TEFCA participants that the privacy of TEFCA information is protected.

TEFCA's approach to data security involves the Common Agreement (with which QHINs must comply) and a certification process in which the QHIN is authorized by HITRUST—currently the only nationally recognized certification body approved by the RCE. The Common Agreement requires the RCE to appoint a Chief Information Security Officer (CISO) who is responsible for monitoring and maintaining the security poster of the TEFCA framework; each QHIN must have its own CISO. The TEFCA Security SOP also establishes a Cybersecurity Council, which is responsible for assessing cybersecurity risks to TEFCA. In addition, QHINs must have an annual technical audit conducted by a third party to assess compliance with the HIPAA Security Rule, the National Institute of Standards and Technology (NIST) Cybersecurity framework, and comprehensive penetration testing.

The Common Agreement also provides liability coverage for cyberthreats, but this coverage is limited to $2 million per incident; QHINs are required to obtain cybersecurity insurance or have equivalent financial reserves. QHINs must also notify the RCE and all potentially impacted QHINs of an incident within 5 days. Data security practices within TEFCA also include data encryption requirements that comply with the HIPAA Security Rule.

***Discussion***

TEFCA Threats and Concerns

Moderator Dr. Hodgkins asked speakers to share their major concerns related to TEFCA and its various processes. Ms. Yeager is concerned about well-intended actors asserting inappropriate exchange purposes. Mr. Gravely noted a concern about the potential threat of capable and nefarious actors and how systems can be protected from such threats.

Health Equity

Mr. James asked how TEFCA will support the collection of information related to health equity. Ms. Henry noted that TEFCA builds upon existing processes and resources such as USCDI, which ONC has updated to include additional data elements that focus on health equity and disparities. Future USCDI versions will continue to incorporate more SDOH data elements. Dr. Worzala added that The Sequoia Project is working with communities to optimize the health care operations XPs.

Auditing and Enforcing

Mr. Ferguson asked how TEFCA ensures that individual participants have consented to the sharing of their personal health information with third parties. Mr. Gravely emphasized that TEFCA was established to ensure trust at each step in the HIE process and that all necessary rules have been followed to eventually allow systems and providers to feel comfortable sharing information without the need to review a consent form. He added that the Common Agreement has a full section on IAS. Dr. Worzala noted that Mr. Alan Swenson may be able to help NCVHS better understand the audit process related to IAS. She added that QHINs can also play an enforcement role and should ensure compliance of all entities downstream of them. RCE CISO Mr. Jonathan Coleman noted that IAS providers must have a relationship with the credential service provider, who must conduct individual identification verification to Identity Assurance Level 2 (IAL2) prior to using a credential. A token in the specification could be used to help provide the assurance that the requestor is who they say they are. Mr. Ferguson responded that a provider may interpret that they cannot participate with IAS if they cannot review the consent themselves.

Dr. Watzlaf asked how QHINs would conduct an audit if downstream entities tailor SOPs to their specific needs or alter SOPs slightly, thus removing the TEFCA standardized processes. Mr. Gravely noted that SOPs should not be altered and QHINs should share that principle with downstream entities. Ms. Yeager added that the TEFCA QTF outlines how monitoring will take place and how verification will take place on

a periodic basis. She noted that noncompliance will be handled accordingly to the severity of the issue, but could result in the loss of a QHIN's digital certificate for TEFCA and removal from the directory.

Endpoints

Mr. James asked how TEFCA exchanges enable access to electronic endpoints and how those endpoints will be accessed through FHIR. Ms. Yeager noted that the TEFCA directory is being revised to accommodate FHIR, noting that currently the endpoints are the QHINs, participants, and sub-participants involved. The directory is refreshed periodically and a copy of directory data is stored locally.

Public Health

Mr. Chrysler noted that TEFCA is not assuming the Common Agreement is the only agreement needed to work with public health information systems and asked how TEFCA will address specific needs of these systems. Dr. Worzala noted that the Common Agreement will enable a principal and delegate relationship that can help manage the complexity of public health organizations. In addition, CDC and ONC are working to help the public health community understand how the public health field is being modernized. Dr. Worzala emphasized that TEFCA's main role in public health will be to encourage reporting of public health data in a more flexible way.

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

In late 2022, OCR and SAMHSA published an NPRM on Confidentiality of Substance Use Disorder (SUD) Patient Records (42 CFR 2; also referred to as Part 2), and the final rule was issued in February 2024. This modification of Part 2 includes the following: The final rule also:

- Increases coordination among providers treating patients for SUD
- Strengthens confidentiality protections through civil enforcement
- Enhances integration of behavioral health information with other medical records to improve patient outcomes
- Permits use and disclosure of Part 2 records based on a single patient consent given once for all future uses and disclosures for treatment, payment, and health care operations (TPOs)
- Permits redisclosure of Part 2 records by CEs and business association in accordance with the HIPAA Privacy Rule, with certain exemptions
- Provides new rights for patients to obtain an accounting of disclosures and to request restrictions on certain disclosures
- Provides HHS with civil enforcement authority, including the potential imposition of civil money penalties for violations of Part 2
- Requires breach notifications for breaches of Part 2 records

In 2023, OCR published an NPRM on Proposed Modifications to the HIPAA Privacy Rule to Support Reproductive Health Care Privacy. This NPRM proposes to strengthen privacy protections by prohibiting the use or disclosure of PHI by a regulated entity for either of the following purposes: (1) a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided, and (2) the identification of any person for the purposes of initiating such proceedings. This prohibition would apply where relevant criminal, civil, or administrative investigation, or proceeding is in connection with one of the following: (1) reproductive health care sought, obtained, provided, or facilitated in a state where health care is lawful and outside of the state where the investigation or proceeding is authorized; (2) reproductive health care that is protected,

required, or expressly authorized by federal law, regardless of the state in which care is provided; and (3) reproductive health care that is provided in the state where the investigation or proceeding is authorized and is permitted by the law of the state in which such health care is provided. OCR is currently working on a final rule.

In 2024, OCR updated its HIPAA guidance on the Use of Online Tracking Technologies by HIPAA-Covered Entities and Business Associates. This guidance reminds CEs that they can use online tracking technologies provided that the entities comply with their obligations under the HIPAA rules. This guidance also explains what tracking technologies are and how they are used, and provides a general overview of how the HIPAA rules apply to regulated entities' use of tracking technology. Updates to the guidance include new examples of when visits to an unauthenticated webpage may or may not involve the disclosure of electronic PHI, additional tips for complying with the HIPAA rules when using online tracking technologies, and guidance about OCR's enforcement priorities in online tracking investigations.

Mr. Noonan noted that large data breaches must be reported to OCR. Since 2018, the number of breaches have increased and the number of individuals affected by breaches substantially increased. Breaches involving ransomware and network servers have increased since 2019 as well.

Mr. Noonan concluded his presentation by describing two OCR initiatives: the Right of Access Initiative and the Risk Analysis Initiative. OCR announced the Right of Access Initiative in 2019 as an enforcement priority to support an individual's right to timely access to their own PHI, as stated in the HIPAA Privacy Rule. OCR receives many complaints alleging denial or no access to health records and thus, through the Right of Access Initiative, it conducts investigations across the country, with 45 settlements to date and three civil monetary penalties. In addition, the Risk Analysis Initiative is a new enforcement initiative that is focused on compliance with the HIPAA Security Rule requirements. Most OCR large breach investigations reveal a lack of compliant risk analysis. Thus, this new initiative seeks to drive better practices to protect electronic PHI, as well as support better overall data security.

***Discussion***

Outreach to Providers

Mr. James asked how OCR is performing outreach to providers for underserved populations, (e.g., Federally Qualified Health Centers) regarding cybersecurity. Mr. Noonan confirmed that OCR has established an outreach initiative that has created a slide deck of more than 100 informational slides. He estimated that this initiative performs more than 200 outreach presentations annually. OCR has also developed other materials, including videos on cyberattacks and lessons learned from previous investigations.

Third Party and Business Associate Breaches

Mr. Ferguson asked about the number of breaches occurring within third parties or business associates. Mr. Noonan noted that business associates are required to comply with the HIPAA Security Rule. When an investigation is initiated by OCR, the primary goals are to respond to the breach reported and understand where and how the breach occurred, as well as what actions have been taken since the breach to secure the organization's data. When a breach occurs at a business associate institution, OCR will open an investigation with both the business associate and the associated CE. OCR will assess whether the organizations had appropriate agreements and processes in place to ensure compliance.

Ms. Monson asked whether OCR plans to release guidance on compliance for CEs and associated third parties and business associates under the current HIPAA Security Rule. Mr. Noonan noted that OCR has released several educational videos and resources to provide guidance.

Reproductive Health Privacy

Dr. Watzlaf asked about the expected publication date of the Final Rule regarding reproductive health privacy. Mr. Noonan noted that publishing this Final Rule is a major priority for OCR but that an estimated date of release is currently unclear.

On-Premises vs. Cloud Network Intrusions

Dr. Hodgkins asked whether OCR differentiates network intrusions that occur via on-premises network devices or cloud networks, particularly given that many larger organizations are shifting to cloud-based environments. Mr. Noonan noted that OCR does not currently evaluate these intrusions separately but could in the future. Dr. Hodgkins asked whether OCR can impose obligations to improve on-premises or cloud network security infrastructure, or whether financial penalties are the sole enforcement response. Mr. Noonan confirmed that OCR can provide technical assistance to resolve issues, as well as the development of a resolution agreement and corrective action plan. If the entity does not wish to make the necessary changes for compliance, the entity will face a civil financial penalty; he noted that very few entities choose to incur the penalty.

**NCVHS Workplan Development—Jacki Monson, Chair, and NCVHS Members**

***75th NCVHS Anniversary Planning***

NCVHS has held previous anniversary events to showcase the progress the Committee has made, discuss major accomplishments, and identify future directions. Meeting participants were invited to share thoughts and ideas for a potential 75th NCVHS anniversary event.

Mr. James suggested reviewing progress made since the 50th anniversary event to showcase what NCVHS has done, noting that NCVHS's efforts are not always visible to all other health care stakeholders and that this event could demonstrate these efforts more explicitly. Ms. Banks added that the event could show how major NCVHS accomplishments have led to downstream work, policies, and NCVHS recommendation letters. Dr. Watzlaf agreed with these suggestions, adding that presenting the process of how NCVHS recommendation letters are reviewed and put into action after they are shared with the Secretary would also be beneficial. Ms. Donald suggested titling the event "Past, Present, and Future" and other Committee members agreed.

Mr. Ferguson suggested inviting previous NCVHS Chairs to share their perspectives. Dr. Hodgkins added that previous DFOs should also be invited to the event. Members also suggested inviting speakers previously involved in NCVHS meetings to hear feedback, as well as individuals who have been affected by NCVHS work to share their perspectives.

Committee members agreed to hold the 75th anniversary event early in 2025, not in September 2024, to enable new Committee members to join and more time to facilitate planning.

**Exploration of Privacy and Security in AI in Technology and Healthcare—moderated by Val Watzlaf and Jacki Monson**

Dr. Watzlaf and Ms. Monson introduced the AI in Technology and Healthcare panel (panelists listed below) and invited meeting participants to post questions to the panel to facilitate discussion, which are summarized in the sections below.

- Jennifer Goldsack, MChem, MA, MBA, OLY, Chief Executive Officer, Digital Medicine Society (DiMe), Member, Board of Directors, Coalition for Health AI (CHAI)
- Jonathan Jungck, Commercial Healthcare Technical Lead, HIPAA Security Officer, Palantir Technologies
- Von Nguyen, MPH, MD, Clinical Lead, Population Health, Google
- Garrett Adams, Lead, EpicCare Ambulatory Research and Development, Epic Systems

***What are the current trends in AI that you are most concerned about?***

Ms. Goldsack shared that this question is likely hinting at the increased use of generative AI techniques across many different types of fields, but she added that this type of technology has been used successfully and safely for many years. She noted that her main concern is that the interest in generative AI is potentially overshadowing the interest in and adoption of more cutting-edge technologies. However, generative AI is only part of how AI plays a role in health care. Mr. Jungck noted that AI is frequently used in clinical decision-making workflows, and Dr. Nguyen highlighted Allowed, an AI tool that translates health-related YouTube videos into several languages. Mr. Adams noted the importance of ensuring that AI tools used by providers are validated and tested, and that providers know how to use the tools effectively.

Dr. Nguyen noted that his team at Google thinks of AI technologies in terms of impact on three stakeholder groups: consumers, caregivers, and communities. He urged participants to think about the use of AI in health care, not just for care delivery, but in broader contexts, specifically those wanted by consumers, caregivers, and communities want. Ms. Goldsack emphasized that the digital future of health and health care relies on the shift of focus from treating people solely when they become sick to preventing sickness and overall promoting health within the health care system.

***What specific use cases can illustrate these AI trends?***

Mr. Adams shared that he uses AI tools that focus on clinical efficiency, which aid in assessing staff shortages and reducing workloads when possible. Another use case is documentation, particularly of how AI can reduce administrative burdens and duplication to enhance efficiency. Other use cases suggested by speakers include identification of benefits for a specific patient, drug development, and clinical trial efficiency.

***Outside of the hospital setting, where is AI going to impact consumers of health care?***

Dr. Nguyen noted that wearable AI technology, such as a Fitbit, is relatively commonplace in society today; he added that wearable and remote sensing tools (including phone-based sensor technology) will likely undergo significant innovation in upcoming years as more validation occurs. He hopes that AI technology will help increase time during check-up visits so that a provider can make eye contact and communicate directly with patients rather than look at computer screen and enter information.

***How can the risks of AI be managed, considering issues that have emerged (e.g., Google and Microsoft withdrawing AI application due to challenges)? How can we perform due diligence to protect the American population?***

Dr. Nguyen acknowledged the severity of risks in this field and shared that Google developed a document called the AI Principles in 2018, which could serve as a starting point for future guidance. He added that a major risk to address is health equity and biased datasets (e.g., data with low diversity). Validation of these datasets is also needed. Mr. Adams noted that his team has developed the AI Trust and Assurance Suite to help users address risks.

Panelists agreed that addressing privacy and security concerns of new AI technologies is paramount during development and testing. Panelists also argued that often when an intrusion into a system occurs, often the AI tool is not to blame but rather the user who may not understand the security risks. Bad actors or actors uninformed of risks have existed in health care long before the implementation of AI technologies. Panelists agreed that the health care field must come together to share expertise and perspectives, discuss risks and opportunities for new and existing technologies, and ensure that the correct testing and validation steps are taken.

***What practices exist for risk management?***

Mr. Jungck noted that Palantir performs proactive training and exercises with its customers to ensure that they understand where data are flowing, where data are stored, and whether their data are being used to train specific models or workflows. He emphasized the importance of education and training in order to highlight risks to consumers. Mr. Adams added that a critical step in risk management is ensuring that the process includes good evaluators and incorporates feedback from evaluators and users to optimize the tool or system.

***How can the process of updating standards and standard versions be improved to optimizing the exchange of health information ?***

Panelists agreed that leveraging FHIR standards is an important step for the exchange of health care information in an interoperable manner.

***What is your vision for a system in which SDOH capture is a priority but non-CEs are necessary for the collection of SDOH?***

Panelists noted that practices are in place for interacting with groups outside of HIPAA, but that changes in policies may be needed to ensure that the field is best positioned for moving into a more digital era of health care.

***How can NCVHS help with AI in health care?***

Dr. Adams suggested that NCVHS continue to engage with experts in the field of AI in health care to understand how technologies are used and how they work. He added that NCVHS could help shed light on jurisdictional boundaries of FDA, ONC, and CMS related to the responsibility of reviewing AI technologies in health care and coverage for care. Guidance on the level of validation and testing for technology would also be helpful. Panelists added that the industry also strives to define common practices and definitions for the field, as well as harmonization of best practices.

Dr. Nguyen added that NCVHS could create a space for community members to share feedback, concerns, and opportunities related to AI in health care.

**NCVHS Workplan Development (continued)—Jacki Monson, NCVHS Chair, Subcommittee on PCS Chairs, and Subcommittee on Standards Co-chairs**

***Subcommittee on Standards***

During this meeting, the Standards Subcommittee held sessions related to TEFCA and VBC to help the Full Committee examine mature and emerging standards and how they coexist to support current and future business needs. Ms. Banks asked meeting participants whether any lessons learned from these panel sessions should be incorporated into the NCVHS workplan to enable further discussion. Mr. Ferguson suggested that the Standards Subcommittee discuss TEFCA implementation specifications for FHIR-based APIs, particularly for non-treatment use cases. Mr. James suggested that the Subcommittee consider ways to ensure that early demonstration and validation of new standards are conducted and properly funded.

Ms. Banks noted that the Subcommittee, or potentially a newly developed Workgroup, aims to facilitate a session on HIPAA exception process outcomes and the relevance of HIPAA in the current health care system and then present the results to the Executive Subcommittee later this quarter. Subcommittee members could meet monthly with the new Workgroup to help facilitate this effort. However, Subcommittee and Full Committee members may not have the bandwidth to participate in another group.

Another topic of importance to the Subcommittee is SDOH, and Ms. Banks asked whether any SDOH-related topics or efforts should be incorporated into the workplan. Ms. Banks answered for herself, emphasizing that SDOH data and secondary uses of SDOH data are critically important and developing an ad hoc Workgroup (tentatively called the Population Health Workgroup) is one approach forward. Ms. Monson supported this suggestion and emphasized that this effort must be highly focused. Mr. Ferguson agreed that a Workgroup focusing on the original capture of SDOH is needed. Ms. Banks will add this topic as an agenda item for the next Executive Subcommittee meeting.

***Subcommittee on Privacy, Confidentiality and Security***

Dr. Watzlaf provided a summary of the PCS Subcommittee's section of the NCVHS workplan, which begins by stating that the Subcommittee aims to continue work that builds upon previous efforts—such as previous recommendation letters for data collection during a PHE or strengthening the Security Rule.

A future focus area for the Subcommittee is reproductive health information privacy and security. An NPRM was released on April 12, 2023, to strengthen the Privacy Rule protections by prohibiting the use or disclosure of PHI to identify, investigate, prosecute, or sue patients, providers, and others involved in the provision of legal reproductive health care, including abortion. The public comment period closed in June 2023, and HHS received nearly 26,000 comments (one of which is from NCVHS). Key proposed amendments to the rule include adding the language that "providing" and "facilitating" health care is also protected, prohibiting regulated entities from using or disclosing PHI to identify a person to initiative an investigation, or requiring a signed attestation that requests for PHI are not for a prohibited purpose. The new attestation requirement will require that all CEs and business associates obtain a signed attestation if the PHI is requested for any of the following purposes: health oversight activities, judicial and administrative proceedings, law enforcement purposes, and use by coroners or medical examiners. Attestations may be electronic but cannot be combined with other documents. NCVHS' comments to the NPRM included:

- HHS should consider not distinguishing between care provided that is illegal vs. legal in the state in which that care is performed.
- HHS should consider prohibiting disclosures for investigations involved in any health care, not just reproductive health care.
- HHS should consider requiring attestation for all requests of PHI, rather than limiting the requirement to requests potentially related to reproductive health care.
- HHS should consider requiring that the attestations include a pledge not to redisclose the records to another party for any of the prohibited purposes named in the attestation.
- HHS should consider clarifying uses of PHI for "public health" to ensure that the modified Privacy Rule does not produce unintended consequences regarding public health.
- HHS should consider addressing relationship of the modified Privacy Rule to health information access and exchange, including in telehealth, telemedicine, medical devices, apps, wearables, interoperability, information blocking, and TEFCA.
- HHS should consider specifying plain language for the CE Notice of Privacy Practices that is clear and understandable to all patients.
- HHS should examine the definition of "de-identified data" and consider NCVHS's 2017 recommendations on the topic.

The PCS Subcommittee hopes to extend additional recommendations to other health care entities, including patient's phone applications not used as part of a CE's practice; geofencing across health care facilities; tracking of non-prescription data (e.g., prenatal vitamins, pregnancy tests); data analysis to predict pregnancies; and telehealth or telemedicine services for reproductive health care.

Several topics related to reproductive health have also become a significant focus for the Subcommittee, including documentation and coding gaps. Health care providers do not always document reproductive health information for fear of prosecution. Relevant clinical codes for miscarriages and ectopic pregnancies typically include "abortion" in the code description, which leads physicians to fear prosecution. In addition, the Subcommittee aims to address professional repercussions in relation to reproductive health. The Subcommittee recently learned of a hospital with a new policy for terminating life-threatening pregnancies that required the physician to obtain a signed statement from another physician confirming that the pregnancy threatens the life of the mother. This requirement delays treatment for potentially life-threatening conditions, likely leading to eroded trust in obstetrics and gynecology (OB/GYN) physicians and fewer residents entering the profession. Further, the Subcommittee wants to focus on people most impacted by the Dobbs decision, particularly by strengthening privacy protections to ensure that needed health care is obtained. The Subcommittee also wants to address concern about protections for gender-affirming care; strengthened protections and a whole-government approach are needed. Next steps for the Subcommittee include reviewing the HHS Final Rule regarding Reproductive Health Care Data anticipated in spring 2024, prioritizing areas not included in that Final Rule or NCVHS' response to the NPRM, formulating a project scope outcome, and developing a recommendation letter to address areas lacking in that Final Rule.

A future focus area for the Subcommittee is accounting for PHI disclosures. The 2011 Health Information Technology for Economic and Clinical Health Act (HITECH) Act directed HHS to modify the Privacy Rule to require that an accounting of disclosures includes disclosures for TPO purposes through an EHR during the 3 years before the request. In 2018, OCR published an RFI that included 53 questions on whether and how HHS could modify the HIPAA Rules to support care coordination and case management, and promote VBC, while preserving the privacy and security of PHI. A question focused on accounting of disclosures received 1,300 comments, many of which described the industry burden regarding accounting

of disclosures. For this effort, the Subcommittee will next review comments to the 2021 NRPM and the 2018 RFI, discuss emerging themes with OCR, and hold briefings with industry for more input.

Another future focus area is privacy and security related to AI in health care. For this area, the Subcommittee will review previous briefings and other research, engage with other agencies to explore key questions, and create a project scope outline. The Subcommittee has also identified privacy and security of health data exchanges through TEFCA as a future focus area; for this effort, the Subcommittee will decipher input from expert panelists and potentially combine this effort with Beyond HIPAA efforts or facilitate it as a joint PCS and Standards Subcommittee project. The final future focus area mentioned is Beyond HIPAA, and this effort will build upon the Committee's previous work.

***Discussion***

Ms. Hines noted that a new AI Federal Advisory Committee (FAC)—National AI Advisory Committee (NAIAC)—was recently established and suggested that the PCS Subcommittee contact previous NCVHS member and current NAIAC member Frank Pasquale (Cornell University) to discuss potential overlaps with any future PCS Subcommittee work. Ms. Monson suggested narrowing the scope of AI-related work to privacy and security in health care. Dr. Hodgkins suggested adding equity to that scope; he added that conversations in this meeting related to AI may be of interest to NAIAC. Committee members agreed to review information on this new FAC and engage with it in the future. Ms. Hines read a comment received via email recommending that the Federal Trade Commission may want to be involved in these conversations because wearables and health applications, which are not CEs, using AI often do not sufficiently protect patient information.

Dr. Hodgkins suggested that the PCS Subcommittee prioritize IAS as a focus area.

**Closing Remarks & Adjourn—Jacki Monson, Chair**

Ms. Monson thanked Ms. Hines for her dedicated service to NCVHS and noted that her expertise and passion will be greatly missed as she begins retirement. Ms. Monson also thanked Ms. Chrysler for her participation in the Full Committee. Lastly, Ms. Monson thanked speakers, panelists, and attendees for their input, feedback, and discussion during this meeting.

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

[redacted]

Chair Date