Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
March 30, 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-10/*

The National Committee on Vital and Health Statistics (NCVHS) convened virtually on March 30, 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, BSN, MBA
Vickie Mays, PhD, MSPH
Margaret Skurka, RHIA, CCS, FAHIMA
Debra Strickland, MS
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA
Wu Xu, PhD

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

NCVHS Staff
Maya Bernstein, JD
Lorraine Doo, MPH, CMS
Natalie Gonzalez, JD, LLM
Marietta Squire, NCHS

Others
Nate Kim, ASPE
Ryan Mintz, MS, ASPE

In addition to those who presented virtually during the meeting (listed above), 86 individuals followed the meeting online.

ACTIONS

1. The Committee unanimously approved the Subcommittee on Privacy, Confidentiality, and Security's letter and recommendations on data collection and use during a public health emergency as amended during the meeting.

2. The Committee unanimously approved the Subcommittee on Standards' letter and recommendations on modernizing aspects of HIPAA and other HIT standards to improve patient care and reduce provider burden as amended during the meeting.

The final versions of the letters and attachments will be posted on the NCVHS website.

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

Ms. Hines invited National Committee on Vital and Health Statistics (NCVHS) members and speakers to introduce themselves and state any conflicts of interest that pertain to this meeting. No attendees stated a conflict of interest.

Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members to the meeting and reviewed the meeting agenda. The primary goal of this abbreviated NCVHS Committee meeting was to review, finalize, and approve recommendation letters from the Subcommittee on Privacy, Confidentiality, and Security (PCS) and the Subcommittee on Standards. Ms. Monson noted that both Subcommittee discussions included public comment periods prior to Committee votes on the respective recommendation letters.

Subcommittee on Privacy, Confidentiality, and Security's Recommendations on Data Collection and Use During a Public Health Emergency—Melissa Goldstein and Valerie Watzlaf, Subcommittee Co-Chairs

The PCS Subcommittee has drafted a letter of recommendations for the HHS Secretary for review and approval by the full NCVHS Committee: "Data Collection and Use During a Public Health Emergency." Ms. Goldstein provided an overview of the letter, adding that the document presented during the meeting included comments and in-line edits from four Committee members.

Review of Cover Letter

Ms. Goldstein provided an overview of the cover letter, which includes the following:

- A brief description of NCVHS's history in advising Secretaries of the Department of Health and Human Services (HHS) on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules
- A description of the September 20, 2020, hearing on Privacy, Confidentiality, and Security Considerations for Data Collection and Use during a Public Health Emergency (PHE), including the hearing's purpose, preparation for the hearing, and how the discussions led to the current recommendations
- A list of the recommendations
- A summary paragraph at the end of the letter

The NCVHS Committee then reviewed the letter to adjudicate and resolve substantive comments prior to its vote on the letter. Other changes such as typographical errors and references will be incorporated after the Committee meeting.

Ms. Goldstein noted that the recommendations and corresponding justifications are described in more detail in the appendix following the cover letter. Ms. Goldstein clarified that the PCS Subcommittee retained many in-line edits made by Committee members to the previous version of the letter as tracked changes rather than accepting them to show the changes during this meeting. In-line edits, including those made during the meeting, were accepted either during or immediately following this meeting. The paragraphs below summarize changes to the cover letter in response to both comments from the most recent review by Committee members as well as issues raised during the meeting.

Per Mr. Landen's in-line edits, the reference to HHS "Secretary" was changed to "Secretaries" to reflect that NCVHS has advised multiple HHS Secretaries on Privacy and Security Rules since the passage of HIPAA.

Ms. Goldstein stated that the recommendations were rephrased to ensure parallel structure for all five recommendations, which is why the phrase "NCVHS recommends" was not added to Recommendations

3-5. Instead, the sentence above the five recommendations now states "NCVHS makes the following recommendations to HHS."

Per Ms. Chrysler's in-line edits, references to "federal, state, and local partners" were amended throughout the letter to include tribal and territorial partners. At some points in the letter, this list of partners was changed to "at all levels of the government." Ms. Goldstein also noted that the PCS Subcommittee changed references regarding public trust in data collection and usage to "trust in" or "trustworthiness of" to match other NCVHS documents and phrasing.

Mr. Landen noted inconsistent phrasing of whether recommendations address data collection and reporting, adding that some sentences described data "collection and reporting" while others only described data "reporting." The Committee agreed that the letter should address both data collection and reporting, and it removed the phase "for PHE reporting" from Recommendation 5 for consistency with the rest of the cover letter.

Regarding the last paragraph, Mr. Landen expressed concern regarding the statement that NCVHS would work with HHS to "help carry out" the recommendations, noting two potential issues. First, "help carry out" is vague and does not specify what assistance, if any, that NCVHS would provide. Second, NCVHS makes recommendations but is not an operations-oriented body, and the phrase "help carry out" implies an active role in implementing the Committee's recommendations. Ms. Goldstein responded that the intent of that phrase was to state that NCVHS would continue to provide advice and recommendations during implementation, but she agreed with Mr. Landen's concerns and removed the phrase.

Ms. Bernstein inquired whether nongovernmental organizations (NGOs) such as community-based organizations (CBOs) are included within the scope of the recommendations, including whether implementation of the recommendations may actively engage NGOs. Dr. Watzlaf replied that the Committee considers "industry" in the context of the phrase "implementation within the industry" to include NGOs. Dr. Mays concurred and noted that recommendations for implementation purposefully used broad definitions for nongovernmental partners. Other Committee members agreed with this approach.

Review of Recommendations

Ms. Goldstein explained that a new sentence was added to the beginning of the Appendix to clarify that the recommendations are based on the September 2020 hearing and consideration of reports by other organizations.

The paragraphs below summarize changes to the five recommendations and associated background text in response to both comments from the most recent review by Committee members as well as issues raised during the meeting:

Recommendation 1: Develop a governance strategy specific to PHEs in collaboration with federal, tribal, state, territorial, and local partners that increases trustworthiness in data collectors, data stewards, and those share the data collected in and after the PHE.

Mr. Landen noted that the definition of data assets in the first paragraph for Recommendation 1 was quoted verbatim from a U.S. Government Accountability Office (GAO) report and recommended adding the hyperlink to this report in the footnotes. Ms. Chrysler expressed concern that the GAO report states that data governance ensures that agencies' data assets are accessible, which raises questions about

proper data stewardship and compliance with HIPAA and other privacy and security regulations. Mr. Landen agreed with Ms. Chrysler's concerns but noted that this language was excerpted from the GAO report. The Committee decided to place the direct quote from the GAO report within quotation marks to clarify the source of that language.

Regarding paragraph 2, the Committee decided to add a footnote with a hyperlink to the Belmont Report. This report, first published in 1979, established bioethics standards for human data reporting.

Paragraph 4 describes lessons learned from other infectious disease outbreaks (e.g., HIV, Ebola virus, Zika virus) and natural disasters. The Committee broadened the reference from "federal, state, and local government" to "governmental entities" to recognize that other governmental entities may also play a role in PHE response. In the description of the importance of rapid data access to PHE response by government agencies, Mr. Landen noted that public health data also inform agencies' allocation of funding and resources to interdict or remediate PHEs. The Committee agreed with Mr. Landen's suggestion and added "decisions about allocation of resources" to this description.

During the September 2020 hearing, a panelist noted that state and local public health agencies follow different practices to collect and report public health data and that state and local agencies should proactively embed improved privacy and security practices. Both Dr. Watzlaf and Ms. Chrysler commented that the variation in privacy and security practices between states and localities often creates significant barriers and gaps for health data sharing. Some states already have embedded privacy and security practices, while other states do not have standardized practices. Dr. Watzlaf and Ms. Chrysler opined that standardizing privacy and security practices across states and localities would enable faster data sharing between federal, state, and local agencies. Ms. Goldstein responded that paragraph 5 of Recommendation 1 recounts a panelist's statement, and Recommendation 4 describes interstate variation in privacy and security practices in more detail, and therefore the Committee agreed to retain the panelist's statement. Ms. Goldstein also highlighted that NCVHS and HHS can provide legal advice to states and localities on standardizing privacy and security practices.

Recommendation 1 addresses the need to provide guidance to business associates during future PHEs. Mr. Landen asked whether the reference to business associates only applies to those that contract with HIPAA Covered Entities (CEs), and he noted that the letter did not address guidance for business associates of health organizations not covered by HIPAA. Mr. Landen noted that a broader definition of business associates as part of a national data governance strategy could more comprehensively address health data privacy and security concerns in future pandemics. Ms. Goldstein explained that paragraph 6 of Recommendation 1 specifically relates to Notifications of Enforcement Discretion (NEDs), which are sent to HIPAA CEs and their business associates. The description of potential compliance issues includes an example from early 2020: following the issue of an NED, a business associate disclosed protected health information (PHI) to public health agencies without the consent of the respective CEs. Thus, paragraph 6 seeks to clarify the respective privacy and security roles of CEs and their business associates following an NED. The Committee amended the text to more clearly specify the recommendation's applicability to business associates of HIPAA CEs, including capitalizing "Business Associates" to stress its alignment with the HIPAA definition.

Paragraph 6 also describes how HIPAA CEs contractually establish and monitor PHI usage and security by business associates, including the release of PHI to "various agencies and organizations" during a PHE. Ms. Goldstein suggested that "various agencies and organizations" should be precisely defined. Ms. Chrysler asked whether this reference applies to situations in which a CE or business associate is required to report to a government agency during a PHE. Mr. Landen recommended clarifying that "various agencies and

organizations" are those to which a CE or its business associates must report public health data. Mr. Landen added that more universal guidance on PHI reporting can reduce the burden on CEs and their business associates when they required to report health data to multiple state and local governments. Dr. Mays noted that disaggregation of data can still create issues when reporting to multiple government agencies, and this disaggregation must be considered.

In the eighth and final paragraph under Recommendation 1, the Committee agreed to change an instance of "data governing strategies" to "data governance strategies" to be consistent with the rest of the letter.

Recommendation 2: As part of this data governance strategy, develop a data stewardship responsibilities, based on fair information principles, for all entities collecting, using, and sharing data during a PHE.

The Committee discussed the first sentence, which recommends that HHS establish and employ data stewardship responsibilities for public health and clinical entities. Ms. Goldstein noted that this recommendation was originally focused on HIPAA CEs. Mr. Landen noted that data stewardship extends beyond public health and clinical organizations and highlighted electronic health record (EHR) systems as an example. Previous NCVHS recommendations regarding data stewardship covered all relevant entities rather than just HIPAA CEs; these recommendations are mentioned in the current letter to the HHS Secretary. The Committee agreed to broaden the language to cover all entities.

The Committee then discussed paragraph 2 about revisiting HIPAA de-identification standards. NCVHS recommended updates to de-identification standards in 2017, but HHS did not implement these recommendations. Mr. Landen suggested deletion of this paragraph because it addresses issues that are not necessarily related to PHEs. Ms. Goldstein and Dr. Watzlaf replied that multiple panelists from the September 2020 meeting specifically highlighted the lack of updates to de-identification standards. Panelists asserted that the overreliance on de-identification to protect PHI and lack of updates has eroded public trust in PHI protections, which could be further eroded during future waves of the COVID-19 pandemic or future PHEs. The Committee agreed to retain this paragraph about de-identification and added text to the beginning of the paragraph to clarify that the recommendation is based on panelist comments during the September 2020 hearing.

Paragraph 3 centers on potential unethical uses of public health data. The Committee agreed to clarify that HHS should focus on data use that extends beyond the original purpose(s) for which those data were collected. The paragraph provides an example: SARS-CoV-2 samples are collected to identify specific variants, yet the related sequence data include patient genomic data that could be misused for other purposes. Multiple Committee members noted that some types of public health data (e.g., mortality data) are often used for reasons other than their original purpose. Ms. Chrysler stated that when agencies collect public health data for broader purposes, they specify and publicly disclose how these data may be used. In contrast, SARS-CoV-2 variant monitoring has a narrow scope, and collection of SARS-CoV-2 samples does not disclose other potential uses of the genomic data. Therefore, the Committee agreed to not add specific recommendations regarding public health data usage for additional purposes but rather highlight this issue as a focus for HHS.

The Committee agreed with Mr. Landen's suggestion to clarify the first sentence of the last paragraph, which recommends that HHS better communicate efforts regarding data stewardship and protection to the public, by separating the sentence into two components.

Recommendation 3: Support the development of accelerated interoperable information sharing for PHEs that prioritizes privacy and security.

In the first paragraph for this recommendation, real-time data were defined as data that are continually collected, processed, analyzed, and made available for immediate usage, and near-real-time data were defined as a snapshot of recent historical data. Dr. Wu expressed concern over these definitions and noted that public health agencies often use the most recently available data, which is not the same as near-real-time or historical data. Mr. Landen contextualized these definitions by highlighting the larger goal of ensuring that relevant health data are available for public health agencies as quickly as possible. In addition to real-time and near-real-time-data, this recommendation applies to batch data that must be analyzed, validated, and harmonized prior to release to public health agencies—a process that creates minor delays between initial data collection and release. Mr. Landen proposed deleting the data definitions to focus the paragraph on the larger goal of faster data releases, and the Committee agreed to delete these definitions.

The Committee agreed to clarify language about a panelist's comments about states' lack of funding to "modernize to using new standards" for privacy and security. If the language is confirmed to not be a verbatim quote from the panelist, the Committee will modify the phrase to "modernize to accommodate new standards" following this meeting.

The Committee accepted Mr. Landen's recommendation to clarify that accelerating the development of an interoperable system for health data sharing is an investment to better prepare for future PHEs.

Recommendation 4: Review the current process for issuance of PHE waivers, Notices of Enforcement Discretion, and sub-regulatory guidance.

Ms. Bernstein revised Recommendation 4 to read "NCVHS recommends that HHS review the current process for issuance of PHE waivers, Notices of Enforcement Discretion, and sub-regulatory guidance." Ms. Hines noted that the recommendations need to be articulated with parallel structure, thus if the Committee agrees to this change, the other four recommendations must be edited accordingly.

Mr. Landen stated that the main recommendation language above should specify the goals of the review to better justify its need. He also suggested listing these desired outcomes as a new first paragraph of the explanatory test rather than incorporating them throughout the explanatory text. Dr. Watzlaf stated that much of the explanatory text following the recommendation was added by the Committee to provide context regarding laws that govern PHE waivers, NEDs, and sub-regulatory guidance during PHEs.

Ms. Love recommended changing the language of the recommendation to "review the current process *for specificity* in issuance." Mr. Landen agreed that more specificity is needed, but he noted that the explanatory text describes specific issues such as providing advance notice before waiving certain HIPAA requirements through a PHE waiver or NED. Ms. Goldstein agreed and noted that NEDs issued at the beginning of the COVID-19 pandemic provided broader exemptions than most NEDs. Thus, ensuring that sufficient privacy and security protections remain in place during the next PHE requires a thorough review of the process for issuing NEDs, including limits on the breadth of exemptions and how long such exemptions apply. Based on this discussion, the Committee agreed to add summary bullet points below the recommendation that outline the key goals and ideal outcomes for this review.

Recommendation 5: Address inequities in the collection and timely reporting of datapoints on disaggregated race, ethnicity, geography, and age in use now and in the future at the federal, tribal, state, territorial, and local levels for PHE reporting.

Based on Dr. Watzlaf's suggestion, the Committee agreed to remove the phrase "for PHE reporting" from the recommendation.

Mr. Landen asked the Committee to clarify how granular individual-level data relate to the recommendation's focus on disaggregated data. Multiple Committee members replied that individual-level data are a type of disaggregated data. Mr. Landen agreed, and the Committee left this language unchanged.

The Committee accepted Mr. Landen's grammatical edits in the paragraph that outlines efforts by the Kaiser Family Foundation to analyze COVID-19 vaccination rates by race and ethnicities, as well as Ms. Chrysler's grammatical edits in the paragraph that describes the Office of Management and Budget (OMB) standards for race and ethnicity reporting.

Mr. Landen proposed dividing a sentence that includes multiple ideas, including (1) intra- and interstate variation in policies on public health reporting by race and ethnicity; (2) monitoring how these types of variation change over time; (3) exploring solutions for improving data sharing between HIPAA-compliant and non-HIPAA-covered entities; and (4) ensuring privacy and security. The Committee agreed to divide this sentence following the meeting.

The final paragraph for Recommendation 5 describes how COVID-19 exposure notification and vaccine scheduling technologies were not as readily available to some populations for multiple potential reasons, including lack of access to broadband internet, limited English proficiency, and geographic or financial reasons. Mr. Landen noted that the last sentence of this paragraph states that "technologies have failed to ensure effective communication," but many of these communication issues can be linked to the selection of available technologies rather than limitations with the technologies themselves. The committee agreed and replaced the quoted phrase with "many of the notification and scheduling technologies were ill-suited for the capabilities of those populations."

Public Comments

Rita Torkzadeh submitted the following question through the meeting Q&A function:

> "Regarding vendors, non-EHR apps may be relevant such as those developed for COVID-19 notification and reporting. Related question and comment: may be relevant such as those developed for COVID-19 notification and reporting related question and comment. Do public health emergency innovations involving individuals and patients such as using COVID-19 notification apps and sharing test results collected at home fit in this letter and discussion focused on technology and consent?"

Ms. Goldstein responded that privacy and security concerns regarding non-EHR apps are addressed later in the letter. Furthermore, the final letter will be posted on the NCVHS website.

Action: Vote on Letter of Recommendations

The Committee unanimously approved the Subcommittee on Privacy, Confidentiality, and Security's letter and recommendations on data collection and use during a public health emergency as amended during the meeting. Once final edits are incorporated, members agreed that the Executive Subcommittee will review the final draft prior to finalizing for submission to the HHS Secretary.

Subcommittee on Standards' Recommendations to Modernize Aspects of HIPAA and Other Health Information Technology (HIT) Standards to Improve Patient Care and Achieve Provider Burden Reduction—Rich Landen and Denise Love, Subcommittee Co-Chairs

The Subcommittee on Standards has drafted a letter of recommendations for the HHS Secretary for review and approval by the full NCVHS Committee: "Recommendations to Modernize Aspects of HIPAA and Other HIT Standards to Improve Patient Care and Achieve Provider Burden Reduction." Mr. Landen provided an overview of the letter and its recommendations.

Background for Recommendations

The Subcommittee on Standards based its recommendations on comments made by industry representatives during an NCVHS Listening Session in August 2021 as part of the NCVHS Convergence 2.0 Project, which seeks to update HIPAA and other HIT standards based on technological advances since HIPAA's passage in 1996. The four recommendations address key needs that were emphasized by industry representatives and that are well known within the health care industry and the Centers for Medicare & Medicaid Services (CMS). The Subcommittee on Standards agrees with Listening Session participants that implementation of these recommendations would provide clear value to HHS and the health care industry.

Mr. Landen stressed that the recommendations address critical immediate needs rather than the full scope of needs identified by the Convergence 2.0 Project. Further, these immediate needs are compatible with consensus areas and longer-term recommendations of the Convergence 2.0 Project. The four recommendations also match the implementation approach set forth in the 2020 Intersection of Clinical and Administrative Data (ICAD) Task Force report, which recommends focusing on short-term actions to build toward more comprehensive and integrated solutions.

Review of Recommendations

Recommendation 1: Publish the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7® Fast Healthcare Interoperability Resource (FHIR)® standard to support application programming interfaces (APIs) to automate payer and provider prior authorization workflows.

Streamlining electronic prior authorization processes through updated health care data standards remains a critical need for the health care industry as well as NCVHS and the HHS Health Information Technology Advisory Committee (HITAC). The 2020 ICAD Task Force also emphasized the need to streamline prior authorizations and health care payments by implementing the HL7 FHIR standard. Testing of the FHIR standard by many large health care organizations demonstrated the readiness of this standard for large-scale implementation.

Current health care data standards are sufficient to begin nationwide efforts to improve electronic prior authorizations (ePAs) for most use cases, but as ePA implementation continues, data standards will need to be updated to account for all potential use cases. In January 2021, CMS published a final rule adopting ePAs, which was the first time a government agency recommended adopting FHIR. However, this rule applies only to certain CMS programs and not to HIPAA CEs, and CMS has since relaxed multiple aspects of the 2021 rule related to implementation of ePAs.

Mr. Landen explained that the letter provides examples of current manual processes for obtaining prior authorizations—including one derived from a public comment by the American Hospital Association

during the August 2021 Listening Session that describes the use of fax machines and contact centers with long hold times. Mr. Landen noted that moving toward an ePA system may require some health care providers to install new software, but that implementation of this system will reduce the burden on providers and eliminate the adverse effects of prior authorization delays on treatments for patients.

Recommendation 2: Adopt a standard or standards for electronic attachments as soon as possible to meet today's business needs.

Implementation of an electronic attachment standard would enable health care providers to exchange additional information that is not contained within standard health record transactions. Information in attachments can exist as codified data, free text, and images, and can include laboratory results, magnetic resonance imaging (MRI) scans, specialist reports, patient history, operative notes, and consent forms. This information can be critical for clinical decision-making, electronic prior authorization workflows, claims, and referrals.

Adopting a common standard is a prerequisite for implementing an interoperable electronic prior authorization system and for reducing the burden associated with obtaining prior authorizations. Furthermore, both HITAC and the ICAD Task Force report identified that failure to adopt a common standard and reduce prior authorization burden will adversely impact patients and health outcomes.

The health care industry is currently divided on whether modernizing health record transactions should focus more on electronic attachments (e.g., documents) or expanded databases and additional data elements. The Subcommittee on Standards believes that, although advances in database interoperability will eventually lead to a more database-driven approach, an electronic attachment standard would meet immediate needs among the health care industry and set a precedent for future HIPAA updates that address future advances in health care database interoperability. Thus, the Subcommittee recommends that HHS publish a standard on electronic attachments to meet immediate needs.

Recommendation 3: HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards.

The proposed CMS Interoperability and Prior Authorization rule in Recommendation 1, which includes adopting FHIR as the data standard, would be the first agency rule to adopt an application programming interface (API)-based standard. Unlike FHIR, the current HIPAA X12 and National Council for Prescription Drug Programs (NCPDP) standards are built around electronic data interchange (EDI) rather than APIs.

FHIR is designed to work in conjunction with the X12 278 (Health Care Services Review) standard, which is required for HIPAA CEs, as well as the X12 275 standard, which has not been mandated under HIPAA. Currently under HIPAA, CEs adopting FHIR must also adopt X12 278, and adopting both standards increases the burden on HIPAA CEs and decreases the efficiency of health data exchange for some business cases. Thus, the Subcommittee on Standards recommends that CEs should be allowed to adopt FHIR without being required to use X12 278 when business cases do not require the X12 278 standard. In addition, greater clarity is needed in federal guidance on X12 278 and X12 275 requirements, regardless of whether HHS adopts FHIR.

Mr. Landen noted that HIPAA is a broad mandate that spans many types of health care organizations, and HIPAA standards for transactions have failed to keep pace with technological advances such as improved APIs, new health care data streams, and new data standards such as FHIR. Improved flexibility in HIPAA

transaction standards would enable health care providers to capitalize on increased efficiencies and capabilities of newer technologies, which can reduce health care costs and burdens on providers.

Recommendation 4: Streamline the process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely.

Members of the health care industry have often complained that the HIPAA rulemaking process does not deliver necessary and timely updates to adopted standards, including changing rules to account for new technologies and challenges. Even when proposed rules or rule changes are listed within the HHS Unified Agenda, many of these proposed changes are not adopted, creating a large amount of uncertainty for the health care industry regarding which proposed rules may affect their organizations. Without approved rules for addressing current challenges, many health care organizations develop workarounds to HIPAA processes, adding inefficiencies to health care systems.

This recommendation urges HHS and CMS to continue to consider ways to modernize and streamline the HIPAA rulemaking process to better meet industry needs. This recommendation aligns with previously recommended steps in the NCVHS HIPAA Predictability Roadmap, 2020 ICAD Task Force Report, and the forthcoming Convergence 2.0 Project Recommendations.

Mr. Landen stated that streamlining the HIPAA rulemaking process must occur as soon as possible to enable implementation of forthcoming recommendations from the Convergence 2.0 Project, such as incorporating requirements for universal device identifiers (UDIs) and value-based purchasing (VBP) programs.

Based on Ms. Goldstein's suggestion, the Committee agreed to clarify that Recommendations 1-3 address more immediate industry needs, while Recommendation 4 outlines a longer-term planning process for future HIPAA updates. Ms. Love asked whether Recommendation 3 presents more intermediate-term needs compared to Recommendations 1 and 2. Mr. Landen replied that, although the larger need for regulatory flexibility is more of an intermediate-term need, adopting the FHIR standard requires immediate action. Ms. Hines agreed and noted that the previous Subcommittee chair had stated that Recommendation 3 should be implemented as soon as possible.

Public Comments

FHIR Standard Implementation in Smaller Organizations

Matt Reid submitted the following comment through the meeting Q&A function:

> "Standards might have been tested by large health systems but not small medical practices or solo clinics, also not by the EHR vendors that supply health IT to medical specialties. There is a massive gap between the resourcing capabilities of independent medical practices and large health systems. Testing must occur within and among small rural solo medical practices.
>
> Second, the statement about testing large organizations is sufficient does not align with the HITAC Electronic Prior Authorization Task Force report to ONC that states 'testing is crucial especially across physician practices of all sizes and specialties to make sure the technology functions well across practice setting and in production.'"

Mr. Landen responded to this comment by noting that, although testing of FHIR was primarily performed by the HITAC Electronic Prior Authorization Task Force, the Subcommittee consulted with this task force when formulating its recommendations. Although FHIR testing occurred primarily in larger health care organizations, smaller organizations, EHR vendors, and other IT developers were included.

The Subcommittee concluded that FHIR meets the criteria for CMS to begin the rulemaking process to update data standards, which will solicit public comments through the *Federal Register*. The CMS rule promulgation system includes a period between publication of the final rule and when that rule goes into effect. As a result, smaller health care entities will have multiple opportunities to further express their concerns regarding FHIR and other new data standards.

Amendments to the HIPAA Direct Data Entry (DDE) Exemption

Amber Thomas provided a comment through the Q&A function:

> "We appreciate the committee's recommendations as it relates to prior authorization and health care attachment standards in part because of the challenges with payer portals to conduct this task. Did the committee evaluate based on January's committee meeting whether to take up a recommendation specific to amending the direct data entry (DDE) exemption, i.e., payer web portals, to be more user friendly and less burdensome to providers?
>
> While the recommendations set forth in this letter are helpful in reducing provider burden, not addressing payer portals simultaneously is like mopping the floor when the sink is overflowing. Thank you for the continued dedication to this important work."

Mr. Landen replied that the Subcommittee on Standards considered amending the DDE exemption as urgent as regulatory changes for electronic prior authorizations, which is why the DDE exemption was not included in this letter. However, the Subcommittee will likely propose a recommendation to amend the DDE exemption during the summer 2022 NCVHS meeting as part of the larger framework to update HIPAA regulatory standards.

National Council for Prescription Drug Programs (NCPDP) Comments

Margaret Weiker, Vice President of Standards Development for NCPDP, submitted the following oral comments:

> "In Recommendation 1, I am assuming you all are referring to medical prior authorizations and not pharmacy prior authorizations. I do not know if you need to perhaps clarify that that you are just referring to medical prior authorizations.
>
> Recommendation 3. I want to ensure it does not preclude the use of NCPDP's standards that maybe used as an API as Rich mentioned during his PowerPoint presentation. NCPDP is in the process of migrating its telecommunication standard format from an EDI format into a JSON format, which obviously can be used for API. I just want to ensure that Recommendation 3 does not preclude that NCPDP could use that recommendation.
>
> Recommendation 4. I wholeheartedly support, as I can imagine you all know that. I have been one of those people complaining about this process for several years now. And just remind the committee that NCPDP started in August of 2017 to have our standards updated under HIPAA. It is now March

> 2022, and we have no NPRM. In the unified agenda, the date has been changed three times and still no NPRM. I do not know if perhaps you would want to use that as an example or even perhaps a recommendation number five would be to issue the NPRM for the pharmacy standards that have been recommended by this committee.
>
> Thank you for the opportunity to comment."

In response to Ms. Weiker's question regarding Recommendation 1, Mr. Landen clarified that the January 2021 CMS rule on electronic prior authorizations specifically addressed medical prior authorizations. Regarding Ms. Weiker's concern that Recommendation 3 may preclude the use of other API-capable formats such as JavaScript Object Notification (JSON) formatting, Mr. Landen replied that Recommendation 3 focuses on the larger transition to API-capable formats rather than solely on FHIR, so JSON and similar formats would not be precluded.

Recommendations for an Electronic Attachment Standard

Kathy Sykes submitted the following question through the Q&A function:

> "Is there an attachment standard recommendation?"

Mr. Landen noted that NCVHS has previous made recommendations regarding electronic attachment standards. At this time, NCVHS is only recommending that such standards should be adopted, with the decision of which specific standard to adopt lying with CMS.

Additional Public Comments

Alix Goss submitted the following comment through the Q&A function:

> "We need Recommendation 3 to get underway."

Lisa McKeen submitted the following comment through the Q&A function:

> "The attachments in the X123 275 would be greatly helpful for clearinghouse, et cetera. [sic]"

Mike Denison, Senior Director, Regulatory and Standards Engagement at Change Healthcare submitted the following public comment by email:

> "As a technology enabler and solution provider, Change Healthcare supports X12, HL7, HL7 FHIR, and NCPDP healthcare standards as well as other industry standards such as JSON and OAuth (for example). It should be recognized that X12, HL7, and NCPDP healthcare standards can and have been internet API enabled and in production use today in a similar manner to the HL7 FHIR IGs and API specification.
>
> I applaud the subcommittees work and support all four recommendations in the NCVHS letter and continue to be supportive of *all* healthcare standards that enable systematic workflow automation based on our customer needs and preferences."

Action: Vote on Letter of Recommendations

The Committee unanimously approved the Subcommittee on Standards' letter and recommendations on modernizing aspects of HIPAA and other HIT standards to improve patient care and reduce provider burden as amended in the meeting.

Next Steps & Adjourn—Ms. Monson, Chair

Ms. Monson thanked Subcommittee staff members and the NCVHS team for their support. Ms. Monson especially thanked Natalie Gonzales for her multi-year support in developing the PCS Subcommittee's recommendation letter and noted that this meeting was Ms. Gonzales' final meeting as an NCVHS member. Ms. Monson then adjourned the meeting just after 2pm eastern.

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

Jacki Monson, JD, Chair
National Committee on Vital and Health Statistics

September 6, 2022
Date