Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
December 7, 2022
Virtual Meeting

MEETING SUMMARY

Note: *For details on this meeting, please refer to the transcript and slides posted here:* https://ncvhs.hhs.gov/meetings/full-committee-meeting-12/

The National Committee on Vital and Health Statistics (NCVHS) was convened virtually on December 7, 2022. The meeting was open to the public. Present:

Committee Members
Jacki Monson, JD, Chair
Tammy Banks, MBA, FACMPE
Denise Chrysler, JD,
James Ferguson
Melissa Goldstein, JD
Richard Landen, MPH, MBA
Denise Love, MBA
Vickie Mays, PhD, MSPH
Margaret Skurka, RHIA, CCS, FAHIMA
Debra Strickland, MS
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA, UPitt
Wu Xu, PhD

Executive Staff
Sharon Arnold, PhD, ASPE, Exec. Staff Director
Rebecca Hines, MHS, NCHS, Exec. Secretary

NCVHS Staff
Maya Bernstein, JD, ASPE/OSDP, HHS
Lorraine Doo, MPH, CMS, HHS
Gwen Mustaf, NCHS, CDC, HHS
Grace Singson, PharmD, MS, ASPE, HHS

Invited Speakers
Kin-Wah Fung, MD, NIH, National Library of Medicine
Cason Schmit, JD, Texas A&M University

Others
Jim Craver, MAA, NCHS, CDC, HHS
John Halter, JD, NCHS, CDC, HHS
Susan Jenkins, PhD, ASPE, HHS

In addition to those individuals who presented virtually during the meeting (listed above), 98 people followed the meeting online.

ACTIONS

1. The Committee voted to approve the draft recommendations (with unsubstantial refinements related to wordsmithing and formatting) related to data access for Tribal Epidemiology Centers (TECs) and Other Designated Tribal Public Health Authorities (ODTPHAs). The final version of the letter with these draft recommendations will be posted on the National Committee on Vital and Health Statistics (NCVHS) website.
2. The Committee voted to approve the establishment of an 11th version of the International Classification of Diseases (ICD-11) Workgroup.

—DAY ONE—

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

Ms. Hines invited NCVHS members and speakers to introduce themselves and state any conflicts of interest pertaining to the meeting. No attendees stated a conflict of interest.

Ms. Hines highlighted that the Standards Subcommittee released a Request for Comment (RFC) to receive input to inform recommendations on adopting proposed updated standards from X12 and proposed updated and new operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) from the Council for Affordable Quality Healthcare's (CAQH's) Committee on Operating Rules for Information Exchange (CORE). Comments are due on December 15, 2022. The Standards Subcommittee will hold a hearing on January 18-19, 2023, to discuss RFC responses as well as additional testimony related to updated standards and operating rules shared during the hearing.

Ms. Hines notified meeting attendees that they can subscribe to receive NCVHS e-newsletter updates on the NCVHS website.

Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members and invited speakers to the meeting and reviewed the meeting agenda.

Update from the Office of the Assistant Secretary for Planning and Evaluation (ASPE)—Sharon Arnold, Executive Staff Director

NCVHS Membership Updates

Dr. Arnold began her presentation by encouraging Committee members to nominate potential future Committee members, noting that individuals may also self-nominate. Additional details on Committee member nominations and expectations for membership can be found on the NCVHS website. Dr. Arnold added that Ms. Love's term on the Committee will be extended by 180 days to June 13, 2022, to enable her to support the Standards Subcommittee's efforts in early 2023 (most notably the hearing on January 18-19).

Budget

The U.S. Department of Health and Human Services (HHS) submitted its fiscal year (FY) 2024 budget request during September 2022 to the Office of Management and Budget (OMB). This request will be reviewed by OMB and eventually become part of the President's FY2024 budget that is typically released

on the first Monday in February. However, HHS has not yet received a finalized FY2023 budget. The federal government is operating on a continuing resolution that will expire on December 16, 2022. Congress is expected to either pass a final appropriation at that time or issue another continuing resolution. A lapse in funding could result in a government shutdown.

2026 HHS Strategic Plan

ASPE recently published the 2022-2026 Strategic Plan, which outlines five strategic goals that focus on HHS' major priorities to (1) protect and strengthen equitable access to high-quality and affordable health care; (2) safeguard and improve national and global health conditions and outcomes; (3) strengthen social wellbeing, equity, and economic resilience; (4) restore trust and accelerate advancements in science and research; and (5) advance strategic management in order to build trust, transparency, and accountability. The Plan also includes an overview of HHS' progress toward the outlined goals, as well as future directions for HHS.

Impact of Elections

During recent elections, four states voted on ballot initiatives regarding the legalization of marijuana. Several states have also recently voted on abortion rights, following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* that overturned *Roe v. Wade*. HHS has issued a report and plan of action in response to the *Dobbs v. Jackson Women's Health Organization* decision that will support President Biden's Executive Orders 14076 and 14079.

In August 2022, HHS Secretary Xavier Becerra and Administrator of the Centers for Medicare & Medicaid Services (CMS) Chiquita Brooks-LaSure issued a letter to U.S. governors requesting that they work with CMS to apply the Medicaid 1115 waivers to provide increased access to abortion for women from states where reproductive rights are under attack and where women may be denied critical medical care. This letter also stressed that current abortion restriction laws do not negate providers' responsibilities to comply with federal laws protecting access to emergency health care.

Response to the Ongoing COVID-19 Pandemic

Dr. Arnold emphasized that addressing the COVID-19 pandemic continues to be a major priority for HHS, as new strains of the virus continue to evolve. Remaining apprised of new findings from ongoing clinical trials and research studies, as well as guidance from the Centers for Disease Control and Prevention (CDC), enables HHS to plan its health care policies and public health policies that affect the nation overall. Since the previous Committee meeting, several notable developments related to the pandemic have occurred. On October 13, 2022, Secretary Becerra renewed the declaration of public health emergency that has existed nationwide since January 27, 2020. The declaration now ends on January 11, 2023. Secretary Becerra previously indicated to governors across the country that HHS will provide states with 60 days' notice prior to the termination of the public health emergency declaration.

In August 2022, CDC relaxed COVID-19 guidelines and quarantine requirements for people exposed to COVID-19. CDC continues to recommend that individuals receive vaccinations, mask when indoors and in public spaces, engage in self-surveillance when exposed to COVID-19, and undergo testing and isolation when ill with COVID-19 symptoms. In addition, CDC has recommended the Novavax monovalent COVID-19 vaccine as another primary series option for adults aged 18 years or older. This recommendation brings the total number of authorized vaccines in the United States to four for adults and three for children (aged 6 months or older). During summer 2022, the U.S. Food and Drug Administration (FDA)

granted an emergency use authorization (EUA) for an updated bivalent booster that targets the ancestral strain of COVID-19, as well as Omicron-derived variants. CDC began to recommend this booster for adults and children (aged 12 and above) during September 2022 and extended that recommendation to children aged 5-11 years during October 2022.

In November 2022, the Health Resources and Services Administration (HRSA) announced a $350 million initiative for HRSA-supported health centers to promote COVID-19 vaccination among underserved populations. ASPE released a report on the impact of COVID-19 vaccinations that estimated vaccine-associated reductions in COVID-19 cases, hospitalizations, and deaths from December 2020 to July 2021. ASPE estimated that vaccinations were associated with reductions of approximately 25.3 million cases, 1.38 million hospitalizations, and 213,000 deaths. ASPE released an additional report in October 2022 that estimated that the Administration's vaccination program, which helped greater than 90 percent of seniors become fully vaccinated and greater than 70 percent of seniors receive booster vaccinations, and prevented more than 650,000 hospitalizations and more than 300,000 deaths among seniors and other individuals enrolled in Medicare in 2021.

In September 2022, FDA updated its COVID-19 testing policy to encourage developers to seek traditional pre-market reviews instead of EUAs. In addition, the National Institutes of Health (NIH) established a new website through its Rapid Acceleration of Diagnostics (RADx) Program that enables users to anonymously report their at-home testing results.

In response to a presidential memorandum addressing the long-term effects of COVID-19, HHS developed two reports that together create an actionable plan to address long COVID and associated conditions. The first report, the *National Research Action Plan on Long COVID*, details the current status of research and outlines future studies that are needed to better understand approaches to preventing and treating long COVID. The second report, *Services and Supports for Longer-Term Impacts of COVID-19*, highlights resources for health care workers and people affected by broader effects of COVID-19 (including long COVID, mental health, substance abuse, and loss of caregivers or loved ones). In addition, ASPE has started to examine the medical supply chain, which has shown significant vulnerabilities during the pandemic; ASPE recently released a report evaluating the causes of device and supply shortages.

Mpox, Influenza, and Respiratory Syncytial Virus

COVID-19 is not the only infectious disease requiring current HHS attention. On August 4, 2022, Secretary Becerra declared a public health emergency related to monkeypox and renewed that declaration on November 2, 2022. In early December 2022, the World Health Organization (WHO) began to promote the use of a new preferred term, mpox, as a synonym for monkeypox. Both names will be used simultaneously for 1 year. U.S. federal public health agencies will also adopt the use of "mpox," which is viewed as a less stigmatizing term. To address the mpox outbreak, HHS has undertaken two major actions. First, CDC launched the mpox Vaccine Equity Pilot Program in which state and territorial health departments, tribal governments, federally funded tribal health care facilities, and cities receiving mpox vaccines through the Strategic National Stockpile may submit proposals for projects designed to identify innovative approaches to reach populations disproportionately affected by mpox. The Administration for Strategic Preparedness and Response made 1.1 million vials of JYNNEOS, the mpox vaccine, available to states and jurisdictions and purchased an additional 5.5 million vials to arrive in the upcoming months. Given the low number of recent cases, HHS does not expect to renew the emergency declaration for mpox when it ends in January 2023. However, HHS will continue to monitor case rates and encourage at-risk individuals to receive a free vaccine.

During the past 2 years, the COVID-19 pandemic has affected viral respiratory illness activity. For example, influenza circulation, typically responsible for a large portion of respiratory disease cases in the fall and winter, has been relatively low compared to previous years. However, in fall 2022, the United States is experiencing a surge of respiratory diseases, including COVID-19, which may continue to circulate at high levels through the winter. Flu hospitalization rates are now higher than the rates at this time of year for the past decade. Respiratory syncytial virus (RSV) is the leading cause of hospitalizations among children younger than 1 year old, and increasing rates of RSV-associated emergency room visits and hospitalizations among older children have been observed.

Opioid Crisis

On September 29, 2022, Secretary Becerra renewed the public health emergency declaration regarding the opioid crisis, which means that the United States is now entering the sixth year of this crisis. In November, CDC released clinical practice guidelines that include new evidence and recommendations on the treatment of acute, sub-acute, and chronic pain. The Substance Abuse and Mental Health Services Administration (SAMHSA) recently awarded nearly $1.6 billion through the State Opioid Response and Tribal Opioid Response grant programs. HHS also continues to work with international partners to address the opioid crisis. For example, Canada and the United States recently published a white paper on federal surveillance and response to substance use and harms during the COVID-19 pandemic.

Health Coverage and Access to Care

In August 2022, ASPE released a new report based on research performed by ASPE that indicates that the national uninsured rate has reached a historic low of 8 percent in early 2022, with 5.2 million individuals having gained coverage. With the enactment of the Inflation Reduction Act on August 16, 2022, even more Americans will have health insurance through the Affordable Care Act. The enactment of this new law reduces drug costs for more than 63 million people across the country with Medicare. The new law will also save the 13 million people covered under the Affordable Care Act approximately $800 per year in insurance costs. This law will also provide people with Medicare coverage with lower drug prices, a $35 monthly co-pay maximum for insulin, a limit on out-of-pocket expenses in Medicare Part D, and reduced costs under Medicare's new ability to negotiate drug prices. In addition, the enhanced tax credits for Affordable Care Act marketplaces will continue for 3 years to help people afford their premiums and obtain coverage.

In September 2022, HHS approved a 12-month extension of postpartum, Medicare, and Children's Health Insurance Program (CHIP) coverage in Hawaii, Maryland, Ohio, Indiana, North Carolina, and West Virginia under the administration's American Rescue Plan. In alignment with previously approved state extensions, an estimated 360,000 Americans in 27 states and the District of Columbia (DC) are now eligible for 12 months of essential postpartum medical coverage. In addition, as of October 2022, all 50 states and DC now offer dental coverage for Medicaid enrollees who are pregnant and postpartum for at least 60 days after pregnancy.

In October 2022, Secretary Becerra issued a final rule to fix the "family glitch," a provision that causes family members of an employed individual to be ineligible for premium tax credit even though they require these credits to afford high-quality insurance coverage. This final rule will help about 1 million Americans gain coverage or see their coverage become more affordable. To strengthen and expand access to high-quality comprehensive health care for all children, CMS announced three key actions. First, a new guidance document reminds states of their mandate to cover behavioral health services for children in Medicaid and encourages states to leverage all available resources to strengthen mental health care for

children. A second guidance document urges states to expand school-based health care for children, including mental health care. HHS also issued a proposed rule that would require states to report quality measures to strengthen Medicaid and CHIP to ensure that millions of children and families have access to the highest quality of care. CMS has also provided a roadmap for states to help connect children with complex medical conditions to Medicaid services.

Mental Health Care

During 2022, the federally mandated crisis number, 988, became available to all landline and cell phone users, providing a single three-digit number to access a network of more than 200 local and state-funded crisis centers. In September, HHS released new data that illustrate that during the first month of the transition to the 988 Lifeline, a 45 percent increase in overall call volume and a substantial improvement in answer rates and wait time was observed. Federal funding for the 988 Lifeline will increase by 18-fold in FY2022.

On September 12, 2022, HHS approved the first Medicaid mobile crisis intervention services program to be launched in Oregon. This new Medicaid option, created through the American Rescue Plan, will strengthen behavioral health care and make communities safer by ensuring that law enforcement can focus more on accountable policing and less on work that is more appropriate for mental health counselors or social workers. HHS also released a roadmap for behavioral health care integration on September 16, 2022. This roadmap details policy solutions that will facilitate integration of mental health and substance use care into the larger health care systems.

Non-Discrimination in Telehealth

During the week of the 32nd anniversary of the Americans with Disabilities Act, HHS and the Department of Justice issued guidance on non-discrimination in telehealth services. This guidance provides clarity on how federal non-discrimination laws require accessibility for people with disabilities and limited English-proficient persons in health care provided via telehealth services.

Department of Homeland Security Final Rule

On September 8, 2022, the U.S. Department of Homeland Security issued a final rule applicable to non-citizens who receive or wish to apply for benefits provided by HHS and states that support low-income families and adults. The rule details how the Department of Homeland Security will interpret the "public charge" related to inadmissibility and will help ensure that non-citizens can access health-related benefits and other supplemental government services to which they are entitled by law without triggering harmful immigration consequences.

Proposed Changes to Part 2

The Office for Civil Rights (OCR) and SAMHSA recently proposed changes to the confidentiality of substance use disorder patient records under 42 Code of Federal Regulations (CFR) Part 2, which protects patient privacy and records concerning treatment related to substance use from authorized disclosures. The proposed changes would improve coordination of care for patients receiving treatment while strengthening privacy protection to help ensure that individuals do not forego lifesaving care due to concerns about record disclosure. This action fulfills the requirement in Section 3221 of the Coronavirus Aid Relief and Economic Security (CARES) Act that requires HHS to better align Part 2 with certain aspects of HIPAA. The deadline for comments related to these proposed changes is January 31, 2022.

Subcommittee on Privacy, Confidentiality, and Security—Val Watzlaf and Melissa Goldstein, Subcommittee Co-Chairs, and Cason Schmit, Texas A&M University

Update on Recent Activities

Recent efforts of the Privacy, Confidentiality, and Security (PCS) Subcommittee have sought to build upon previous work performed by the Subcommittee. Reports and letters developed in 2017 (i.e., Report on De-identification of Protected Health Information under HIPAA) and 2019 (i.e., Recommendations for HHS Actions to Improve Privacy Protection for Health Information not Subject to HIPAA Regulations and Health Information Privacy Beyond HIPAA: A Framework for Use and Protection—A Report for Policy Makers) have helped provide a foundation for 2022 efforts, which include Recommendations to Strengthen Cybersecurity and the to-be submitted Recommendations regarding PCS Considerations for Data Collection and Use During a Public Health Emergency.

The Subcommittee conducted a panel during January 2022 on improving the collection of race/ethnicity data, and the findings from this panel will be used to develop a future recommendations letter. During the July Full Committee meeting, the Subcommittee convened two panels, one with experts in legislative developments related to data privacy and another with experts in current cybersecurity issues; these topic areas are both under consideration by the Subcommittee for future efforts.

During 2022, the Subcommittee engaged with Mr. Cason Schmit of Texas A&M University to perform and deliver an environmental scan. Goals of this environmental scan include to (1) identify and analyze current health and health care data governance operations and issues that enhance, serve as challenges, or require updating in the areas of data protection, confidentiality, privacy, and security of health data; (2) identify experts within and external to the U.S. government to share PCS expertise in health and health care data to assist the PCS Subcommittee and Full Committee on issues that emerge during the scan; and (3) outline issues for the Full Committee to consider and discuss.

Dr. Watzlaf presented the following additional focus areas under consideration by the Subcommittee:

- Data de-identification by revisiting the 2017 NCVHS recommendations related to this topic
- Artificial intelligence (AI) and machine learning (ML) tools
- Law enforcement access to and use of private information
- Consumer surveillance and data security
- HIPAA interactions with broader privacy laws under consideration
- Availability of data for public health purposes
- Outreach to OCR
- Embracing cybersecurity in the health care industry
- Security principles and safety for patients and consumers of health-related devices, medical devices, and other devices with medical functionalities
- Education and training of the workforce on cybersecurity
- Cybersecurity flaws that lead to unavailability of data, devices, and systems.
- Unexpected or unintentional consequences of interoperability rules involving HIPAA covered entities (CEs) that transfer data to non-HIPAA CEs
- Standards for terms of service for health apps
- Privacy and security issues involving genomic data
- Data use and service agreements for wearables and mobile health devices
- Impact of changes in PCS on data access

Dr. Watzlaf provided a timeline for the PCS Subcommittee's upcoming activities, shown below:

- **Q1/Q2 2023:** Discuss and frame issues for project selection
- **Q2/Q3 2023:** Develop project scoping documents
- **Q3/Q4 2023:** Present scoping documents to the Full Committee for approval
- **Q4 2023 and Beyond:** Conduct projects and draft recommendations

Ongoing and Emerging Issues in Privacy and Security in a Post-COVID-19 Era: An Environmental Scan

The PCS Subcommittee recently commissioned a brief environmental scan of recent PCS issues in health, health care, and the public health sector to guide the Subcommittee and full Committee in their efforts to identify new major projects to pursue. Mr. Schmit emphasized that the environmental scan was completed on a short timeline and should not be considered a comprehensive overview of all developments in PCS since 2018. Mr. Schmit presented an overview of the report, the details of which are described in the sections below:

Significant Changes in the Privacy Landscape Since 2018

Since 2018, five states (California, Colorado, Connecticut, Utah, and Virginia), have passed and enacted new comprehensive privacy laws. As of August 2022, four states (Minnesota, New Jersey, Ohio, and Pennsylvania) have new privacy laws under active consideration. The Uniform Personal Data Protection Act, which aims to help health care practices define acceptable and compatible data privacy practices, was recently introduced into three jurisdictions. Bills on AI data have been introduced in three states (Alabama, Colorado, and Illinois), and bills on biometric data have been introduced in three states (Illinois, Texas, and Washington).

In addition to the state laws, many federal policy developments have occurred. The federal government has enacted the 21st Century Cures Act regulations related to information blocking. In addition, the Common Rule's revision became effective in 2018. Federal privacy laws under consideration include the American Data Privacy and Protection Act, Federal Trade Commission (FTC) Advance Notice of Proposed Rulemaking (ANPRM) on commercial surveillance and data security, possible updates to the Common Rule related to the meaning of "identifiable" private information, and FDA draft guidance on cybersecurity in medical devices.

FTC ANPRM on Commercial Surveillance

The public comment period for the FTC ANPRM on commercial surveillance and data security closed on November 21, 2022. The Federal Trade Commission (FTC) will review comments received and decide on whether it will proceed with the rulemaking process, which requires an NPRM that will include proposed regulatory text and potential alternative language, as well as a new public comment period to provide stakeholders and members of the public time to provide feedback. After that feedback is reviewed, FTC may develop a final rule. Mr. Schmit emphasized that, if a final rule is developed, challenges to this rule should be expected (e.g., from the consumer or industry perspective).

Notably, FTC has broad jurisdiction that includes HIPAA CEs. Future rules could create compliance confusion or have unintended impacts on beneficial data practices, including health care and public health applications. Mr. Schmit emphasized that early collaboration between HHS and FTC could mitigate possible unintended consequences and thus NCVHS should consider providing recommendations to HHS related to this topic. Potential areas for NCVHS to address in these recommendations include beneficial data practices that could be impeded by future FTC rules (e.g., learning health systems, precision public

health, private-sector assistance in public health surveillance), harmful health-related data practices, conflicts with existing privacy frameworks (including HIPAA), and group harms.

Common Rule

NCVHS also has the opportunity to provide advice to HHS on the Common Rule legal definition of "identifiable" private information. The revised Common Rule directs Common Rule agencies to reexamine the legal definitions of what constitutes identifiable private information and identifiable biospecimens within 1 year and regularly every 4 years. Mr. Schmit noted that he has not seen any reports detailing whether any changes or other outcomes have resulted from the reexamination. Agencies under the Common Rule can alter legal interpretations if "appropriate and permitted by law" and are required to assess analytic technologies or techniques that can generate identifiable private information and specimens. Mr. Schmit noted that any input from NCVHS and HHS on this topic would be timely, including the recommendation of "no changes."

Alternative Approaches to Privacy and Enforcement

Mr. Schmit highlighted several alternative approaches to privacy and data protection, shown below:

- **Consumer Protection:** protection through consumer privacy rights (e.g., notice and consent)
- **Data Protection:** principle-based protections (e.g., purpose limitation, minimization) and protections that "follow the data"
- **Antitrust:** protection focused on oversight on entities of sufficient size as defined by law
- **Information Fiduciary:** protections through new duties of confidentiality, loyalty, and care imposed on controllers/processors

Mr. Schmit then presented approaches to enforcement. The traditional enforcement approaches involve government agency–deployed enforcement (e.g., empower existing agencies, create new agencies) and individual right of action (e.g., right to sue, class actions). Possible alternative enforcement approaches involve deputizing of intermediaries to enforce standards, scaling of legal standards and penalties with the scope of data activities, profit disgorgement, and personal liability for executives.

Deidentification

Mr. Schmit highlighted two reasons for requiring deidentification: legal mechanisms and ethical protections. The rapidly changing environment challenges outdated 2012 guidance related to deidentification, causing difficulties in using the current standards. In addition, unintentional consequences may arise due to deidentification, leading to group harms and "data genocide" (which can result when suppressing data to reduce individual harms associated with data disclosure prevents the accurate representation of a particular group).

The PCS Subcommittee held a hearing in May 2016 related to deidentification. This hearing led to the development of 12 recommendations (i.e., Deidentification of Protected Health Information Under HIPAA, 2017) that were shared with the HHS Secretary. These recommendations did not include a suggestion to update or change the current standard. No obvious actions on these recommendations have been undertaken, and many of these recommendations are still relevant to current challenges. Because the current guidance is increasingly out of date, NCVHS may consider exploring solutions to individual and group harms related to methodological approaches in data aggregation and deidentification in order to update previous recommendations and then resubmit a letter to the Secretary.

AI Challenges

AI poses a number of significant challenges from a PCS standpoint. Most notably, AI is a moving regulatory target because of the ongoing, rapid technological advancements and changing definitions of what constitutes AI. AI also poses difficulties in ensuring transparency for the public, regulators, and developers and users of AI algorithms. Regulators often experience obstacles in understanding the function of specific AI algorithms, as well as the possible consequences and meaningful impacts of those algorithms. Further, the ubiquity of AI in all sectors raises concerns about the use of AI in maintaining and exacerbating structural inequities or creating entirely new structural inequities. Another major concern related to AI is group harms, including harm related to comprehensible groups (e.g., those that are legally protected, such as because of sex, race, religion, or those that are not legally protected, such as dog owners and video game players) and incomprehensible groups (e.g., those based on mouse movements and click patterns).

The White House published the Blueprint for an AI Bill of Rights in 2022, which outlines principles related to safe and effective systems, algorithmic discrimination protections, data privacy, notice and explanation, and human alternatives, consideration, and fallback. The National Institute on Standards and Technology (NIST) has also drafted a report on an AI Risk Management Framework that is intended for voluntary use and to improve the ability to incorporate trustworthiness considerations into design, development, use, and evaluation of AI products, services, and systems. The comment period to provide feedback on the NIST draft report closed during October 2022.

NCVHS has the opportunity to provide timely advice to HHS on AI policies. Some issues to consider for this advice include (1) standards and requirements for algorithmic impact assessments (e.g., unlawful discrimination, inequitable impact, group harms), (2) standards and requirements for AI transparency, and (3) scaling standards, duties, or penalties based on the size and sophistication of the data controller. Currently, federal laws do not distinguish between automated and traditional manual data uses and practices and thus some advice in this area should also be considered by NCVHS.

Increasing Privacy Threats

Mr. Schmit's report also includes a section on increasing privacy threats and law enforcement's use of health data. Commercial genetic databases and surveillance data can be purchased from data brokers by law enforcement agencies. Balancing the benefits and harms of law enforcement disclosure provisions and existing privacy laws is a challenge. Other privacy rights may also be at risk, including those related to the recent overturn of *Roe v. Wade*. This change allows states to place increased restrictions on abortion access and could lead states to prosecute legal violations based on HIPAA and non-HIPAA health care data. The recent Supreme Court decisions have increased concerns that the scope of privacy rights may continue to contract in the future.

Mr. Schmit highlighted that NCVHS has the opportunity to provide advice to HSS on the topic of law enforcement access to health records. NCVHS could help define appropriate and inappropriate law enforcement uses of health data, but this process is likely challenging. He recommended that NCVHS explore the following topics related to law enforcement access to health data: (1) narrowing the scope of HIPAA law enforcement exception, (2) imposing data protection requirements on data disclosed for law enforcement purposes (e.g., data minimization, purpose limitations), and (3) enacting higher legal standards and restrictions for generalized law enforcement data requests.

Discussion

Group Harms

Dr. Mays asked Mr. Schmit to elaborate on how NCVHS can approach addressing individual harms and group harms. Mr. Schmit noted that, currently, legal frameworks use the Consumer Protection Approach, which focuses entirely on mitigating individual harms. The Data Protection Approach provides one method for addressing group harms by creating specific principles intended to mitigate group harms. The Information Fiduciary Approach also addresses group harms.

Data Linkage and Reidentification

Dr. Lucila Ohno-Machado, of University of California, San Diego, asked whether any bills in development address the issue that linking data from different sources presents additional risks for reidentification, as well as the need to request explicit consent for linking. Mr. Schmit noted that he has not observed any bill explicitly addressing this topic; however, many existing bills and other legislation implicitly address this issue.

Artificial Intelligence

Dr. Watzlaf asked whether any additional topics related to AI could be addressed by NCVHS. Mr. Schmit noted that he can re-review his environmental scan findings and share additional topics at a later date.

Law Enforcement Access to Human Samples

Ms. Chrysler noted that New Jersey police were recently able to subpoena infant blood samples that are typically used to evaluate newborns for congenital and metabolic conditions. In some states, those samples are retained long-term and can be accessible to police, which implies possible breaches in privacy for relatives of the infant providing a blood sample. However, these samples are used for research surveillance projects, such as evaluating prenatal exposure to mercury in lake water. Mr. Schmit noted that he has recently written about this topic (link here), adding that many of the oldest legal privacy and confidentiality protections exist between an individual and either a religious leader or a physician. He added that those laws exist to enable individuals to speak candidly and receive needed help. In the case of infant blood samples, Mr. Schmit noted that individuals are effectively creating a social contract with the government in that they are supporting the greater public by giving up some privacy and providing those infant blood samples. He emphasized that this topic requires much additional discussion, particularly related to how laws define for what legal conduct these samples can be used.

Common Rule Support

Dr. Mays asked how NCVHS can effectively support possible changes to the Common Rule, particularly changes in response to possible concerns related to the latest revisions. Mr. Schmit noted that good arguments exist for no additional changes to the Common Rule and good arguments exist to continue recommending changes, noting that presenting both types of arguments to HHS may be helpful. He emphasized that a major challenge to Common Rule revisions is the moving target of deidentification and the risks associated with reidentification. He noted that the current definitions of "identifiable" within HIPAA and the Common Rule are different and that an argument exists for a narrower definition of the Common Rule. However, harmonizing these definitions could simplify associated regulations. Revisiting this topic, as well as definitions of "identifiable" and discussing risks associated with those definitions, is critical to supporting the Common Rule revisions.

Uniform Personal Data Protection Act Adoption

Ms. Goldstein noted that the Uniform Personal Data Protection Act was only introduced in three jurisdictions, which will likely not lead to extensive uniformity in its implementation, and asked Mr. Schmit

to elaborate on its impact in this context. Mr. Schmit noted that the purpose of this Act was to simplify the United States' currently patchworked privacy framework. A lack of federal legislation related to this topic has led many organizations are working to produce model legislation to simplify the regulatory structure across all states.

Community Involvement in SDOH Data Collection

Ms. Banks asked Mr. Schmit for guidance on how to enlist community service organizations as partners in collecting social determinants of health (SDOH) data because these organizations are not HIPAA CEs. Mr. Schmit noted that some developments in the use of community information exchanges have occurred to enable the sharing of community health data to help create a more comprehensive health care–related view of an individual. Those types of activities can help community organizations become engaged as partners.

Tribal Epidemiology Centers Data Access and Privacy Recommendations—Wu Xu and Val Watzlaf, NCVHS Members

Draft Recommendations Review and Discussion

During the July 2022 meeting, the NCVHS Committee heard from expert panelists about the significant and ongoing challenges experienced by Tribal Epidemiology Centers (TECs) in accessing much-needed public health care data collected by federal, state, and local public health agencies, as well as health care providers. Recent publications from the Government Accountability Office (link here) and HHS Office of the Inspector General (OIG; link here) further highlight and confirm these challenges. Reports have also emphasized that these longstanding barriers to data access contributed to delays in TEC and Other Designated Tribal Public Health Authority (ODTPHA) responses to the COVID-19 public health emergency.

Of the 12 TECs, 1 focuses on serving the public health needs of urban Native Americans, and the remaining 11 serve the public health needs of specific geographic areas. Each of these TECs, as well as ODTPHAs, are deemed to be public health authorities under HIPAA and therefore have authorized access to use data, monitoring systems, delivery systems, and other protected health information within the possession of HHS. HIPAA permits CEs (e.g., health care providers, health plans, and government agencies) to disclose data, including identifiable data, to TECs and ODTPHAs so that these health authorities may perform public health functions. State and local governments, as well as health care providers, may also share data with TECs and ODTPHAs. During the July meeting, panelists and Committee members heard from public commenters that many federal, state, and local public health authorities are not aware of the TECs' and ODTPHAs' legal authorization for data access.

Dr. Xu highlighted that drafting these recommendations was the collective effort of herself, Ms. Banks, Ms. Chrysler, Ms. Hines, Ms. Love, Ms. Mays, Dr. Singson, and Dr. Watzlaf. Based on the information provided to the Committee during July, NCVHS concurs with and supports the GAO and OIG recommendations, noting that those recommendations focus only on access by TECs to HHS public health data. Therefore, the Committee sought to develop specific recommendations for HHS actions needed to improve timely access to public health data for TECs and ODTPHAs from federal, state, and local public health authorities, and from health care providers. Drs. Watzlaf and Xu presented five proposed additional recommendations for consideration by NCVHS to share with HHS.

Recommendation 1: Expand the December 2020 guidance regarding public health authorities under HIPAA to clarify that all AI/AN [American Indian/Alaska Native] entities designated as public health authorities—including TECs and ODTPHAs—meet the definition of "public health authority" in 45 CFR §164.501 and

should be able to access data on the same basis as any other public health entity, so that they can carry out their mission to protect the public's health.

Dr. Xu reminded the Committee that the acronyms for TEC and ODTPHA will be explicitly spelled out in the recommendation letter. No other comments on Recommendation 1 were received.

Recommendation 2: Given the importance of the GAO and OIG recommendations, prioritize their rapid implementation, determine any gaps in their implementation and develop a plan to fill those gaps to complete implementation quickly.

No comments or suggestions were received related to Recommendation 2.

Recommendation 3: Lead a collaborative national effort to provide TECs/ODTPHAs timely access to all relevant public health data recognizing that their data needs are not limited to data provided by HHS Operating Divisions (CDC, Indian Health Service [IHS], CMS, etc.). TECs and ODTPHAs have an urgent need for public health data from states, local agencies, and health care providers to support and conduct public health in their territories. In its federal leadership capacity, HHS should identify constructive approaches (e.g., distribute clear written guidance) to make sure that all federal, state, and local public health agencies clearly understand that TECs/ODTPHAs are designated as public health authorities, and should promote their unobstructed, timely access to authorized public health data.

Mr. Landen and Ms. Chrysler recommended updating the word "territories." Dr. Mays suggested using the phrase "areas of responsibilities," and all participants agreed with this suggestion. Participants also discussed using the phrase "areas of obligation and responsibility" but agreed to omit "obligation" because that word implies a legal requirement.

Participants suggested updating the recommendation to state "all needed public health data" or "requested public health data" instead of "relevant public data." Participants agreed to use the term "requested." Participants also agreed to incorporate a footnote into this recommendation to describe the "minimum" level of data that must be shared with TECs and ODTPHAs.

Ms. Goldstein recommended that the phrase "to make sure" be changed (possibly to "to clarify") because the ability to make sure agencies understand policies is a difficult notion. Ms. Love also suggested replacing the word "promote" in the last sentence. Participants agreed to update the last sentence of the recommendation to the following: "In its federal leadership capacity, HHS should identify constructive approaches (e.g., distribute clear written guidance, public outreach) to instruct all federal, state, and local public health entities that TECs/ODTPHAs are designed as public health authorities, in order to facilitate their unobstructed, timely access to authorized public health data."

Recommendation 4: Investigate and determine the infrastructure, communication, and personnel needs necessary to improve TEC/ODTPHAs' data exchange systems, data modernization needs, and other data infrastructure capacity for a timely and quality response in meeting the public health data and surveillance requirements for AI/AN populations. This could include disseminating explanatory information to state and local public health agencies; facilitating the development of common templates for data sharing agreements; and providing consultation or technical assistance for specific data sharing issues.

Ms. Goldstein recommended updating the recommendation to state, "This could include, for example, disseminating" instead of "This could include disseminating."

Recommendation 5: Identify and publicize a process within HHS from which TECs and ODTPHAs can seek redress should barriers arise for the timely access of such data.

Mr. Landen recommended replacing "from which" with "through which." Participants agreed with this suggestion.

Vote

Dr. Xu made a motion to approve the recommendation letter (with additional non-substantive refinements related to wordsmithing and formatting), which was seconded by Mr. Landen. Ms. Hines requested that members in favor of approving the letter raise their hand virtually. All 12 NCVHS members present voted in favor of approving the letter, and thus the letter is approved (with non-substantive changes) and thus the motion is approved.

Subcommittee on Standards—Tammy Banks, Rich Landen, and Denise Love, Subcommittee Co-Chairs

Update on Convergence 2.0 Project

The Convergence 2.0 project aims to standardize information to reduce burden throughout the health care system in post-pandemic America and develop actionable recommendations within the HIPAA ecosystem related to data harmonization, privacy, and data security. This project involved creating a Joint Electronic Prior Authorization (ePA) Request for Information (RFI) Task Force with the Health Information Technology Advisory Committee (HITAC). Ms. Banks served as Co-Chair of the Joint ePA RFI Task Force, and Mr. Landen and Ms. Strickland participated as members. The ePA RFI Task Force developed a report in response to Office of the National Coordinator for Health Information Technology's (ONC's) ePA RFI; responses to this RFI were due March 10, 2022.

In addition, the Standards Subcommittee regularly engages with leadership from ONC and the Office of Burden Reduction and Health Informatics (OBRHI).

The Standards Subcommittee held a Listening Session related to the Convergence 2.0 project during June 2022. This session involved an industry stakeholder roundtable discussion and focused on topics related to adoption of HIPAA standards and new drivers of health care data exchange. As a result of this listening session, the Standards Subcommittee developed a letter that was shared with HHS that included the following four actionable recommendations for consideration:

- **Recommendation 1:** Update relevant HIPAA policies to allow for the adoption and use of more than one standard per business function.
- **Recommendation 2:** Enable HIPAA CEs to support one or more versions of adopted standards for business functions.
- **Recommendation 3:** Expand ONC's existing authority to facilitate the coordination of SDOH data standards efforts across HHS agencies and offices (e.g., CMS, ONC, CDC, NIH, IHS), to include a formalized public process that would include non-federal entities (e.g., State, Tribal, Local and Territorial governments [STLTs], private health and health care systems) to align national standards with evolving and complex national and local reporting and information needs.
- **Recommendation 4:** HHS develop and publish a guidance framework for Standard Development Organizations (SDOs) and other industry stakeholders that outlines how to develop and report

measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.

Ms. Banks highlighted two reports that informed the Convergence 2.0 efforts: (1) NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry and (2) Recommendations to Modernize Adoption of HIPAA Transaction Standards.

Requests from X12 and CAQH CORE

Transaction standards inform the electronic exchange of health-related information between two parties to facilitate financial or administrative activities. HHS has adopted certain standard transactions for the electronic exchange of health care data under HIPAA. The Affordable Care Act defines required operating rules as the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard.

One of the roles and responsibilities of NCVHS is to receive requests for new or updated standards and operating rules from SDOs and Operating Rule Authoring Entities. After receiving requests for updated standards, NCVHS will then obtain input from industry, including Designated Standards Maintenance Organizations regarding the requested modifications. For updated and new operating rules, NCVHS will obtain industry input on how the operating rules support the adopted HIPAA transactions. Following engagement with industry, the NCVHS Standards Subcommittee will formulate recommendations to share with the HHS Secretary.

X12 has requested that NCVHS recommend that the Secretary update version 5010 of the Professional, Institutional, and Dental claims guides, as well as Payment/Advice guides by adopting version 8020. These transaction standards are currently widely adopted. All other adopted transactions will remain on version 5010. Ms. Banks presented the number of enhancements requested for each of the relevant guides: Professional (1,041), Institutional (1,136), Dental (333), and Payment/Advice (259). In addition, CAQH CORE has requested updates to adopted operating rules, including (1) Eligibility & Benefits Data Content Rule, (2) Claims Status Infrastructure Rule, (3) Payment & Remittance Advice Infrastructure Rule, and (4) and Eligibility & Benefits Infrastructure Rule. Additional proposals from CAQH CORE include updates for the Connectivity Rule vC4.0.0, Eligibility & Benefits Single Patient Attribution Data Content Rule, Attachments to the Prior Authorization Infrastructure Rule, Attachments to the Prior Authorization Data Content Rule, Attachments to the Health Care Claims Infrastructure Rule, and Attachments to the Health Care Claims Data Content Rule.

NCVHS Actions to Address X12 and CAQH CORE Requests

The Standards Subcommittee heard presentations from CAQH CORE and X12 during August 2022 and engaged in collaboration with the Workgroup for Electronic Data Interchange (WEDI), which was named an advisor to HHS in the HIPAA statute. WEDI has conducted informational sessions, facilitated the WEDI Industry Survey, and conducted the Member Position Advisory event in November 2022. In addition, NCVHS issued an RFC to receive feedback on the proposals from X12 and CAQH CORE; comments are due on December 15, 2022. The Standards Subcommittee also engaged in consultative conversations with CMS OBRHI and ONC. The Subcommittee will hold a virtual hearing on January 18-19, 2023, to obtain input on the following:

- Need for and benefits of the proposed changes from X12
- Need for and benefits of the updates to the adopted operating rules

- Need for and impact on implementation of proposed operating rules
- Available cost benefit information for implementation of the updated version of the standard transactions, and updated or new operating rules
- How the requests from X12 and CAQH Core support the objectives of HIPAA and the Affordable Care Act

Developments in the Transition to ICD-11—Margaret Skurka, Jamie Ferguson, and Val Watzlaf, Standards Subcommittee Members, and Kin-Wah Fung, NLM

WHO adopted ICD-11 in 2019, and it became effective on January 1, 2022. To date, several countries have implemented ICD-11. The United States will adopt ICD-11 mortality coding as a requirement for WHO membership and morbidity coding for death certificates, billing, and payments. U.S. adoption of the morbidity components will occur as a HIPAA-mandated medical code set. Goals for U.S. adoption of ICD-11 include the following:

- Avoid a repeat of the protracted and costly U.S. transition from ICD-9 to ICD-10 by developing a shared understanding of lessons from ICD-10 transition, as well as differences between ICD-10 and ICD-11
- Reach consensus on the research questions to be answered to inform evaluation of cost and benefit of the transition to ICD-11 for mortality and morbidity coding, as well as identify impacts of not transitioning to ICD-11 for morbidity
- Identify key topics and messages to communicate to industry in order to foster early stakeholder engagement and preparation for the ICD-11 transition

NCVHS activities related to implementing ICD-11 began in 2019 with an expert roundtable meeting. In November 2019, NCVHS recommended that HHS (1) evaluate the impact of different approaches to the transition and implementation of ICD-11 in the United States for mortality and morbidity classification to guide policy and decision-making and (2) provide timely leadership on strategic outreach and communications to the U.S. health care industry about transition to ICD-11. In September 2021, NCVHS further recommended that HHS conduct research to evaluate the impact of different approaches to the transition to and implementation of ICD-11, and to perform outreach and communicate regularly with the health care industry about the transition.

The purpose of this section of the Committee meeting is to vote on the establishment of an ICD-11 Workgroup comprised of NCVHS members, federal subject matter experts, and other recognized subject matter experts to ensure a balance of perspectives are included. If approved for establishment, this Workgroup will define its membership, conduct an environmental scan of research to date, and guide development of an expert roundtable meeting to convene experts and stakeholders. The goals of the eventual expert roundtable meeting will be to provide national coordinated leadership; compile diffuse independent study efforts with federal subject matter experts to facilitate collaboration and coordination of current research efforts; improve coordination of work with the U.S. delegation to WHO on requesting any needed changes to ICD-11 in advance of implementation; and consider a public/private collaborative to coordinate the research agenda identified during NCVHS' 2019 roundtable meeting. The overarching goal of the Workgroup will be to craft recommendations to inform development of sound policy for the transition to ICD-11.

Mr. Ferguson then presented several questions that the potential Workgroup can study to inform ICD-11 policy decisions:

- Overall, how well does ICD-11 meet U.S. needs as a HIPAA coded set?
- What are the benefits of U.S. ICD-11 adoption and implementation?
- What are the costs for U.S. implementation of ICD-11, as well as the costs for not implementing ICD-11?
- Of the classification codes most used and most needed in the United States, how many can be managed in ICD-11 natively with existing stem codes alone, using post-coordinated cluster coding with existing stem codes and extensions, or using cluster costing including new extensions specific to U.S. needs?
- How does the code set coverage in the above scenarios vary by use case (e.g., for Medicare payment, CDC reporting, clinical research studies)?

Update on NCHS/NLM Collaborative Work in ICD-11 for Morbidity Coding

Dr. Fung provided an overview of collaborative work performed by the National Center for Health Statistics (NCHS) and the National Library of Medicine (NLM) related to ICD-11 morbidity coding since the April 2021 Committee meeting. Dr. Fung's previous presentation to the Committee involved a feasibility study of replacing ICD-10-clinical modification (CM) with ICD-11 morbidity coding; the results of this study were published in the *Journal of the American Medical Informatics Association* (link here). This feasibility study found that for 943 frequently used ICD-10-CM codes, representing 60 percent of usage from each chapter, ICD-11 can achieve 23.5 percent full representation without post-coordination; 8.6 percent full representation with post-coordination (which can be increased to 35.2 percent with minor enhancements); and 67.9 percent partial representation. Based on the General Equivalence Maps published by CMS, only 24.3 percent of ICD-CM codes have an exact match in ICD-10-CM. The study concluded that a transition from ICD-10-CM to ICD-11 may not be more disruptive than the transition from ICD-9-CM to ICD-10-CM. Thus, the authors recommended that ICD-11 be considered seriously as a candidate to replace ICD-10-CM, noting that this transition does not require clinical modifications as were used in the ICD-9-CM and ICD-10-CM transitions. Even if ICD-11 cannot entirely replace ICD-10-CM, some alternatives to a full transition to ICD-11 include (1) generating an ICD-11-CM as a linearization of ICD-11, (2) maintaining an additional set of ICD-11 extension codes to provide for necessary post-coordination, and (3) adopting most of ICD-11 coding as is with only a small number of new codes needed.

In addition, NLM has been conducting a new study to evaluate practical strategies to replace ICD-10-CM with ICD-11 for morbidity coding. During this study, NLM has adopted a new method for sampling that examines all codes in one chapter—the chapter of diseases of the digestive system—which contains 817 codes. The new sample has been used in addition to a sample that covers the most frequently used codes in each ICD chapter, as in the previous feasibility study. Dr. Fung described the current study's mapping approach which follows these steps:

- **Step 1:** Select an ICD-10-CM.
- **Step 2:** Determine whether an ICD-11 stem code exactly matches this ICD-10-CM code. If an exact match exists, mapping is complete.
- **Step 3:** If an exact match does not exist, review the ICD-11 foundational layer to identify a possible match. If an exact match is found, then mapping is complete.
- **Step 4:** If an exact match has not been identified, use post-coordination to determine whether a code can be found by combining stem and extension codes.
- **Step 5:** If an ICD-10-CM code does not have a match after all previous steps, develop a new stem code for the specific use case.

The final results of the current study are not available, but Dr. Fung will share them at a future Committee meeting.

Discussion

Pitfalls of ICD-10 Coding

Dr. Mays noted that one problematic area in ICD has been the coding related to psychiatric diagnoses, particularly when aligning them to the Diagnostic and Statistical Manual of Mental Disorders (DSM). She added that the National Institute of Mental Health has employed a Research Doman Criteria (RDoC) approach and asked how NCVHS should address these issues. Mr. Ferguson noted that NCVHS would convene stakeholders and experts in the field to discuss these issues with the proposed Workgroup. Dr. Fung confirmed that the topic raised by Dr. Mays is important to consider in future discussions. Ms. Love noted that another shortcoming of ICD-10-CM was that medication coding was handled as poisonings or accidents; she asked whether ICD-11 could employ a different approach. Dr. Fung noted that ICD-11 can use post-coordinated extension codes for medications to improve the amount of information provided. For example, an extension code could be used to denote whether a medicine is associated with a particular adverse event.

ICD-11 Codes

Dr. Watzlaf asked whether the ICD-10-CM codes without an exact match in ICD-11 are specifically gaps for the United States or broader gaps in the coding. Dr. Fung confirmed that these gaps are likely applicable to other countries and could be proposed as official additions to ICD-11. However, codes that are specific to the United States may exist and could be maintained as codes in the US extension. Mr. Ferguson added that WHO is currently in a stage of ICD-11 implementation where it is requesting additional codes and changes to ICD-11 from countries adopting the policy, and noted that findings from Dr. Fung's study can be used to help identify those additional codes.

Dr. Xu asked whether Dr. Fung has sufficient resources to expand his current study to assess more ICD-11 chapters, if needed. Dr. Fung noted that his team will consider evaluating more chapters (possibly the chapter on mental health) after completing the scope of the current study and reviewing feedback from other stakeholders.

Mortality Coding Updates

Dr. Mays noted that, in previous Committee meetings, NCHS and NIH had mentioned that some changes were urgently needed related to mortality coding in ICD-11 and asked whether this topic has been discussed further. Ms. Hines noted that Dr. Bob Anderson, Chief of the Mortality Statistics Branch at NCHS, has been completing an assessment related to this topic and should have results soon to share with the Committee. Mr. Ferguson recommended that the ICD-11 Workgroup, if established, should coordinate with Dr. Anderson's efforts.

Mr. Landen added that, unlike in morbidity coding where providers perform the coding themselves, mortality reported by states and NCHS is completed in plain language and the coding (i.e., converging the plain language into ICD-11 codes) is performed by NCHS. Thus, he noted that coding support via algorithms will be needed.

WHO ICD-11 Efforts

Dr. Mary Stanfill of United Audit Systems Inc (UASI), is a volunteer with the International Federation of Health Information Management Associations (IFHIMA) and serves as its representative to the WHO Family of International Classification (WHO-FIC). She noted that WHO has established a scientific

committee, a morbidity/mortality reference group (of which Dr. Stanfill is a member), as well as committees to address any requests for changes to the code set and foundation of ICD-11. She noted that many of these committees' efforts are completed by volunteers and that the work will be supported by an electronic management platform. The overall goal of WHO's ICD-11 is to provide a global standard that is consistent and interoperable. Mr. Ferguson asked whether WHO expects feedback to be provided in a limited timeframe. Dr. Stanfill noted that WHO will likely continue accepting requests for changes for the near future.

Vote for Establishment of ICD-11 Workgroup

Ms. Love made a motion to approve the recommendation to establish an ICD-11 Workgroup, which was seconded by Ms. Banks. Dr. Mays requested clarification that the details discussed during the meeting would be incorporated into the project scope. Mr. Ferguson confirmed that the proposal includes opportunities for addition of details. Ms. Hines requested that members in favor of the proposal to establish the Workgroup raise their hand virtually. All 12 NCVHS members present voted in favor of approving the establishment of an ICD-11 Workgroup, and thus the motion is approved.

NCVHS 2023 Report to Congress—Jacki Monson, NCVHS Chair

NCVHS is a public advisory committee to HHS that is charged with assisting and advising the HHS Secretary on health data, statistics, privacy, and national health information policy, as well as strategies to best address identified issues. To perform this duty, NCVHS performs the following functions:

- Monitors the nation's health data needs and current approaches to meet those needs
- Identifies emerging health data issues, including methodologies, platforms, and models for managing health information systems
- Assists and advises HHS in the implementation of the Administration Simplification provisions of HIPAA to inform decision-making regarding data policy by HHS, states, local governments, and the private sector
- Advises the Secretary and Congress on the status of the implementation of Part C of the Social Security Act and assisting the Secretary in complying with the associated requirements
- Studies issues related to the adoption of uniform data standards for patient medical record information and the electronic interchange of such information and reports recommendations related to these issues to the Secretary

Every 2 years, NCVHS develops the NCVHS Report to Congress (RTC), which should address (1) the extent to which persons required to comply with Part C of the Social Security Act are cooperating in implementing the standards adopted under such part; (2) 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; (3) whether the federal and state governments are receiving information of sufficient quality to meet their responsibilities under such part; (4) any problems that exist with respect to implementation of such part; and (5) the extent to which timetables under such part are being met.

NCVHS completed the 14th RTC in 2021. This RTC included an overview of five major trends in health information, updates on the progress and status of HIPAA implementation (related to transaction and medical code set standards, as well as privacy, security, and breach notifications), a review of near-term national health information challenges and opportunities, and a preview of the Committee's proposed near-term activities. The five major trends in health information were the following:

1. New technologies, platforms, and models for managing health information—with varying degrees of maturity and implementation—have emerged to meet pressing business needs.
2. Patients' roles in accessing and using their health data have expanded and evolved.
3. The convergence of clinical and administrative data standards is gaining recognition and crossing the boundaries of traditional data and program silos.
4. The COVID-19 pandemic has exposed grave weaknesses in public health information infrastructure.
5. Health information privacy and security challenges have proliferated.

The 2021 RTC detailed progress related to, and the status of, HIPAA implementation by including sections on HIPAA transactions and medical code set standards and privacy, security, and breach notifications; Ms. Monson reviewed the topics included in each of these sections, listed below:

Transactions and Medical Code Set Standards

- Transactions
- Status of transactions in 2020
- HIPAA transactions initiatives and actions during 2019-2020
- Medical code sets, as well as terminologies and vocabularies initiatives and actions, during 2019-2020
- Administrative simplification initiatives and actions during 2019-2020

Privacy, Security, and Breach Notifications

- Proposed changes to the Privacy Rule
- Updated guidance on HIPAA and Family Educational Rights and Privacy Act of 1974 (FERPA)
- Guidance on HIPAA, health information exchanges, and disclosures of personal health information for public health purposes
- HIPAA and COVID-19
- HIPAA breach notifications
- HIPAA enforcement
- The HIPAA Right of Access Enforcement Initiative

The 2021 RTC also detailed (1) how more than 1,000 breaches involving hacking and ransomware occurred between 2016-2020, with 429 breaches occurring in 2020; (2) OCR's HIPAA enforcement actions during 2020; and (3) the percentage of industry implementation of HIPAA between 2013-2020. The national health information challenges and opportunities highlighted in the 2021 RTC included (1) the need for comprehensive, integrated, national health information standards; (2) the need to address increasing challenges to privacy, confidentiality, and security; (3) need for enhanced data sources to support payment reform and price transparency; (4) need for equitable information technology to provide access for all end users; and (5) need for a nationwide, digitized infrastructure to enable pandemic information collection and sharing. The 2021 RTC highlighted four focus areas to consider for NCVHS efforts in the future, including promoting convergence of clinical, administrative, social, and public health data; improving the health care industry's security posture; monitoring and advising on ICD-11 readiness; and identifying new approaches for data collection, sharing, linkages, and analytical methods to address health inequities.

The reporting period for the 2023 RTC will be January 1, 2021, to December 31, 2022. This report can be framed as a new report, an update to the previous report, or a brief synopsis that is attached to the previous report. Ms. Monson proposed the following topics to consider for the 2023 report: (1) notable changes and activities during the past 2 years, (2) significant and notable policy issues, and (3) priority

focus areas. Ms. Monson asked participants to share their suggestions on how to approach the 2023 RTC, as well as possible topics to address in this report.

Discussion

Participants agreed to approach the report with two strategies: (1) first evaluate what notable progress and changes have been made since the 2021 report and (2) highlight future priority areas. Participants also agreed that the 2023 RTC will likely be either a shortened report or an update to the previous report, not an entirely new report. Ms. Monson recommended that the NCVHS Subcommittees review progress made in their respective areas of expertise since 2021 and share their findings with the full Committee to help inform the RTC's direction. Ms. Monson and Ms. Hines agreed to develop a timeline for RTC development and share that timeline, as well as the general strategies highlighted during today's meeting, with the Executive Subcommittee next week for review. Following the Executive Subcommittee meeting, Ms. Monson and Ms. Hines will share any findings with the Committee, as well as the RTC development timeline, for discussion and review.

Participants identified the following future priority areas to highlight in the RTC: cybersecurity, sexual orientation and gender identify/SDOH data collection, reconciling race/ethnicity fields that differ across HHS and the OMB, Beyond the HIPAA Privacy Rule, Convergence 2.0, and ICD-11.

Ms. Hines confirmed that the 2023 RTC could be released as late as December 2023, but could also be completed on a more compressed timeline.

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

Ms. Sara Rosenbaum, a Harold and Jane Hirsh Professor of Health Law and Policy at George Washington University, shared that her comments will focus on reducing racial and ethnic health disparities by including race/ethnicity data fields on Uniform Billing (UB) Forms and claims forms. Including these fields on billing forms will facilitate a better understanding of health disparities and how interventions can reduce these disparities. Ms. Rosenbaum emphasized that billing forms, including the CMS 1450 (also known as UB-04) and CMS 1500, are an established part of national health care infrastructure and that adding the race/ethnicity fields into these forms would be simple and would not require new data collection methods.

Closing Remarks and Adjourn—Ms. Monson, Chair

Ms. Monson thanked Subcommittee staff members, invited speakers, and the NCVHS team for their support and adjourned the meeting.

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

/s/
Jacki Monson, JD, Chair — August 30, 2023
National Committee on Vital and Health Statistics — Date