Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
November 29-30, 2023
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-15/

The National Committee on Vital and Health Statistics (NCVHS) was convened both in person and virtually on November 29-30, 2023. 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, University of Michigan
Catherine Donald, MBA, Alabama Department of Public Health
James Ferguson, Kaiser Permanente
Michael Hodgkins, MD, MPH, Consultant
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

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

Invited Speakers
Kelly Baden, Guttmacher Institute
Bob Bowman, MA, CAQH
Michael Cimmino, MPH, CMS
Carmela Couderc, ONC
Kin-Wah Fung, MD, NIH
Alix Gross, POCP
Travis Hoppe, PhD, MS, NCHS
Daniel Kalwa, CMS
Jami Lookabill, CMS
Vickie Mays, PhD, MSPH, UCLA
Steve Posnack, MHS, MS, ONC
Patrick Romano, MD, MPH, FAAP, FACP, UC Davis
Cathy Sheppard, X12
Grail Sipes, JD, OSTP
Mary Stanfill, MBI, ACHIP, RHIA, CCS, CCS-P, FAHIMA, UASI
Dan Vreeman, DPT, MSc, HL7
Margaret Weiker, NCPDP

In addition to those individuals who presented virtually during the meeting (listed above), 86 people followed the meeting online on Day 1 and 73 followed on Day 2.

ACTIONS

1. The Committee approved the Privacy, Confidentiality, and Security (PCS) Subcommittee letter and recommendations (with additional non-substantive refinements related to citations and formatting) to the Department of Health and Human Services (HHS) Secretary on strengthening the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule.

—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.

Agenda Review—Jacki Monson, Chair

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

Strengthen the HIPAA Security Rule—Valerie Watzlaf and Subcommittee on Privacy, Confidentiality, and Security

NCVHS is charged with studying and identifying privacy, confidentiality, and information security measures to protect individually identifiable health information. Cyberattacks, which have become more prevalent in recent years, can disrupt the health care continuum, causing delays in procedures and tests for patients. Cyberattacks are associated with longer hospital stays, increased incidence of complications from medical procedures, and increased mortality rates. Thus, the NCVHS Full Committee sought to explore the scope and breadth of security risks and ways to address them to protect patients in the health care system. During 2021 and 2022, NCVHS held hearings to better understand these issues. In late 2022, NCVHS submitted a letter to the HHS Secretary titled "Recommendations to Strengthen Cybersecurity in Healthcare," which incorporated feedback received during the previous years' hearings. During 2023, the Full Committee heard presentations from the Director of the Office for Civil Rights (OCR) and the Deputy Director for Health Information Privacy, Data, and Cybersecurity at OCR, both of whom stressed the need to address the recent and dramatic increase in cybersecurity incidents in the health care system and to develop a robust risk analysis. OCR's other previous work has found that covered entities (CEs) and business associates were not consistently compliant in implementing the Security Rule's requirements for a risk analysis and risk management program. This lack of compliance may be due to inconsistent guidelines or excessive costs for small entities and business associates.

In response to this information, the PCS Subcommittee has drafted a letter titled "Recommendations to Strengthen the HIPAA Security Rule," which incorporates feedback and expertise shared by OCR and other relevant stakeholders. In this letter, the PCS Subcommittee outlines the following recommendations to strengthen the HIPAA Security Rule:

- **Recommendation 1:** Require in the HIPAA Security Rule that all CEs and business associates implement a security program, and that the Rule specify the same minimum security controls for all CEs and business associates.
- **Recommendation 2:** Require in the HIPAA Security Rule that CEs and business associates adopt a risk-based approach in their security program.

- **Recommendation 3:** Include a step-by-step risk analysis procedure within the Security Rule.
- **Recommendation 4:** Define compensating controls more specifically in the Security Rule and provide examples.
- **Recommendation 5:** Reinforce the need to evaluate artificial intelligence (AI) systems and data within the Privacy and Security Rule as part of risk analysis for all and any new technology.
- **Recommendation 6:** Standardize cyber incident reporting in the HIPAA Security Rule, and harmonize any such requirements in HIPAA rules with incident reporting provisions applicable to health care critical infrastructure actors and health care federal contractors.

Discussion

Review of Recommendations

Dr. Watzlaf confirmed that the recommendation letter does not include a detailed, risk-based approach for small CEs to follow, but instead provides general guidelines and requirements. Mr. James recommended including more information to help entities construct their risk-based approach because many new employees to the health care industry may lack the knowledge or expertise with HIPAA to develop such a plan. Mr. Ferguson noted that, in addition to the recommendations, the PCS Subcommittee has included language that requests more explicit guidance from OCR regarding the level of detail needed for the risk-based approach.

Mr. Landen suggested emphasizing the new information and requirements proposed in this recommendations letter. He also suggested revising Recommendation 3 to include an external risk analysis procedure, not one internal to the Rule, to enable a more flexible approach to changing or emerging threats to the health care system. However, this risk analysis procedure must be included *in* the Rule, not externally, in order to enforce its use.

Committee members reviewed and updated the six recommendations to the following (changes in italics):

- **Recommendation 1:** Require in the HIPAA Security Rule that all CEs and business associates implement a security program, and that the Rule *require* the same minimum security controls for all CEs and business associates.
- **Recommendation 2:** Require in the HIPAA Security Rule that, *in addition,* CEs and business associates adopt a risk-based approach in their security programs.
- **Recommendation 3:** *Require* a step-by-step risk analysis procedure within the Security Rule *that conforms with guidance from the National Institute of Standards and Technology (NIST) of the Department of Commerce and the Cybersecurity and Infrastructure Security Agency (CISA) of the Department of Homeland Security*.
- **Recommendation 4:** Define compensating controls more specifically in the Security Rule and provide *a wider range of* examples *that apply to a greater variety of types of entities*.
- **Recommendation 5:** *Strongly reinforce* the need *to account for* artificial intelligence (AI) systems and data within the Privacy and Security Rule as part of *the* risk analysis for all and any new technology.
- **Recommendation 6:** *Establish a consistent floor for* cyber incident reporting in the HIPAA Security Rule, and harmonize any such requirements in HIPAA rules with incident reporting provisions applicable to health care critical infrastructure actors and health care federal contractors.

Dr. Watzlaf read a comment regarding these recommendations from Dr. Eugenia McPeek Hinz (Duke University), who asked whether HIPAA coverage will be extended to include electronic health information

(EHI) releases. Ms. Monson noted that this comment may fall outside of the scope of the Security Rule and should be a discussion topic in future Subcommittee meetings.

Review of Rationale and Supporting Information to Recommendations

Ms. Bernstein noted that the recommendations letter references data findings from the Ponemon Institute, which releases information management survey reports with very low response rates (indicating possible biases in the collected data). Thus, Ms. Bernstein recommended including different evidence in the letter's content.

Ms. Bernstein also noted that some of the key points within the text supporting the recommendations may warrant brief definitions to assist the reader's understanding. For example, "quantum computing" is defined in a footnote but not in the body text. "Defense-in-depth" (DID) should also be defined in a footnote based on NIST resources; Ms. Monson will provide Ms. Bernstein a citation for this definition. Participants agreed to move the example describing MOVEit to the beginning of the "minimum encryption requirements for data security and use of crypto agility" section to illustrate current problems faced in the health care system.

Vote

Mr. Landen made a motion to approve the recommendation letter (with additional non-substantive refinements related to wordsmithing, formatting, and updates discussed during today's meeting), which was seconded by Ms. Strickland. Ms. Hines called for a vote of the NCVHS Full Committee members; 13 members voted in favor of approving the letter and thus the letter was approved (with non-substantive changes).

Standards Subcommittee Invited Presentations—Tammy Banks, Co-Chair of Standards Subcommittee

This session focused on enhancing the NCVHS Full Committee's understanding of (1) the Office of the National Coordinator for Health Information Technology's (ONC's) and the National Standards Group's (NSG's) recent activities and potential collaborations, (2) the status and current activity of standards and operating rules enforcement, and (3) the approaches used by standards development organizations (SDOs) and certification bodies to evaluate and assess the readiness of new and updated standards prior to release for national implementation or certification.

The Standards Subcommittee requested that each speaker, when applicable, present on how their SDO completes the following activities:

- Assess and report on backward compatibility or specific anticipated issues with updates to standard versions.
- Assess whether current health information technology (HIT) systems can support the functionality and the impact of a new or updated standard version (e.g. updated X12 transaction standards) across other mandated standards (e.g., attachment standards).
- Assess cost and value of changes within a standard, anticipated cost and value of the changes at the time of expected implementation, and anticipated cost and value of implementation of the standard in the cross-transduction environment where it will be used with other standards.
- Assess potential risks and impacts of new or updated standards across other existing standards, and in consideration of potential plans for the future of International Classification of Diseases, 11th Revision (ICD-11) implementation.

Evaluation and Assessment of the Readiness of New and Updated Standards—Steve Posnack

ONC supports the Interoperability Standards Advisory (ISA), which is a model used to identify, assess, and determine recognized interoperability standards and implementation specifications for industry use to fulfill specific clinical HIT interoperability needs. ISA includes a variety of use cases, provides metadata to support each use case, and identifies common limitations of a standard.

Understanding the adoption level of a standard is more difficult. For example, a standard may be adopted for a single use case but not for many other use cases that are applicable. ONC also supports the use of tools to test standards, particularly to assess standard performance. Many SDOs categorize standards according to their level of maturity (e.g., draft versus final or validated). The ISA categorization process involves characterizing standards as either "pilot" or "production," to indicate the standard's maturity and represent the level of investment provided by industry to test and validate the standard.

ISA also provides resources to support standards testing. Testing can significantly improve the understanding of a standard and its future use. ONC also considers the cost of implementing a new standard, which may include purchasing licenses for access; Mr. Posnack emphasized that this cost is not typically a barrier to use. In addition, ONC's U.S. Core Data for Interoperability (USCDI) library of data elements and use cases can help implementers understand the use of particular data elements associated with particular standard transactions. ONC also includes regulatory impact analyses, as well as any other analyses that may be critical, in proposed updates to a given standard or other relevant updates in order to receive feedback on these outputs.

Mr. Posnack concluded his presentation by emphasizing the importance of providing sufficient time for the ICD-11 transition to ensure its proper testing throughout the implementation process.

Discussion

Ms. Banks requested that ONC review and provide feedback on NCVHS's scoping document that will be presented later in this meeting.

Update from National Standards Group—Michael Cimmino, Daniel Kalwa, and Jami Lookabill

Mr. Cimmino opened NSG's presentation by noting that the comment periods for the proposed rule to adopt updated retail pharmacy standards and the proposed X12 rules for updating health care attachments have closed; NSG is now reviewing all comments received. Regarding the latter, commenters have expressed concerns that the rule may impact other rules pertaining to prior authorization (PA). In addition, given NCVHS's recent recommendation letter to adopt Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) updated operating rules, NSG anticipates engaging in rulemaking that will propose to adopt updated operating rules for the eligibility, claim status, and remittance advice transactions.

During previous NCVHS meetings, the Full Committee agreed to not recommend Version 008020 for specific X12 standards. As a regulatory party responsible for enforcing HIPAA transaction standards, NSG is reviewing all stakeholder feedback regarding adoption of Version 008020 of the updated X12 transaction standards. NSG has also sought input from industry on the subject.

NSG continues to explore opportunities related to supporting HIPAA administration simplification. In addition, NSG is working to modernize the standards development and adoption process by incorporating more testing of standards. Mr. Cimmino cautioned NCVHS Full Committee members about

the low level of interest, support, and readiness for ICD-11 adoption within the U.S. health care industry. He emphasized the importance of overcoming the challenges experienced during the transition from ICD-9 to ICD-10-CM.

Mr. Kalwa then provided an overview of NSG's HIPAA processes related to violations of electronic transactions, operating rules, code sets, and unique identifiers. Violations of health information privacy rights and rules related to privacy enforcement, security, or breach notifications should be shared with OCR, not NSG. NSG enforces administration simplification standards by responding to complaints about HIPAA standard noncompliance and conducting proactive compliance reviews. Through these processes, NSG aims to reduce the burden on compliant entities who conduct transactions with trading partners that are not compliant and by streamlining billing and insurance-related functions, enabling providers and health plans to spend less time on these tasks. NSG's efforts are focused only on HIPAA CEs, which include health care providers that submit transactions electronically, health plans, and clearinghouses. Ms. Lookabill described the Centers for Medicare & Medicaid Services (CMS's) process for addressing administration simplification complaints and compliance:

Process to Address Complaints

- **Phase 1 (Intake):** NSG reviews and assesses the complaint of noncompliance to determine whether the complaint is within its enforcement scope and whether information from the complainant or Filed Against Entity (FAE) is needed.
- **Phase 2 (CMS Contact):** CMS contacts the complainant and FAE with updates related to the complaint and requests a response within 30 days.
- **Phase 3 (FAE Response):** The FAE responds that (1) the complaint is false, (2) the FAE has rectified the noncompliance and provided documentation to showcase compliance, or (3) the FAE can acknowledge the noncompliance.
- **Phase 4 (Corrective Action Plan):** CMS issues a corrective action plan that is monitored as the FAE executes it; the complainant also receives updates on the plan's progress.
- **Phase 5 (Resolution):** The FAE demonstrates compliance to CMS, which verifies the compliance; the complainant also confirms compliance.
- **Phase 6 (Closure):** CMS closes the complaint, mails notices to the FAE and complainant, and updates the public Enforcement Report.

Process to Review Compliance

- **Phase 1 (Selection and Contact):** CMS randomly selects a CE that has identified a point of contact that is responsible for the compliance review.
- **Phase 2 (Submission):** CMS provides to the CE instructions and resources, and the CE submits transaction files and other requested artifacts within 30 days of receipt of instructions.
- **Phase 3 (Review):** CMS reviews documentation artifacts received within 30 days.
- **Phase 4 (Corrective):** If CMS determines that a corrective action plan is necessary, then the CE executes that plan.
- **Phase 5 (Validation):** CMS confirms that the correction actions have been completed and notifies the CE. CMS then closes the review.

Additional information can be found on the CMS website.

Discussion

NSG representatives confirmed that they are resolving complaints relatively quickly and do not have a backlog of complaints. CMS addresses approximately one to two complaints a week; however, most complaints are deemed invalid.

Ms. Banks asked the NSG team to review the Standards Subcommittee's scoping document and provide feedback; Mr. Cimmino confirmed that his team will review the document and provide comments.

Mr. Cimmino noted that NSG is working on the review and evaluation process for Version 008030 of transactions.

CAQH CORE Operating Rule Enforcement Process and Recent Activity—Bob Bowman

CAQH CORE aims to facilitate the development of consensus-based business rules to drive interoperability. HHS has federally designated this committee as the National Operating Rule Authoring Entity for all HIPAA-mandated administrative transactions. CORE convenes industry stakeholders to accelerate automation and develop business processes that streamline health care for patients, providers, and health plans while remaining technology agnostic and standard agnostic. To date, 10 CORE operating rules are currently mandated under HIPAA, and the estimated industry cost savings attributed to the operating rules since first mandated is $18 billion. More than 100 providers, health plans, vendors, associations, agencies, and SDOs participate within CORE, and more than 400 of health plans, vendors, and clearinghouses have been awarded CORE certifications.

Organizations that create, transmit, or use health care administrative and financial transactions addressed by CORE operating rules can become CORE-certified. To achieve this certification, the organization must abide by CORE certification policies, adopt CAQH CORE operating rules, pass CORE certification testing, and attest to HIPAA compliance.

CORE enforcement policies enable industry to monitor, regulate, and correct itself to avoid and prepare for enforcement audits and penalties. Any health care provider that is an end user of a CORE-certified product, as well as organizations involved in an alleged non-conformant transaction, can submit a complaint. Most complaints are filed by providers or provider-facing vendors. Over the previous 3 years, only three organizations submitted enforcement complaints, all of which were resolved through collaboration among the involved parties.

The CORE certification enforcement process begins with confirmation that the trading partner in question is CORE-certified and an attempt to solve disputes following the Enforcement Template Letter. If the CORE-certified trading partner is not cooperating, the organization may document instances of noncompliance, followed by a "Request for Review of Possible Non-Conformance" form. CORE will then facilitate discussion and resolution among trading partners. If the CORE-certified trading partner is unable or refuses to resolve the complaint, CORE can revoke its certification seal. If the trading partner is not CORE certified, the organization interested in filing a complaint can contact CAQH CORE; it can also encourage the trading partner to become CORE certified.

Assessing New and Updated Standard's Business Value and Technical Rick Across Standards—SDOs

Dan Vreeman, HL7

Health Level 7 International (HL7) focuses on understanding the capabilities of data instances. Forward compatibility implies that standards will be compatible for the entire duration of the standards release, whereas backward compatibility implies that new standards will be compatible with older versions. Backward compatibility can be challenging but critical when an updated or new standard meets an emerging need and that standard must interact with many previous processes; HL7 provides Fast

Healthcare Interoperability Resources (FHIR)–related materials to aid in addressing backward compatibility issues.

HL7 categorizes standards according to three levels to reflect the amount of consensus review and stability of that standard: (1) normative, which indicates that a standard has been approved by a rigorous American National Standards Institute (ANSI) process and is stable; (2) trial use, which indicates that a standard has been well reviewed and is now ready for production but may cause breaking changes in future versions; and (3) informative, which indicates that a standard assists the implementer but does not make rules that implementers are required to follow. HL7 also categorizes artifacts along a maturity level framework called the FHIR Maturity Model (FMM), which indicates to implementers the stability level of an artifact:

- **FMM 6 (Normative):** Normative ballot and locked by change rules.
- **FMM 5:** Published in two cycles and implemented by more than five systems in more than two countries.
- **FMM 4:** Published, tested, and community consult required for breaking changes.
- **FMM 3:** Formal balloting and 10 distinct comments from three organizations.
- **FMM 2:** Tested to support interoperability of three independently developed systems.
- **FMM 1:** No quality assurance warnings, substantially complete, and ready for use.
- **FMM 0 (Draft):** Published in current build.

HL7 is dedicated to creating rigorous processes for standards development and implementation. HL7 launched the Standards Implementation Division to help close the gap between publication and implementation of a specification. One approach to closing these gaps is testing, which HL7 completes on all specifications before and after publication. HL7 holds implementation-focused data competitions (e.g., implementationathons, connectathons), as well as invests in developing software for validating specifications and data that conform to those specifications. Today, most HL7 specifications are created with reference implementation software, which can also be used by other users to test the specification as well. Four additional mechanisms are used by HL7 to test the implementability and community readiness of specifications: (1) ensure that barriers to participation in specification testing are low, (2) regularly survey industry to understand how standards are used, (3) enable close collaboration with international and national stakeholders to obtain helpful feedback, and (4) support the HL7 FHIR Accelerator Program. HL7 has also worked with the Cambria Grove Innovator Fellowship to create a value-metrics framework, which categorizes the benefits of a specification and can help showcase metrics that some stakeholders may value.

HL7 continues to work to ensure that its developed standards function well with other standards, noting that addressing conflict between standards requires collaboration among the involved parties. For example, the Da Vinci FHIR Accelerator program developed three implementation guides focused on the PA process. The PA support implementation guide provides specifications for translating into and out of the HIPAA-mandated X12 Review Information Transaction Set (278) standard. During development of the specifications, HL7 worked directly with X12 to map aspects of the X12 transactions to FHIR.

To conclude, Dr. Vreeman commented on how HL7 standards could aid in the adoption of ICD-11. One of ICD-11's key innovations is the use of post-coordination. HL7 works with the authorities of major coding systems to develop guidance about use of their terminologies in HL7 standards. HL7 has not yet developed a guide for ICD-11, but HL7 has recently initiated a collaboration with the World Health Organization (WHO) to support the adoption of ICD-11. One limitation related to ICD-11 licenses for

individual entities is that these licensees are not permitted to create mappings from other terminologies to ICD-11 without a specialized agreement from WHO.

Margaret Weiker, NCPDP

The National Council for Prescription Drug Program (NCPDP) is an ANSI-accredited standards developer (ASD) that provides a forum and marketplace for a diverse membership focused on health care and pharmacy business solutions to advance interoperability. NCPDP uses a consensus-building process to develop national standards for real-time electronic exchange of health care information. Through its problem-solving forum, NCPDP also develops and standardizes best practices for product labeling, dosing instructions, patient communications, education, and other practices important to safeguard patients.

In order to address backward compatibility related to version updates, NCPDP develops many types of crosswalks (i.e., mappings) between the currently adopted version of a standard and the proposed new version of the standard. NCPDP also develops extensive change logs in each implementation guide, and the NCPDP Strategic National Implementation Process (SNIP) Committee creates transition guidance for the telecommunications and script standards. NCPDP recently held an educational summit on the telecommunications standard F6, as well as a high-level webinar on the same standard; both of these meetings were recorded and can be viewed on NCPDP's website. NCPDP reports on anticipated issues with version updates by creating a transition guidance crosswalk table that indicates (1) a previous version's output, (2) the output in the updated version, and (3) a description of the new value in the updated standard. NCPDP has developed the Script Testing Tool that all entities can use to test new script standards and become certified that the electronic health records (EHRs) meet the necessary requirements; this tool will soon be transitioned to ONC.

As a member-driven organization, NCPDP relies on its members, stakeholders, and implementers to determine whether any proposed version changes are not technically feasible. NCPDP employs its Data Element Request Form (DERF) to collect information on how proposed updates may affect specific standards. NCPDP's Standardization Committee then reviews the concepts of each DERF to determine indirect effects on other standards as well. Typically every 3 years, members evaluate proposed changes and vote on when to adopt a new version of a standard. In relation to assessing the costs associated with a changed standard, NCPDP does not directly evaluate costs, but its members and stakeholders do. The DERF can also capture some information that can indicate estimated cost savings or burden associated with a changed standard. Ms. Weiker emphasized that not promulgating a Final Privacy Rule in a timely manner often hinders the adoption of standards updates and increases the costs of implementing new standards.

In the event that NCPDP must implement ICD-11, most changes will involve adding a code value to existing data elements; however, larger pharmacy systems may be affected by alphanumeric and special character standards. Currently, NCPDP is more focused on addressing changes in the National Drug Code than those in ICD-11.

Cathy Sheppard, X12

X12 is an ASD that develops standards that are supported across industries, including health care, insurance, and government. Supporting organizations across the health care industry provides X12 access to a large library of expertise to address new needs in health care. Currently, millions of organizations across the world have infrastructure that supports X12 transactions, and data exchanged in those transactions are effective, well-defined, and mature.

X12 believes that the concept of backward compatibility must be emphasized and expanded in order to advance standards generationally. Instead of backward compatibility, X12 believes that the field must be focused more on cross-compatibility, which involves transactions across versions or syntax versions that can interact effectively. X12 emphasizes the importance of shared definitions and nomenclature to enable backward compatibility, without which the field will not be able to improve standards in the ways that implementers need them to be improved.

Ms. Sheppard noted that ASDs, such as X12, are limited in what they can report on independently. ASDs can share reports on comparisons between the output of new and old standards, but much of the reports will derive from trading partners that share information back to the ASD after using updated standards. In addition, different trading partners may use different internal processes, leading to different readouts. X12 has conducted forums to convene various other ASDs and its own trading partners to discuss their experiences with a new or updated standard. X12 has also developed a new maintenance process that includes a predictable schedule of releasing one standard per year. Additionally, X12 has identified several partners to provide implementation testing of these new standards.

The discussion about X12 supplemented Ms. Weiker's earlier comment encouraging NCVHS to emphasize the costs of not updating and implementing standards. The costs of missed opportunities and increasingly non-standard proprietary solutions are high.

Discussion

Mr. Bowman confirmed that CORE enforcement is only applied to organizations that have completed the CORE certification.

Ms. Weiker noted that the Script Testing Tool was developed initially to test the version 2015 script standards. The tool has been updated to the current version of the script standard. This tool enables any organization, including pharmacies, to test the resultant transactions. Accredited organizations can also use the tool to provide certification for EHRs.

Ms. Weiker and Ms. Sheppard confirmed that their respective SDOs do not state the level of testing that a standard must undergo and emphasized the difficulty in obtaining data on cost from trading partners. In order to resolve difficulties in obtaining such data, a federal agency would need to issue a mandate that the SDO could promote.

NCVHS Workplan Development Part I—Tammy Banks, Standards Subcommittee, and Valerie Watzlaf, PCS Subcommittee

Overview

During this session, Ms. Banks reviewed the contents and process to develop the scoping document titled "Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange (Modernization 1.0)." The Modernization 1.0 effort builds upon previous NCVHS work, including the Predictability Roadmap, Convergence 1.0 and 2.0, the ONC Intersection of Clinical and Administrative Data Taskforce that included NCVHS member participation, and letters to the HHS Secretary on cybersecurity and public health emergencies (PHEs). First, the Modernization 1.0 team reviewed what has changed since HIPAA, in terms of industry business models, data flows, and technology, before reviewing historic documents, testimonies, and Requests for Information (RFIs), in order to identify high-priority issues to share with the Full Committee for review.

The Modernization 1.0 document includes background information, a problem statement, and descriptions of challenges, scope, and workplan development. To date, the Standards Subcommittee, PCS Subcommittee, and Full Committee have reviewed the document and provided feedback, which has been incorporated into the document. The team has discussed the draft with the Executive Committee and will soon share it with ONC and NSG for feedback. Following this meeting, the team will draft a full workplan and present it during the April Full Committee meeting.

Review and Discussion

Participants reviewed the scoping document and provided the following feedback:

Review of Introduction

Ms. Bernstein noted that administrative simplification refers to transaction and code set standards and to privacy and security standards. She will review the document and provide feedback on how best to emphasize this point in the content. Ms. Doo noted that OCR has advised NCVHS to clearly refer to transaction standards under HIPAA administrative simplification in order to differentiate between transaction and code set standards and privacy and security standards; she will review the document and share specific feedback to update the document accordingly. Ms. Hines suggested incorporating a citation to NCVHS's *Beyond HIPAA* report within the introduction's bulleted list (specifically the point that begins with "New actors have emerged since the passage of HIPAA.")

Mr. Landen suggested updating the text to state that "25+" years have passed since the passage of HIPAA, not 25.

Participants agreed to updating "non-covered disclosure of personal health information (PHI)" to "non-covered disclosure of personal data, including personal health data and personally identifiable information (PII)" because a non-covered entity would not have access to HIPAA-covered PHI. Ms. Chrysler suggested updating the bullet point in question to the following: "Increased real world or commercially available data, including personal health information, can be accessed and used by entities that are not covered by HIPAA." Ms. Hines proposed that Ms. Chrysler and Ms. Bernstein review the document to ensure that PHI and PII (or other similar definitions) are used properly and distinctly.

Mr. James proposed updating the language of one of the bullet points to "address health equity, reduce disparities, and improve community health" instead of "address health care, disparities, and community health."

One public attendee suggested that generative AI be referred to as a technology, not a tool. Mr. James suggested discussing this distinction in a future meeting, noting that his colleagues recommend using the term "tool."

Ms. Bernstein suggested updating the final bullet point to state "this data flow is outside the safeguards of HIPAA" instead of "this data flow is outside the safeguards of HIPAA and instead is under the Federal Trade Commission (FTC) or other federal agencies."

Mr. Ferguson proposed including a citation to the information presented during the previous NCPDP and HL7 presentations in the Introduction's bulleted list, particularly the point related to ICD-11 syntax and structure.

Review of Problem Statement
Participants agreed to update the problem statement to state, "NCVHS has determined that there is a broad industry requirement to modernize the *HIPAA transaction* standards adoption framework," as well as update the remaining text of the Problem Statement accordingly.

Review of Challenges
Participants agreed to update one listed challenge to "does not *address* the need for tighter privacy and security protections," instead of "does not balance."

Mr. Ferguson suggested updating the language related to a "lack of agreed upon mechanism" to "lack of agreed upon set of criteria." The following text was updated accordingly.

Review of Project Scope
Ms. Bernstein proposed updating the first paragraph to state "other Committee products" instead of "PCD Subcommittee guidance." Dr. Watzlaf suggested incorporating a citation to the *Beyond HIPAA* report to this paragraph.

Review of Goals
Mr. Ferguson suggested updating the second bullet point under the Goals section to state "explore ways to strengthen HIPAA, *as well as protecting data currently* outside of HIPAA."

Review of Product
Currently, the language in this section states "actionable recommendations for specific federal agencies, states, localities, EHR vendors," but NCVHS only provides recommendations to the HHS Secretary, not other organizations. Thus, the language of this paragraph requires an update.

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

Dr. Mays noted that the discussions during the meeting related to PCS versus standards is important but can be beneficial. The PCS Subcommittee can identify possible issues, and the Standards Subcommittee can identify helpful solutions.

Farewell and Thank You to Rich Landen—Alix Goss, POCP

Ms. Goss presented on Mr. Landen's contribution and accomplishments during his two terms with the NCVHS Full Committee, as well as broadly throughout his career. Mr. Landen has worked throughout the health care system, beginning as a hospital orderly and expanding to work with national committees, SDOs (including X12), CAQH CORE, and various workgroups and advisory boards. Mr. Landen was appointed to the NCVHS Full Committee in September 2015 and was re-appointed in 2019. Mr. Landen also served as Co-Chair of the Standards Subcommittee with Ms. Goss and on the Executive Committee. During his time with NCVHS, he was committed to advancing the next generation of HIPAA health information approaches to reflect 21st century realities. He and Ms. Goss were integral to the development of the Predictability Roadmap and recommendations to accelerate the updating, adoption, and use of administrative standards and operating rules. In addition, several participants, including Ms. Banks and Mr. James, emphasized the positive impact of Mr. Landen's expertise and support on their careers and experience with NCVHS.

—DAY TWO—

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. As a member of the Alabama Department of Public Health, Ms. Donald recused herself from presentations and discussions regarding reproductive health and privacy. No other members stated any conflicts of interest.

Welcome Remarks/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

Fiscal Year (FY) 2022-2026 HHS Strategic Plan

Dr. Arnold began her presentation by providing an overview of the FY2022-2026 HHS Strategic Plan, which outlines five strategic goals:

1. Protect and strengthen equitable access to high quality and affordable healthcare.
2. Safeguard and improve national and global health conditions and outcomes.
3. Strengthen social well-being, equity, and economic resilience.
4. Restore trust and accelerate advancements in science and research for all.
5. Advance strategic management to build trust, transparency, and accountability.

This strategic plan helps HHS agencies focus on key HHS priorities even as new challenges arise.

HHS Highlights Within Recent Months

Dr. Arnold highlighted recent HHS updates within the past 4 months:

- On November 15, Congress passed a continuing resolution (CR) that funds most of HHS through February 1, 2024. HHS does not yet have insights into its FY24 budget.
- Within the past 4 months, the HHS Secretary issued PHE declarations for the Hawaii wildfires (declared on August 11, renewed on October 31) and Hurricane Idalia (declared for Florida on August 30 and for Georgia on September 12).
- On October 30, the Biden-Harris Administration issued Executive Order (EO) 14110: Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. This EO seeks to ensure safe, responsible, and ethical development and implementation of AI, including requirements for AI safety testing. HHS is collaborating with other federal agencies to identify and mitigate potential AI-related risks, including AI usage in health care.

COVID-19 Updates

Following the end of the COVID-19 PHE declaration on May 11, 2023, weekly COVID-19 hospitalization and mortality rates (rather than infection case rates) have become HHS's primary measures for quantifying

impacts of COVID-19. During 2023, hospitalization and mortality rates peaked in September and have since declined.

The end of the PHE declaration did not affect the Emergency Use Authorizations for many COVID-19 treatments, including antivirals and injectable inpatient treatments. The conclusion of the PHE declaration ended the requirement for insurance plans to cover testing and vaccines without patient cost-sharing. HHS continues to offer delivery of at-home antigen test kits, and all Americans became eligible to receive free test kits on November 20.

Updated COVID-19 vaccine boosters became available on September 11, 2023; as of November 30, 13.9 percent of U.S. adults have received the updated booster. This booster is monovalent and encodes antigens from the Omicron XBB1.5 variant. Eligible adults may receive this booster, as well as seasonal influenza and respiratory syncytial virus vaccines, during the same clinic or pharmacy visit. For uninsured patients, HHS announced the HHS Bridge Access Program for COVID-19 Vaccines and Treatments Program, which is a public-private partnership that provides COVID-19 vaccine access through local pharmacies and existing public health infrastructure.

HHS also has multiple initiatives to address post-acute sequalae of COVID-19 (PASC) (i.e., "long COVID"). HHS is currently establishing a Federal Advisory Committee (FAC) for long COVID that will include a wide range of disciplines, including medicine, behavioral health, human services, and patients with lived experience. In September, the Agency for Healthcare Research and Quality (AHRQ) announced nine awards to expand multidisciplinary long COVID clinicals. The National Institutes of Health (NIH) Research COVID to Enhance Recovery (RECOVER) initiative is also continuing research on PASC treatments, including clinical trials.

Mpox Update

In summer 2022, the United States experienced a major outbreak of Mpox. Because of efforts of both HHS and the lesbian, gay, bisexual, transgender, queer intersex, and asexual (LGBTQIA+) community, by summer 2023, the Mpox case rate was less than one new case per day, which is a 99 percent reduction in case rate from summer 2022.

Opioid Crisis Updates

On September 26, 2023, Secretary Becerra renewed the PHE declaration for the opioid crisis for another 90 days. To assist rural areas in responding to the opioid crisis, the Health Resources and Services Administration recently announced the distribution of more than $500 million to multiple rural opioid response programs across 47 states. These programs train emergency care providers on recognizing potential overdoses and usage of naloxone to prevent fatal overdoses. In August 2023, the Substance Abuse and Mental Health Services Administration launched a new program for improving access for overdose treatment, including expanded access to naloxone.

Health Care Coverage and Access to Care

Open enrollment season under the Patient Protection and Affordable Care Act is currently under way through January 15, 2024. To increase enrollment, CMS recently launched a $5 million effort for both in-person and virtual outreach to rural communities for health insurance enrollment. HHS is also helping rural hospitals avoid closure by enabling them to be classified as the new health care provider type of "rural health care entity."

LGBTQIA+ Research Agenda

NIH and other HHS agencies are supporting the implementation of the first federal research agenda on LGBTQIA+ equity. This research agenda includes increased federal capacity to collect data on sexual orientation, gender identity, and sex characteristics.

Supply Chain Resilience

On November 27, 2023, HHS conducted the first meeting of its Supply Chain Resilience Council. This council seeks to support advanced development of new supply chain solutions, enhance enforcement of relevant regulations, and improve supply chain visibility. The Food and Drug Administration (FDA) has made multiple efforts to address recent supply chain problems, including programs for (1) product quality and (2) quality management maturity programs. ASPE is also addressing supply chain issues that have recently created shortages of prescription and over-the-counter medications.

Changes to Race and Ethnicity Data Collection

The Office of Management and Budget (OMB) recently made recommendations regarding race and ethnicity data collection standards to HHS and the U.S. Chief Statistician. Recommendations include asking a single question that covers both race and ethnicity (rather than two questions), requiring a response to this question by default, and changing terminology.

Discussion

Mr. James asked about the timeline of changes to race and ethnicity data collection for medical coding, noting that recommended changes will require substantive implementation efforts. Ms. Arnold replied that the U.S. Chief Statistician is expected to make final recommendations in summer 2024, including for a transition schedule. The NCVHS Full Committee recommended that the U.S. Chief Statistician recognize the scope of medical coding changes but did not recommend a specific schedule or deadline. More information will be available by August 2024.

Workgroup on Timely and Strategic Action to Inform ICD-11 Policy—Jamie Ferguson, Workgroup Co-Chair; Mary Stanfill, Patrick Romano, and Vickie Mays, Workgroup Members; Kin-Wah Fung, and Carmela Couderc

Overview of ICD-11 and NCVHS Efforts—Jamie Ferguson, Kaiser Permanente

ICD-11 was adopted by WHO in 2019 and became effective on January 1, 2022. NCVHS is currently evaluating three components of ICD-11: (1) mortality reporting (e.g., cause of death), (2) morbidity coding (e.g., specific diagnoses) for health care and public health purposes, and (3) morbidity coding as a HIPAA-mandated medical code set for health care billing and payment. As a member of WHO, the United States is treaty-bound to implement ICD-11 for mortality reporting, whereas usage of ICD-11 for morbidity reporting is not required.

To evaluate ICD-11 and develop recommendations regarding ICD-11 implementation, NCVHS held an ICD-11 expert roundtable meeting in August 2019 to discuss relevant issues and concerns regarding both mortality and morbidity reporting. In November 2019, NCVHS recommended that HHS (1) evaluate the impacts of different approaches for implementing ICD-11 for mortality and morbidity classification and (2) provide timely leadership on strategic outreach and communications to the health care industry regarding ICD-11 implementation. However, the COVID-19 pandemic delayed the evaluation of ICD-11. To restart

this process, NCVHS sent a recommendation letter to HHS in September 2021 with similar recommendations to the 2019 letter.

NCVHS's goal regarding ICD-11 is to offer recommendations to inform development of sound U.S. policy for implementing ICD-11 as a HIPAA code set. To achieve this goal, the NCVHS has four objectives:

1. Avoid a repeat of the protracted and costly U.S. transition from ICD-9 to ICD-10 by identifying lessons learned from the ICD-10 planning process and transition, as well as how implementation of ICD-11 will differ from that of ICD-10.
2. Conduct research to inform a relatively smooth transition from ICD-10-CM to ICD-11 for morbidity coding.
3. Identify efforts (e.g., research, new stem codes, post-coordination strategies) to avoid the need for a full clinical modification (CM).
4. Identify key topics and messages for the U.S. health care industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

On December 7, 2022, NCVHS established the ICD-11 Workgroup, which now includes 17 members from eight different agencies outside of NCVHS. In spring 2023, NCVHS completed an environmental scan of published literature on ICD-11 to identify research gaps. On June 13, 2023, the ICD-11 Workgroup issued an RFI regarding ICD-11 implementation with a 30-day response period.

On August 3, 2023, NCVHS conducted an expert roundtable meeting to gather key stakeholder inputs on ICD-11 implementation. This meeting revealed significant variation between stakeholder understanding of relevant ICD-11 concepts, including post-coordination and extension codes. Key themes from this meeting included the following:

- ICD-11 presents opportunities for modernization, automation, and reduction of administrative burden.
- Coordinated governance and funding are needed to ensure effective implementation.
- ICD-11 maintenance process—both at WHO and within the United States—must be well understood and managed to ensure U.S. usage of ICD-11.
- More ICD-11 content analyses are needed to assess potential implementation approaches.
- Stakeholder understanding of technical implementation costs is lacking.
- The role of ICD-11 in clinical documentation use cases, as well as other new use cases, should be analyzed more comprehensively.
- Education and workforce challenges and changes needed for ICD-11 could be profound.

Following the expert roundtable meeting, the ICD-11 Workgroup developed a Phase I Findings report, which incorporated insights from the roundtable meeting. NCVHS also issued a second ICD-11 RFI with a 90-day response period to gather additional stakeholder inputs. This second RFI seeks additional stakeholder inputs on ICD-11 content requirements; opportunities for reducing administrative and coding burden; ICD-11 governance requirements; and impacts of ICD-11 implementation on other standards (e.g., Systemized Nomenclature of Medicine – Clinical Terms [SNOMED-CT]), the health care workforce, and resource allocation.

A Practical Strategy to Use ICD-11 for Morbidity Coding in the United States Without a Clinical Modification—Kin-Wah Fung, NIH, NLM

Study Design

Dr. Fung's team tested the coverage (defined in this study as matching an ICD-11 stem code, foundation entity, and/or post-coordination cluster) between ICD-10-CM and ICD-11 using two sampling strategies: (1) sampling a set of 909 commonly used codes across all ICD-10-CM chapters (i.e., horizontal sampling) and (2) examining all 816 codes within a single chapter (i.e., vertical sampling). Mapping for ICD-11 was tested using a stepwise approach: use existing ICD-11 codes (Step 1); use additional ICD-11 foundation entities (Step 2); apply post-coordination with existing ICD-11 extension codes (Step 3); apply post-coordination with new U.S.-specific extension codes (Step 4); and create new U.S.-specific stem codes (Step 5).

Mapping Results

Across both samples (vertical and horizontal), 35.2 percent of sample codes are covered by existing ICD-11 stem codes, 11.3 percent by foundation entities, 42.9 percent by post-coordination using only existing extension codes, and 7.1 percent by post-coordination that includes a new extension code. Only 3.5 percent of the horizontal sample codes require a new ICD-11 stem code.

Conclusions

These results suggest that the vast majority (greater than 90 percent) of existing ICD-10-CM codes can be mapped to ICD-11 using the stepwise approach described above. Notably, this approach requires post-coordination, which has not been used previously for ICD coding. Implementation of post-coordination coding approaches will require changes to coding systems and coder education. Post-coordination approaches must also be compatible with other standards (e.g., FHIR).

Coding guidelines and residual categories must also be harmonized, including relevant inclusion and exclusion criteria. Dr. Fung provided an example of conflicting codes for fecal impaction: Under ICD-11, the impaction code is grouped under constipation-related codes; however, under ICD-10-CM, impaction is explicitly *excluded* from constipation-related codes.

Dr. Fung concluded his presentation by stressing the benefits of avoiding a CM. Avoiding a CM can provide multiple benefits, including the following:

- Avoids costs and delays associated with creation and maintenance of a CM.
- Enables earlier usage of updated ICD coding from WHO.
- Avoids potential differences in coding and incompatibilities between CM and ICD-11.
- Enables the United States to leverage ability of ICD-11 to align with other medical terminologies (SNOMED-CT) and support automated coding.

ICD-11 Governance and Maintenance—Mary Stanfill, American Health Information Management Association (AHIMA)

The United States has inputs into ICD-11 governance and maintenance through the WHO Family of International Classifications (WHO-FIC), which is a network of WHO Collaborating Centres, nongovernmental organizations, and experts from around the world that support ICD-11 governance and maintenance. Multiple U.S. experts participate in various committees within WHO-FIC, but greater coordination among U.S. representatives is needed to provide more consistent inputs on ICD-11 governance.

Currently, any WHO-FIC user can submit a proposal for changes to ICD-11 through the WHO-FIC Maintenance Platform. Users can also use this site to view proposals from other users. Proposed changes can include new stem codes, changes to existing codes, new post-coordination rules, and changes to code hierarchies. Proposed changes are reviewed by relevant WHO-FIC committees and reference groups (depending on the nature of the change proposed) based on three overarching criteria: scientific validity, statistical validity, and existence of relevant use case(s).

The timing of updates—including approved changes—depends on whether changes impact the statistical continuity with previous versions of ICD-11. Changes that impact this continuity (i.e., major changes) are released every 5 years, whereas changes that do not impact continuity (i.e., minor changes) are released annually.

A key priority for WHO-FIC in 2024 is optimizing the ICD-11 maintenance process, including country-specific linearizations and simplification of the proposal review process. WHO-FIC also seeks to better leverage technical knowledge within WHO Collaborating Centres for maintenance and updates.

Quality and Safety Use Case for ICD-11—Patrick Romano, Independent Consultant

ICD-11 has multiple relevant quality and safety use cases, including the following:

- Certification and reporting of causes of death
- Morbidity coding and reporting
- Assessing and monitoring the safety, efficacy, and quality of care
- Data for registries (e.g., cancer registries)
- Tracking antimicrobial resistance
- Providing data for clinical trials and epidemiological studies

ICD-11 has multiple features that support quality and safety use cases. The use of clustering of stem codes and extension codes expressed relationships (e.g., cause and effect) among diagnoses. The underlying foundation and semantic knowledge base provides additional information on quality and safety. ICD-11 also includes robust coding tools with the potential for automated coding from free text in EHRs, which often contain information relevant to quality and safety.

ICD-11 also includes a three-part model for capturing health care–related adverse events. The coding structure includes three components: (1) harm (e.g., pain in specific joint), (2) cause (e.g., orthopedic device causing this pain), and (3) mode of harm (e.g., dislodgement of orthopedic device). In ICD-10-CM, these three components would be encoded using separate codes, whereas under ICD-11, the cause and mode are extension codes attached to the stem code representing harm.

This three-part model was recently tested by Forster et al. (2017) to assess its ability to classify 45 representative patient safety cases. Harm was classifiable in 31 of 45 cases (69 percent). Of these, only 20 cases (44 percent) could be classified according to cause and mode. Five cases (11 percent) had no harm classified, but the cause and mode were classified.

Dr. Romano noted that his personal observations suggest that ICD-11 will create new opportunities for tracking and understanding harms that patients experience in health care. Furthermore, ICD-11 is defined for compatibility with AHRQ's Common Formats framework for describing patient safety events.

Health Information Technology – Interoperability Considerations—Carmela Couderc, ONC

Ms. Couderc began her presentation with an overview of ONC's role in HIT efforts. ONC acts as a resource to the entire health system to support the adoption of HIT and the promotion of nationwide, standards-based health information exchange to improve health care. ONC's priorities include building the HIT digital foundation (e.g., data standards, HHS HIT Alignment Policy), improving interoperability (e.g., usage of Trusted Exchange Framework and Common Agreement), and ensuring the proper use of digital information and tools.

Ms. Couderc then described relevant HIT and interoperability requirements for ICD-11. The USCDI Core Principles determine requirements for HIT interoperability and information sharing. USCDI currently requires ICD-10-CM codes for certified HIT modules when exchanging four data elements: medication reason, referral reason, problems, and encounter diagnosis.

ONC is currently evaluating ICD-11's capabilities to meet this requirement as well as other interoperability requirements (e.g., exchange with SNOMED-CT, FHIR). ONC is also addressing other potential technical challenges regarding ICD-11 including post-coordination approaches and U.S.-specific linearizations.

Role of ICD-11 in Health Equity and Improvements to Treatment and Care for Mental, Behavioral, and Neurodevelopmental Disorders—Vickie Mays, University of California, Los Angeles

In its 2021 letter to Secretary Becerra, NCVHS noted the important role that ICD-11 coding can play in health equity and improved reporting on social determinants of health (SDOH). Previous ICD versions included data on SDOH; for example, ICD-10-CM includes Z-code domains for some relevant SDOH (e.g., "Z55.0: Illiteracy and low-level literacy"). ICD-11 differs from previous ICD versions in its approach to SDOH by emphasizing the relationship between social vulnerabilities, social risk factors, and health status, as well as more granular detail for SDOH. These improvements in linking vulnerabilities, risk factors, and health outcomes are critical for researchers, clinicians, and public health professionals to examine relationships between social and medical vulnerabilities. Previously, researchers needed to propose new Z codes under ICD-10-CM to reflect additional information on SDOH, and similar level of detail in SDOH may be needed in ICD-11.

ICD-11 also changes how mental, behavioral, and neurodevelopmental disorders are coded. Under the Diagnostic and Statistical Manual, 4th Edition (DSM-4) and ICD-10-CM, diagnoses and corresponding coding were based primarily on symptoms presented; to qualify for a diagnosis, a patient would need to present a minimum number of symptoms listed in the DSM-4. In contrast, both the DSM-5 and ICD-11 group diagnoses and corresponding codes reflect underlying etiological factors.

Next Steps for ICD-11 Workgroup—Jamie Ferguson, Kaiser Permanente

The ICD-11 Workgroup began Phase II on October 1, 2023. Based on stakeholder inputs during Phase I, the Workgroup now includes additional members with clinical and health records expertise. In November 2023, the Workgroup provided its Phase I Findings Report to the NCVHS Full Committee.

In 2024, the ICD-11 Workgroup's main focus is to provide additional information to the NCVHS Full Committee to inform and support recommendations from the Full Committee regarding ICD-11. The Workgroup will analyze responses from the second ICD-11 RFI, after which the Workgroup will report key findings from these responses to the Full Committee. The Workgroup expects RFI responses to provide additional details on additional ICD-11 use cases outside of current ICD-10-CM scope, inputs on

alternatives for an ICD-11 CM, changes needed in HIT systems, and opportunities for automation and administrative burden reduction. Depending on RFI responses and additional research, the Workgroup may also conduct additional hearings or expert roundtables related to ICD-11 adoption and implementation.

Discussion

Mr. James noted that the Environmental Protection Agency has a system for tracking when race and ethnicity codes are no longer active, and he asked whether HL7 has a similar system. Ms. Couderc replied that FHIR has a code status system that can inform users whether codes are deprecated (i.e., active but use is discouraged) or inactive.

Dr. Watzlaf thanked Dr. Romano for presenting the ICD-11 three-part model for coding quality and safety issues and asked whether ICD-10-CM has an analogous system. Dr. Romano replied that ICD-10-CM has similar codes for health care–related harms but lacks ICD-11's ability to cluster and post-coordinate these codes to clearly show relationships. ICD-11 will make these relationships much clearer compared to ICD-10-CM.

Dr. Mays asked whether WHO tracks the usage of new ICD-11 codes and determines which codes are required for every patient. Mr. Ferguson responded that the ICD-11 Workgroup will need to continue researching and discussing this question. He has previously participated in similar studies that examined use of SNOMED-CT codes, including code coordination for comorbidities, and similar studies could be performed for ICD-11. Ms. Banks added that increasing usage of value-based care models will likely provide additional data on usage of individual codes.

Ms. Banks asked about potential automation of mapping between ICD-10-CM and ICD-11. Mr. Ferguson responded that the second ICD-11 RFI includes questions on this automation, and the ICD-11 Workgroup also includes experts on automation who can provide additional inputs on this subject. Ms. Stanfill added that, compared to ICD-10-CM, ICD-11 is much easier to automate because of its inclusion of unique resource identifiers, which is why the Workgroup included a question about automating mapping in the second RFI.

Artificial Intelligence in Health Care—Grail Sipes and Travis Hoppe

On October 3, 2023, the White House Office of Science and Technology Policy convened a distinguished group of leaders from across sectors, including health care, academia, industry, and patient advocacy, for a discussion on how AI can be safely deployed to improve health outcomes for all Americans. The Biden-Harris Administration issued EO 14110 on Safe, Secure, and Trustworthy Development and Use of AI on October 30, 2023. This EO was designed to offer comprehensive guidance for the responsible utilization of AI across various sectors. Notably, the EO emphasizes integrating AI into health care, prompting the establishment of an AI Task Force within HHS to create a strategy within 1 year for regulating AI across different phases of drug development. HHS is charged with developing strategies within defined timelines to (1) develop AI-enabled technologies in health care delivery and financing; (2) ensure long-term safety and performance monitoring; (3) incorporate security standards into software development; (4) provide documentation for AI users in local settings; and (5) collaborate with government entities to promote positive AI use, with a focus on equity.

Recent AI initiatives within the federal government include the establishment of the National AI Research Resource Task Force and the release of the Department of Homeland Security's AI Use Case Inventory.

Additionally, OMB has issued a draft memorandum to provide guidance on establishing AI governance structures in federal agencies, advancing responsible AI innovation, increasing transparency, protecting federal workers, and managing risks from government uses of AI. In response to this directive, federal agencies are actively formulating guidance and policies, with a particular emphasis on thorough documentation of AI models. The National Center for Health Statistics (NCHS) initiatives include the introduction of a Semi-Automated Non-Response Detection for Surveys (SANDS) model, an open-access AI tool that helps researchers and survey administrators detect non-responses in open-ended survey text. NCHS also developed model cards, which play a crucial role in documenting AI risks, reducing biases, and providing context for the utilization of these AI systems.

In addition, CDC formulated a roadmap to advance AI initiatives, with a focus on workforce development, community of practices, and infrastructure enhancements. CDC conducted an internal assessment to explore the potential benefits and risks associated with conversational AI technologies, focusing particularly on ChatGPT. Findings showed that a significant challenge in utilizing generative AI lies in ensuring accurate and brand-appropriate responses. An effective solution to enhance accuracy is the implementation of retrieval augmented generation (RAG), which enables large language models (LLMs) to combine elements of both text generation and information retrieval to enhance the quality and relevance of generated content. The incorporation of RAG techniques into LLMs shows substantial promise, especially when applied across various industries. These techniques not only elevate the overall capabilities of generative AI but also introduce new avenues for their application, highlighting the potential for impactful advancements in natural language processing (NLP), content creation, and knowledge dissemination. Moving forward, continued research and development in this domain are expected to further refine and facilitate the widespread adoption of innovative AI approaches.

Discussion

Dr. Hodgkins expressed concern about the predominant focus on the captivating aspects of AI in health care discussions, highlighting a perceived oversight in addressing the practical application of AI to reduce administrative burdens and mitigate burnout among physicians and nurses. Dr. Hoppe noted that, despite being a relatively recent addition to government operations, generative AI is actively being explored by federal agencies, such as CDC, for streamlining administrative tasks. The AI Use Case Inventory provides insights into initial AI applications within agencies, particularly in public health and basic administrative functions such as summarizing meetings or composing emails. These initiatives signify a commitment to leveraging AI for essential internal processes. Notably, advancements in speech-to-text technology have significantly improved transcription accuracy, speaker assignment, and language diversity, thereby enhancing considerations of equity. These transcriptions can be seamlessly integrated with various records, including hospital administration records and ICD-11 codes, fostering enhanced connectivity in health care processes. Dr. Hoppe acknowledged that whereas the technical aspects of AI models have improved, challenges persist in aligning technology with practitioners' expectations and ensuring widespread adoption.

Mr. James asked whether CDC's AI roadmap aligns with the work conducted by the U.S. Department of Veterans Affairs (VA). Dr. Hoppe affirmed that CDC recognizes VA's pioneering efforts in AI and incorporates VA's strategies, extending them to address public health considerations. While acknowledging potential scope differences, CDC aligns its AI roadmap with overarching government directives, highlighting a strong partnership with VA to achieve coordinated advancements in AI within the health care system.

Mr. James asked about standardized methods for documenting the thorough due diligence done during the release of a specific AI system. Dr. Hoppe noted that model cards offer a solution for documenting due diligence in AI system releases. Model cards, which are already adopted in various industries, serve as a comprehensive tool to describe the context of use, biases, and limitations of AI models. The integration of model cards into CDC's general guidance is essential, extending beyond internally developed models to include new AI technologies. Model card integration ensures transparency and facilitates understanding of model characteristics, even in the face of personnel changes over time.

Dr. Watzlaf asked for clarification on ensuring data safety, with a specific emphasis on privacy and security within the framework of the HHS AI Task Force strategy and guidance. Ms. Sipes acknowledged that the HHS AI Task Force has not yet addressed the specific details regarding AI data safety but expressed confidence in the Task Force's ability to address this need. Dr. Hoppe added that a related workstream centers on privacy-enhancing technologies as a solution for managing disclosure and privacy risks associated with AI data. Technologies such as Privacy-Preserving Record Linkage (PPRL), homomorphic encryption, and synthetic data generation offer avenues to mitigate privacy concerns. PPRL facilitates privacy-preserving record linkage, homomorphic encryption enables secure computations on datasets, and synthetic data generation provides an alternative to using real data for training purposes. These techniques contribute significantly to addressing privacy and disclosure challenges in various use cases. Importantly, the use of synthetic data has proven valuable, enabling the creation of mock data for vendors without compromising real patient information and streamlining of processes without the need for manual data creation.

Ms. Monson asked about the approach that health care organizations, regardless of size or type, should take in navigating the rapidly evolving landscape of AI adoption in health care. Specifically, she questioned whether organizations should opt to wait or proactively engage in pilot projects, particularly when valuable health care data are involved. Dr. Hoppe suggested establishing a community of practice as an effective strategy for organizations, especially within the federal sector, to navigate the intricacies of AI adoption. These communities of practice promote collaboration between computer scientists and subject matter experts, creating valuable learning experiences for people engaged in AI development and regulations. Dr. Xu expressed concerns about the limited time and expertise of small providers to participate in communities of practice. She suggested that federal funding should be allocated to support AI research and development. Dr. Hoppe emphasized the abundance of literature on AI ethics and risks and noted that the challenge lies in ensuring that this wealth of information receives wide recognition within relevant discussions or contexts.

Dr. Hodgkins expressed support for the use of model cards and proposed broadening their scope to include details about the training data utilized for an AI tool. This expansion could aid in identifying potential areas of bias in AI. Dr. Hoppe highlighted the importance of routinely updating model cards, emphasizing their value in managing and maintaining AI models in practical applications, especially when users encounter unexpected changes in the model's performance.

Changes in State Laws on Access and Use of Reproductive Health Data—Kelly Baden

Increase in Abortion Restrictions

Following the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, abortion access has varied significantly between states, as tracked by the interactive map on the Guttmacher Institute website. Even before the *Dobbs* decision, many states in the South and Midwest passed numerous restrictions on abortion as well as bans that would go into effect once *Roe v. Wade* was

overturned (i.e., trigger bans). The *Dobbs* decision was immediately followed by additional restrictions as well as lawsuits further restricting abortion access (e.g., current legal challenge to FDA approval of mifepristone). Many states have also continued efforts to ban abortions during early pregnancy, including 6-week abortion bans. However, many of these legislative efforts have faced resistance because of gubernatorial vetoes, legal challenges, and ballot initiatives.

Many states are now seeking to ban interstate travel for abortion care. For example, Idaho passed a statute that criminalizes "abortion trafficking" (i.e., helping a minor travel out of state for an abortion). Similarly, some counties in Texas are attempting to outlaw the use of roads within that county to travel for an abortion. Restrictions on interstate travel will almost certainly elicit multiple legal challenges (e.g., under Fourteenth Amendment protections for interstate travel).

Increase in Protections for Reproductive Health Care

In response to increasing restrictions in many Republican-led states, many Democrat-led states are passing laws that expand abortion access and patient protections, including for out-of-state patients. Examples include the following:

- Washington passed the My Health My Data Act, which strengthens privacy protections beyond HIPAA, including sharing of location information, sharing of health data without patient permission, and the ability of patients to request erasure of data from their medical records.
- California allocated more than $20 million to improve the physical and digital security of reproductive health care clinics.
- Oregon created a Reproductive Health Equity Fund that has already distributed more than $5 million to increase access to abortion care in Oregon.
- Rhode Island passed a bill that enables state-matched Medicaid funds and state employee health insurance plans to cover abortion care.
- Illinois passed legislation that bans the use of data from automatic license plate readers to track out-of-state patients seeking abortion care.

Multiple states are also passing restrictions on the exchange of data and PHI regarding abortion care. Maryland and California limit the exchange and reporting of this PHI to adjudication of health care claims by payers. Maine similarly limited the reporting of abortion data for public health purposes to maternal age, location of abortion, and gestational age; no other information (e.g., other demographic data) can be reported. These restrictions limit the ability of researchers and public health professionals to gather and access data on abortion and reproductive health care.

Twenty-three states and the District of Columbia also protect reproductive health care PHI and abortion care providers. Shield law provisions vary across states and can include protections for reproductive health care, other protected health care services (e.g., gender-affirming care), providers, and bans on sharing covered PHI for out-of-state investigations and other legal proceedings (e.g., civil cases).

Increased Interstate Travel for Abortion Care

The Guttmacher Institute's Monthly Abortion Provision Study estimates the number of abortions provided within each state, and thus can provide insights into interstate travel for abortion care. The total number of abortions in the United States was increasing prior to the *Dobbs* decision and has continued to increase following the decision, even though abortion is now banned in 14 states. States with legal abortion that border states with abortion bans (e.g., Colorado, Illinois) experienced the sharpest increases in abortion

following the *Dobbs* decision. The Guttmacher Institute will soon release additional data on the number of abortions for out-of-state patients.

Additional Impacts of Abortion Restrictions

Abortion restrictions are affecting many people with pregnancies that develop complications. For example, 20 women are suing Texas, arguing that their health was put at risk because the medical exemptions of the state's law were too narrow. Some pregnant patients have developed sepsis while awaiting legal approval for emergency abortions due to obstetric emergencies. Even when states have comprehensive medical exemptions to abortion bans, many health care providers and hospitals may still be overly cautious to perform emergency abortions.

States with abortion bans are also experiencing sharp decreases in obstetrics and gynecology (OB/GYN) residency applications, medical school enrollment, and retention of OB/GYN providers. Abortion bans may also exacerbate the size and prevalence of maternal care deserts (i.e., areas with few or no maternal care providers or facilities), which may lead to increases in maternal mortality.

Birth rates have also increased in many states that ban abortion, particularly in larger states (e.g., Texas) where travel to states with legal abortion is more difficult. The increase in birth rates in these states suggests that many residents of those states may face barriers to travel to receive reproductive health care.

Potential Future Legal Challenges

Access to abortion and other reproductive health care may further change because of multiple current and future legal actions. The U.S. Supreme Court agreed to hear the case of *FDA v. Alliance for Hippocratic Medicine,* in which lower courts ruled to restrict mifepristone access. If the Supreme Court upholds the lower courts' rulings, then access to mifepristone will be restricted or banned nationwide.

Ohio and several other states recently passed ballot measures, including amendments to state constitutions, that protect abortion access. However, multiple Ohio state legislators proposed a bill that would ban Ohio courts from enforcing the recently passed amendment, effectively rendering the amendment moot. Other state legislatures have recently proposed similar legislation to block or limit ballot initiatives that protect abortion access.

Additionally, state shield laws have yet to be legally tested in a case involving PHI requests from out-of-state law enforcement. Similarly, many travel restrictions will likely be challenged under the Fifth and Fourteenth Amendments' protections regarding freedom of travel. These cases may significantly impact access to abortion care and legal protections for patients and providers.

Discussion

Multiple online attendees asked about the status of the proposed modified HIPAA Privacy Rule that protects reproductive health care data. Dr. Watzlaf replied that the rulemaking process is still under way. HHS has received more than 25,000 responses to its Notice of Proposed Rulemaking (NPRM) and is analyzing these responses. Ms. Bernstein added that the proposed Privacy Rule modification may be included in HHS's next published regulatory agenda; if so, the agenda would provide additional information on an expected timeframe for the rulemaking process. Similar to other HIPAA changes, the

rulemaking process would include a 180-day period for compliance review, so any modifications to the Privacy Rule would likely not occur until mid-2024 at the earliest.

Dr. Watzlaf asked whether the Guttmacher Institute seeks to track other types of data (e.g., contraception usage) in its Monthly Abortion Provision Study. Ms. Baden replied that the study seeks to examine changes in contraception behavior as well as additional data on abortion and contraception from family planning clinics. The Guttmacher Institute has observed increases in contraception requests in North Carolina after that state passed a 12-week abortion ban, but more data are needed to confirm this trend.

Dr. Xu asked about the sources of data for reported number of abortions in the Monthly Abortion Provision Study. Ms. Baden replied that the Guttmacher Institute gathers data directly from participating clinics, and then uses Bayesian models to estimate numbers of abortions per state.

Mr. James highlighted the increased birth rates in Texas and noted that many rural counties in that state do not have OB/GYN providers. He asked whether recent abortion bans and other legal restrictions in Texas are worsening the shortage of OB/GYNs in the state. Ms. Baden replied that the Guttmacher Institute does not yet have complete data on this topic; however, evidence suggests that OB/GYN providers are leaving Texas for other states, which is leading to the closure of maternity wards. Mr. James expressed concern that these trends may lead to sharp increases in maternal mortality and poor infant health outcomes.

Ms. Banks asked whether states are continuing to pass laws that enable citizens and organizations outside of law enforcement to sue individuals suspected of assisting abortions. Ms. Baden replied that the 2021 Texas law with these provisions has since been replicated in Oklahoma, and some proposed laws that restrict abortion travel may use similar enforcement approaches.

NCVHS Workplan Development Part II

Subcommittee on Privacy, Confidentiality, and Security—Val Watzlaf

Dr. Watzlaf sought feedback from NCVHS Full Committee members on whether reproductive health information privacy should be included under the topic of health information privacy beyond HIPAA or addressed as a distinct area of focus for the PCS Subcommittee. Dr. Hodgkins expressed a preference for separating reproductive health information from the topic of health information privacy beyond HIPAA. He emphasized the distinct nature of reproductive health information, suggesting that this topic may entail aspects both within and outside the scope of HIPAA. Ms. Bernstein asked for clarification on whether any future PCS Subcommittee efforts will fall within the scope of HIPAA. Dr. Hodgkins suggested that the decision on further work within HIPAA may depend on the Final Privacy Rule. He proposed focusing on exploring health information privacy beyond HIPAA first and deferring any additional work on reproductive health until after determination of the Final Privacy Rule. Ms. Monson noted that exploring AI adoption may fall within the scope of both HIPAA and beyond HIPAA. She proposed gathering insights from health care providers about their use of AI, examining scenarios both within and beyond the scope of HIPAA, during the next Full Committee meeting.

Initial proposed topics for the PCS Subcommittee include the following:

- Enhancing cybersecurity by strengthening the HIPAA Security Rule and exploring areas not covered in previous related recommendation letters.

- Exploring "Beyond HIPAA" issues to include a long-term course of action to develop recommendations for the use and protection of health information not covered by HIPAA, including non-covered entities.
- Evaluating the protection of public health data and considering the development of a public health counterpart to HIPAA.

Subcommittee on Standards—Tammy Banks

Ms. Banks provided an overview of past work by the Standards Subcommittee, focusing on X12 and CAQH CORE proposals, public correspondence, collaboration and presentations, and planning documents. The 2024 Standards Subcommittee workplan includes (1) discussing next steps for the X12 Set 2 proposal with the Full Committee, (2) compiling lessons learned from SDOs, and (3) compiling planning documents and drafting the timeline for the Modernization 1.0 priority topics (pending Full Committee Approval). Initial proposed topics for the Standards Subcommittee include the following:

- Identifying how NCVHS's vision, objectives, and recommendations align with ONC and HHS 2020-2025 strategic plans.
- Analyzing mature and emerging standards to understand how they can coexist to support current and future business needs and workflows.
- Reviewing the relevance of HIPAA in the current health care ecosystem.
- Exploring standards and data harmonization.

Ms. Banks asked for input on the support for these topics and suggestions for potential collaborators and partners, emphasizing the need for additional research and collaboration with ONC, CMS, and SDOs.

Discussion

Dr. Hodgkins raised concerns about reviewing the relevance of HIPAA in the current health care ecosystem, proposing a more proactive approach to recommend any necessary changes to HIPAA. Ms. Banks acknowledged recent findings from the Standards Subcommittee indicating a diminished relevance of HIPAA and gaps in its ability to address current health care needs. She clarified that the Standards Subcommittee is seeking collective input and agreement from the Full Committee on overall direction and planning, with detailed discussions on each topic to follow. Ms. Monson expressed support for each of the topics proposed by the Standard Subcommittee.

Dr. Watzlaf and Ms. Banks discussed the shared proposed topics between the PSC and the Standards Subcommittees, particularly regarding the relevance of HIPAA. They proposed forming a joint workgroup to review the current state of HIPAA and suggest updates as needed. They shared a document that outlines the anticipated partners and considerations for this joint workgroup. Dr. Watzlaf and Ms. Banks asked for feedback from the Full Committee to strengthen the planning document for this collaborative task. They noted that specific considerations related to reproductive health information and AI privacy and security would be addressed separately, and adjustments to federal agency involvement may be needed based on the scope of the joint workgroup. Mr. James suggested framing this discussion as not only a review of HIPAA's relevance but also a focus on the applicability of HIPAA. The goal of the joint workgroup should be to explore ways to enhance the adoption of standards and technologies in the current health care system. Ms. Hines stated that the PSC and Standards Subcommittees plan to identify members from across the Full Committee to collaborate on a specific workplan based on the topics discussed. This joint effort aims to refine the focus, identify key considerations, and develop a strategic plan for addressing the applicability of HIPAA and enhancing the adoption of standards and technologies in the health care system. Ms. Banks noted that the scoping document and proposed considerations for

the joint workgroup have been shared with ONC and CMS, and the Subcommittees are awaiting feedback from these agencies.

Ms. Monson raised concerns about the feasibility and prioritization of the proposed workgroup, considering existing challenges, such as staffing and time constraints. Ms. Arnold stated that staff resources are limited, which poses significant challenges to allocating additional resources for new initiatives. Ms. Banks noted that participation in the joint workgroup is optional and emphasized the need for individuals who are willing to contribute their time and efforts to participate. Mr. James suggested an alternative approach, that is, convening joint meetings of both subcommittees for collaborative discussions and work, rather than creating an entirely new initiative or workgroup. Dr. Hodgkins suggested another alternative approach whereby the two subcommittees jointly identify a subset of tasks that could be addressed in a focused workgroup.

Dr. Watzlaf asked whether separate scoping documents would be needed if the proposed topics are broken down into detailed components. Ms. Monson proposed that the PSC and Standards Subcommittees collaborate to formulate a joint recommendation about the workgroup, which would then be presented to the NCVHS executive staff for additional discussion and decision-making concerning prioritization, topics, focus, and resource management. Ms. Hines added that scoping documents help provide clarity and guidance on the overall focus of the work. These documents serve as valuable tools for project planning and effective communication, but not every topic necessitates an extensive scoping document. Ms. Banks proposed that, rather than creating multiple scoping documents, the subcommittees can formulate a comprehensive workplan. This workplan would delineate the required information, methods for obtaining this information, and resource requirements, as well as facilitate the prioritization discussion with the executive staff and ensure clarity regarding the scope of work. Dr. Watzlaf and Ms. Banks will coordinate a joint subcommittee meeting for further discussions of the workplan.

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

No public comments were received.

Closing Remarks and Adjourn—Jacki Monson, NCVHS Chair

Ms. Monson expressed gratitude for Mr. Landen's 8 years of service to NCVHS, acknowledging his significant contributions to the Committee. She also thanked Full Committee members, Subcommittee members, staff members, and invited speakers for their support and adjourned the meeting.