Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
June 14, 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-13/

The National Committee on Vital and Health Statistics (NCVHS) was convened virtually on June 14, 2023. The meeting was open to the public. Present:

Committee Members
Jacki Monson, JD, Chair, Sutter Health
Tammy Banks, MBA, FACMPE
Denise Chrysler, JD, University of Michigan
Catherine Donald, MBA, Alabama Department of Public Health
James Ferguson, Kaiser Permanente
Melissa Goldstein, JD, GWU
Michael Hodgkins, MD, MPH
Richard Landen, MPH, MBA
Vickie Mays, PhD, MSPH, UCLA
Margaret Skurka, RHIA, CCS, FAHIMA, IU
Debra Strickland, MS, Conduent
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA, UPitt
Wu Xu, PhD, University of Utah

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

NCVHS Staff
Maya Bernstein, JD, ASPE/OSDP
Lorraine Doo, MPH, CMS
Marietta Squire, NCHS

Others
Grace Singson, PharmD, MS, ASPE

In addition to those individuals who presented virtually during the meeting (listed above), 166 people followed the meeting online.

ACTIONS

1. The Committee voted to approve the two draft recommendation letters, with minor refinements related to wordsmithing and formatting, regarding:
    - proposed Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) operating rules and
    - proposed X12 Version 008020 implementation guides (IGs) for specified Health Insurance Portability and Accountability Act (HIPAA) transactions.

    The final versions of these letters containing these recommendations will be posted on the National Committee on Vital and Health Statistics (NCVHS) website.
2. The Committee voted to approve the draft comment letter, with minor refinements related to wordsmithing and formatting, in response to the Notice of Proposed Rulemaking (NPRM) on reproductive health care privacy.

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

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

Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members to the meeting and reviewed the meeting agenda, which focused on NCVHS recommendations and comments on three topics: (1) the proposed CAQH CORE operating rules; (2) the proposed adoption of X12 Version 008020 update for specified HIPAA transactions; and (3) the NPRM regarding reproductive health care privacy.

Review of Three Letters for Discussion and Action

Ms. Banks reviewed NCVHS's role in requests for new and updated operating rules related to HIPAA standards from Operating Rule Authoring Entities, including designated standards maintenance organizations such as X12, Health Level 7 (HL7), and National Council for Prescription Drug Programs (NCPDP). NCVHS obtains industry and public inputs on new and updated operating rules, determines whether these new and updated rules meet the requirements of HIPAA administrative simplification, and makes recommendations on these rules to the Secretary of the Department of Health and Human Services (HHS).

Recommendations on Updated and New CAQH CORE Operating Rules to Support Adopted HIPAA Standards—Tammy Banks and Rich Landen, Co-Chairs, Subcommittee on Standards

Ms. Banks provided an overview of the Full Committee's recommendations letter regarding the proposed CAQH CORE operating rules. CAQH CORE has proposed updates to four current rules: (1) Eligibility & Benefits (270/271) Data Content Rule, (2) Claim Status (276/277) Infrastructure Rule, (3) Payment & Remittance Advice (835) Infrastructure Rule, and (4) Eligibility & Benefits (270/271) Infrastructure Rule.

CAQH CORE has also proposed six additional operating rules: (1) Connectivity Rule vC4.0.0 (to replace existing connectivity requirements and add new requirements to all operating rules), (2) Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule, (3) Attachments Prior Authorization (PA) Infrastructure Rule, (4) Attachments PA Data Content Rule, (5) Attachments Health Care Claims Infrastructure Rule, and (6) Attachments Health Care Claims Data Content Rule.

NCVHS gathered information and stakeholder perspectives on the proposed operating rules by (1) hearing presentations from CAQH CORE to the Subcommittee on Standards in August 2022; (2) collaborating with the Workgroup for Electronic Data Interchange (WEDI) that surveyed its stakeholders on the proposed operating rules; (3) consulting with the Centers for Medicare & Medicaid Services (CMS) Office of Burden Reduction and Health Informatics, CMS National Standards Group, and HHS Office of the National Coordinator for Health Information Technology; (4) holding an NCVHS hearing on January 19, 2023, to hear stakeholder perspectives; and (5) reviewing responses from its Request for Comments (RFC) published in 2022.

Based on these inputs, NCVHS makes five recommendations:

1. Conduct rulemaking to adopt the infrastructure and data content updates to the Eligibility & Benefits and Claim Status operating rules.
2. Conduct rulemaking to adopt the new patient attribution content in the Eligibility & Benefits operating rule.
3. Conduct rulemaking to incorporate the updates to the CAQH CORE Connectivity Rule as it applies to the adopted X12 HIPAA standards in the adopted operating rules.
4. Not adopt the CAQH CORE new proposed operating rules for attachment standards for claims and prior authorization.
5. Exclude the CORE Certification requirement language included in proposed operating rules. CORE Certification is not a requirement of HIPAA.

Appendix A of NCVHS's recommendation letter includes detailed rationale for NCVHS's recommendations, as well as selected excerpts from RFC responses and oral testimonies.

Recommendations on Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 8020)—Tammy Banks and Rich Landen, Co-chairs, Subcommittee on Standards

In 2022, X12 requested that NCVHS review four updated transaction implementation guides (IGs): three under Claims (837)–008020X323 Health Care Claim: Professional, 008020X324 Health Care Claim: Institutional, and 008020X325 Health Care Claim: Dental, as well as one under Payment/Remittance Advice (835)–008020X322 Health Care Claim Payment/Advice. For these four IGs, X12 requested that the required version be upgraded from Version 005010 to Version 008020, whereas requirements for other currently mandated IGs would remain as Version 005010.

X12 also requested that HHS use Version 008020 of the four IGs listed above for the initial steps of the Federal Rulemaking Process. Furthermore, when HHS issues an NPRM regarding the updated IGs, X12 would identify the most recently published version of each IG and provide a list of substantive changes and added functionalities in the newest versions compared to Version 008020. However, NCVHS found that HHS cannot fulfill these requests because CMS must comply with Administrative Procedure Act requirements, which do not allow the process requested by X12.

To gather information and stakeholder perspectives, NCVHS conducted multiple steps, including an X12 presentation to the Subcommittee on Standards, stakeholder survey by WEDI, consultation with partner agencies, and comprehensive review of RFC responses. After reviewing these inputs and further additional information, the Subcommittee on Standards noted a lack of industry consensus on the need for the proposed changes and updates in Version 008020 and insufficient cost and value data to assess potential impacts of implementation. In addition, the Subcommittee found insufficient data to confirm backwards,

or cross-compatibility of Version 008020 for the four transactions with Version 005010 for the other currently mandated transactions.

Based on these findings, NCVHS drafted a letter recommending that HHS not adopt the Version 008020 update at this time for the four specified transactions due to backward compatibility concerns. Mandating the proposed changes to just these four transactions, as opposed to all transactions, would result in multiple versions of HIPAA transactions, including potential usage of Versions 006020 and 008030 for some transactions, e.g., PA attachments, claim status request and response. In addition, Version 008020 cannot accommodate two impending updates to HIPAA code sets based on the International Classification of Diseases, 11th Revision (ICD-11) and potential modifications to the National Drug Code (NDC).

In response to stakeholder inputs regarding upgrades to Version 0080202, NCVHS identified two additional areas related to X12 Version 005010. First, NCVHS encourages HHS to develop and publish additional guidance and education about the use of virtual credit cards (VCCs) as well as increased enforcement efforts for inappropriate VCC usage. Second, NCVHS recommends that the U.S. Food and Drug Administration (FDA) review stakeholder comments and testimony regarding the collection of unique device identifier (UDI) codes in health care claims.

Comments on NPRM "HIPAA Privacy Rule to Support Reproductive Health Care Privacy"— Val Watzlaf and Melissa Goldstein, Co-chairs, Subcommittee on Privacy, Confidentiality and Security

On April 12, 2023, HHS issued an NPRM to modify HIPAA in order to strengthen reproductive health care privacy. The proposed rule would modify the regulations of Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") under HIPAA and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). HHS specifically invited the NCVHS Committee to review the proposed rule and provide comments to the Department, citing the Committee's past work regarding sensitive health information in the proposed rule.

Dr. Watzlaf reviewed the NPRM and presented the following considerations in the NPRM comment letter identified by the Privacy, Confidentiality, and Security (PCS) Subcommittee:

- Remove the distinction between lawful and unlawful reproductive health care in the proposed Privacy Rule.
- Require attestations for all protected health information (PHI) requests rather than limiting attestation requirements to requests for data related to reproductive health care. If the attestation requirement remains limited to reproductive health care, then clearly define types of care "related to reproductive health care."
- Implement appropriate and clear language in the examples of reproductive health care.
- Use all available mechanisms available to HHS to protect patient privacy for reproductive health care. Examples of relevant mechanisms include contract requirements for physicians accepting Medicare, HHS grant requirements for health care grant, and Federal Trade Commission (FTC) oversight of data privacy within digital health applications.
- Clarify the definition of "public health" and "deidentified data" in terms of the public health exception to the attestation requirement.
- Add a statement within attestations by which recipients of PHI pledge not to redisclose the information to another party for any of the prohibited purposes named in the attestation.

- Update the Notice of Privacy Practices, including the use of terminology that complies with Federal Plain Language guidelines.
- Address other relevant areas of Health Information Exchange such as telehealth and applicability of interoperability requirements.

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

Below are brief summaries of the public comments. Full transcripts of the comments can be found in the meeting transcript posted on the NCVHS website.

Alex Shteynshlyuger, Director of Urology, New York Urologist Specialists

Alex Shteynshlyuger commented on the rules for filing complaints of violations of the CAQH CORE rules, the need for a more formalized approach to resolving complaints about compliance reviews, and lack of an enforcement mechanism for standards adoption.

Erin Weber, Vice President, CAQH CORE

Erin Weber requested removal of the sentence in the draft letter: "Operating rules should only be developed and/or adopted for standards which need them." The Patient Protection and Affordable Care Act (ACA) defines operating rules as the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specification. Therefore, additional operating rules cannot be developed if they are already addressed by the standards and their implementation guides. A broad statement on standards that have not been fully implemented or reviewed by industry could restrict future need for operating rules as standards evolve and may need to interact.

This request was echoed by later public comments by

- ***Heather McComas***, Director of Administrative Simplification Initiatives, American Medical Association (AMA)
- ***Rebekah Fiehn***, Director for Coding and Dental Data Exchange, American Dental Association
- ***Terrence Cunningham***, Director of Administrative Simplification Policy, American Hospital Association

Alix Goss, Chair of Policy Advisory Committee, HL7

Alix Goss commented that she does not share the concern about the sentence in the draft letter that standards such as those created by HL7 and NCPDP have their own operating rules embedded within their own implementation specifications or implementation guides. She believes that the sentence reflects testimony and the longstanding positioning of HL7 and NCPDP as encompassing all of the rules needed by the community, and does not preclude collaboration between CORE and NCPDP on innovative work related to medical pharmacy. She suggested retention of the sentence, with clarifying language that collaboration between CORE and standard-setting organizations to meet industry need is not precluded.

Lisa McKeen, HIPAA Privacy and Security Officer, General Dynamics Information Technology (GDIT), affirmed that this sentence, as written, implies that other entities are precluded from participating in collaborations, and agreed with Ms. Goss's suggestion to add clarifying language.

Denise Love, Committee Member, NCVHS

Ms. Love affirmed that the Subcommittee conducted intense due diligence of these proposals in collaboration with industry and CMS. These proposals highlighted many issues that the field can address to improve the standards process going forward.

Niraj Acharya, Independent Practitioner, Kings County, Brooklyn, New York

As a solo practitioner in an inner-city area, Dr. Acharya expressed several concerns about the effects that a requirement to accept virtual credit cards could have on small practices.

Stanley Nachimson, Independent Consultant

Mr. Nachimson expressed concern about the recommendation to not adopt X12 Version 008020 IGs for specified transactions. He commented that some of the rationale for this recommendation seems to be somewhat off in the future and that X12 is being held to a higher standard than other standards that have been recommended in proposed rules. He stated a preference for the Committee's recommendations to state the concerns with these recommendations and the standards and that CMS should consider whether it can meet ICD-11 or whether backwards compatibility exists, to keep the process of updating standards moving forward.

Donna Campbell, Provider Portal Connectivity Product Owner, Health Care Service Corporation

Donna Campbell requested reconsideration of the decision to not support the operating rules regarding the attachments. Rather, trading partners that are already exchanging the X12 275 should be required to adhere to the requirements for the attachment operating rules. This approach would allow for standardization among the trading partners that already support this transaction and moves the field closer to ensuring use and exchange that align with the intention of the TR3s and operating rules.

Diana Fuller, Electronic Data Interchange (EDI)/HIPAA Analyst, State of Michigan Medicaid

Diana Fuller expressed support for NCVHS's recommendation to not adopt X12 Version 008020 for specific transactions. The State of Michigan would only support moving the industry to one standard for the whole suite of transactions. Providers have one EHR system. When multiple standards are allowed, the costs of implementation and maintenance are borne by the clearinghouses, vendors, and payers and any existing issues only multiply.

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

Recommendations on Updated and New CAQH CORE Operating Rules to Support Adopted HIPAA Standards

Discussion

Ms. Banks and Mr. Landen responded to public comments regarding the recommendations letter. Regarding adoption of the attachments operating rules for trading partners already using X12 275 transactions, Ms. Banks noted that the ACA does not allow adoption of operating rules for non-HIPAA standards. Instead, NCVHS recommends that the adoption of the attachments rule be revisited after CMS publication of a Final Rule that names aa HIPAA health care attachments transaction standard.

Regarding the letter's sentence that states that "operating rules should only be developed and/or adopted for standards which need them," Ms. Banks noted this language was based on the ACA and was not intended to preclude collaboration between entities to develop new operating rules. Mr. Landen added that this language was intended to prevent new operating rules from altering standard protocols (e.g., patient name format) and operating rules embedded within IGs established by standards development organizations (SDOs). This language is also intended to clarify the distinction between operating rules and IGs adopted as standards under HIPAA.

To avoid potential confusion and unintended consequences from the existing sentence, multiple Committee members proposed adding a sentence stating "this would not preclude collaboration among entities to develop additional operating rules if needed." Committee members initially voted to approve the additional sentence, with 10 members supporting the revision and 3 members opposing the revision.

Following this initial vote, Ms. Banks expressed concern that the additional sentence may potentially conflict with ACA provisions and would require further review. Mr. Landen expressed additional concern that the added sentence may be misinterpreted as allowing entities that are not HHS-designated operating rule authoring entities to develop operating rules under HIPAA. Based on these concerns, Committee members voted not to approve the *amended* recommendations letter, with 1 member voting for approval and 12 members voting against approval.

Action: Vote on Final Recommendations Letter
Committee members voted to approve the original recommendations letter (i.e., without the additional sentence), with 11 members voting to approve, 1 member voting against approval, and 1 member abstaining.

Recommendation on Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020)

Action: Vote on Final Recommendation
Committee members voted unanimously to approve the recommendation letter without any substantive changes.

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

Committee Comments on NPRM "HIPAA Privacy Rule to Support Reproductive Health Care Privacy"

To guide discussion regarding the NPRM, the Committee reviewed a document that described key themes for consideration regarding the NPRM and the draft of NCVHS's comments letter. Committee members agreed with the need for this NPRM following the U.S. Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* and patient concerns about medical privacy. Dr. Mays noted that concerns about patient privacy impact stakeholders beyond patients and providers, including pharmacists, people who transport patients to medical care, and third parties who facilitate care. Concerns about patient privacy and potential criminal investigations against health care providers are also influencing where many medical residents and physicians choose to practice medicine.

Attestations
The approach of the proposed modification to the HIPAA Privacy Rule that requires entities involved in criminal, civil, and administrative investigations (e.g., law enforcement agencies) seeking PHI related to

reproductive health care must attest that the PHI request does not violate privacy protections in the modified Privacy Rule.

Committee members discussed whether NCVHS should recommend requiring attestations to all PHI requests rather than limiting this requirement to requests involving reproductive health care data. Multiple Committee members expressed concern that "reproductive health care" is not sufficiently defined in the NPRM, and parsing out which specific data and procedures qualify as reproductive health care may cause ambiguity and lack of consistency. Furthermore, the lack of clarity around what data fall under "reproductive health care" may lead to inadvertent sharing of reproductive health data as part of requests for other forms of PHI. Mr. Ferguson highlighted that data related to reproductive health care may encompass numerous different electronic medical record systems, databases, and medical specialties. As a result, requiring the attestation for all PHI requests related to criminal, civil, and administrative investigations may reduce administrative burden.

Furthermore, the proposed rule applies to data *related* to reproductive health care, which may introduce further confusion as many data types could be viewed as related to reproductive health care. For example, women of child-bearing age are routinely asked about pregnancy during primary care visits, and thus, records from these primary care visits could be viewed as related to reproductive health care. Mr. Hodgkins noted that expanding attestations to other forms of health care beyond reproductive health care would expand privacy protections for other forms of health care that are limited or prohibited by recent state laws (e.g., gender-affirming care).

Committee members agreed that the NPRM comment letter will recommend that HHS consider not distinguishing between legal and illegal reproductive health care in the state in which care was provided. Ms. Bernstein noted that the proposed Privacy Rule serves a broader purpose of restoring patient trust in health care privacy protections and ensuring patients that their data will not be used against them; thus, narrowly delineating which care is legal in the state that care is provided may undercut this broader goal.

Additional Mechanisms for Protecting Patient Privacy

Committee members agreed that the NPRM comment letter will recommend that HHS consider leveraging additional mechanisms under its authority beyond HIPAA to protect patient privacy. Additional mechanisms can include requirements for grant funding through HHS agencies (e.g., Health Resources and Services Administration) and requirements for providers accepting Medicare. Committee members discussed that multiple HHS agencies play a role in patient privacy, including FDA, Federal Trade Commission (FTC), Indian Health Service, and Centers for Disease Control and Prevention. HHS can also mandate compliance with health privacy regulations in relevant contracts funded under the 21st Century Cures Act.

Telemedicine

Committee members noted that definitions for "telehealth" can vary widely: some definitions limit telehealth to audio and video interactions between clinicians and patients, while other definitions use a broader definition of "telemedicine" that includes health-related digital applications. Because HIPAA does not cover digital applications, personal health data within those applications have been protected by FTC rather than under HIPAA. The 2020 CMS Interoperability and Patient Access Rule encourages application developers to incorporate application programming interfaces (APIs) to enable patients to download their health data and improve interoperability between health applications. However, the transmission of patient health data between applications and APIs not covered under HIPAA introduces additional PHI disclosure risks. Thus, Committee members agreed to recommend that HHS consider employing a

broader definition of "telemedicine" based on the CMS Interoperability and Patient Access Rule to cover PHI in digital health applications.

Public Health

The proposed modification to the Privacy Rule defines public health as population-level activities (e.g., communicable disease surveillance) and actions to improve public health. Furthermore, the proposed modification does not require attestations for disclosure of data for public health purposes. However, public health activities, particularly for communicable diseases, can potentially involve investigations of individuals (e.g., contact tracing) and administrative or injunctive actions if a person may endanger public health. Thus, Committee members expressed concern that the proposed modification's *population-level* public health data may hinder public health activities and recommended that HHS clarify the distinction between public health disclosures and other disclosures.

Review of Comment Letter

Ms. Bernstein continued the discussion by reviewing the Committee members' comments and edits in the draft of NCVHS's comment letter on the NPRM.

Protecting Third Parties Facilitating Reproductive Health Care

Dr. Mays stated that the current draft of the NPRM does not clearly specify protection for health care providers or any third party seeking, obtaining, providing, or facilitating care associated with reproductive health. Unlike the original HIPAA Privacy Rule, the modified Privacy Rule is intended to protect not only the patient but also the provider and third parties who may facilitate care. Ms. Bernstein emphasized that the Committee communicated in the past to HHS that medical records should not be used against patients seeking health care. However, protection of health care providers is more complex, partly because states are entitled to prosecute any case in which there is a violation of law. For instance, a state can prosecute a provider who is seen as practicing medicine that does not meet the standard of care in that state. Ms. Bernstein and Dr. Mays agreed that the term "standard of care" should be clearly defined in the draft.

Examples on Distinctions Between Legal and Illegal Care

Ms. Bernstein asked whether citing delivery hospitalizations involving preeclampsia and eclampsia is sufficient evidence to support the PCS comments on eliminating the distinction between legal and illegal health care. Dr. Watzlaf confirmed that this reference is a good example.

Standard of Care

Ms. Bernstein highlighted a comment in the draft regarding a sentence that suggests adopting a nationwide, uniform standard of care (e.g., standards developed by American College of Obstetrics and Gynecology) rather than relying on state-specific standards of care to protect health care professionals. Committee members agreed with a suggestion by Dr. Mays to add "midwives" by changing "health care professionals" to "providers" to address this comment.

Examples of Reproductive Health Care

Dr. Mays recommended providing extensive examples of care related to reproductive health care that PCS recommend for HHS to implement. Dr. Mays added that using stronger language in the letter provides more guidance regarding the recommendations provided by the Committee. Mr. Ferguson noted that HHS should use adopted information standards (ICD-10, SNOMED-CT, Logical Observation Identifiers, Names and Codes [LOINC], and RxNorm) to publish specific lists of procedures, conditions, findings, medications, tests, and other information that constitutes reproductive health care. Mr. Hodgkins stated

that using established medical coding (e.g., ICD-10 codes) to identify reproductive health care is challenging and requires a voluminous list of conditions, procedures, and medications. Mr. Ferguson acknowledged that while this may be true, this list can be automated, making it easily accessible.

Ms. Goldstein recommended preceding examples of reproductive health care with the term "including, but not limited to" in order to cover instances of reproductive health care that may not be specified in the proposed Privacy Rule.

Protection of Data Privacy by Entities Not Covered by HIPAA

Mr. Ferguson suggested including Trusted Exchange Framework and Common Agreement (TEFCA) as an example of non-HIPAA covered entities holding covered health information with enforcement of contractual terms. However, Ms. Goldstein stated that using TEFCA to protect data privacy requires more significant research and could not be accomplished soon given the time constraints. Ms. Goldstein added that TEFCA has not been implemented yet and will depend on public health use cases, which have not been fully identified. Ms. Banks recommended that the Committee tasks Mr. Ferguson to review literature on this topic and provide citations to ensure that TEFCA is consistent and enforceable within the proposed rule. Dr. Mays suggested that the Committee contextualizes TEFCA implementation as a future activity that HHS should monitor to avoid any unintended public health outcomes. Ms. Chrysler and Goldstein agreed to review this section of the draft the following day. Other Committee members agreed to the suggestion that Mr. Ferguson takes the lead on TEFCA research.

Protection of PHI in APIs

In response to a question about Fast Healthcare Interoperability Resources (FHIR) APIs, Ms. Bernstein clarified that PCS discussed that HHS should consider requiring attestations, under 45 CFR §164.512(d), (e), (f), and (g), for all requests for PHI that contain reproductive health information or are potentially related to reproductive health records.

Comment Letter Revisions

Ms. Bernstein informed Committee members that she will reconcile the changes between the two drafts of the comment letter the following day. In case of any disagreements, she will send specific paragraphs to individual Committee members for reviews. Ms. Hines noted that the goal is to finalize the comment letter on June 15 in order to meet the deadline on June 16 at 12:00 am EDT. Dr. Mays proposed that Committee members discuss any disagreements with each other to simplify the editing process. Ms. Bernstein emphasized that she represent Ms. Goldstein's comments as best as possible.

Mr. Hodgkins asked whether the Committee will review the reconciled draft again before the proposed rule is finalized. Ms. Bernstein noted that the modified Privacy Rule will be finalized in April 2024, before the end of the current presidential administration. Given the current composition of the Congress, the likelihood that the proposed Privacy Rule would be overturned is low. Ms. Bernstein also emphasized that the Committee could continue to comment on the NPRM and advise the HHS Secretary throughout the rulemaking process for the proposed modifications to the Privacy Rule. HHS is hosting panels during the NCVHS Full Committee meeting on July 19 to discuss the protection of patient privacy for reproductive health care.

Action: Vote on Final NPRM Comment Letter

Dr. Mays made a motion to approve the spirit and intent reflected in the discussion and themes of the comment letter on the NPRM (with additional non-substantive refinements related to wordsmithing and

formatting), which was seconded by Ms. Banks and Dr. Hodgkins. During the discussion of the motion, Ms. Goldstein raised concerns that she does not agree with the tone of certain points in the letter, particularly whether the letter should recommend actual changes to the proposed Privacy Rule or merely recommend that the HHS Secretary *consider* changes. Ms. Bernstein stated that she will review these points with Ms. Goldstein, Dr. Watzlaf, and Dr. Mays to ensure their agreement on the language. Ms. Hines noted that Cathy Donald is not present during this vote due to a tornado warning in her area. Ms. Hines called for a vote of NCVHS Committee members; 12 members unanimously voted in favor of approving the letter and thus the letter was approved.

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

Below are brief summaries of the public comments. Full transcripts of the comments can be found in the meeting transcript posted on the NCVHS website.

Lisa McKeen, HIPAA Privacy and Security Officer, GDIT

Ms. McKeen stated that HHS is working on data protections for digital applications, and that telehealth API applications are required to have blanket agency agreements (BAAs). Users give their own consent; unless the user gives this information to a health organizations or their physician, an HHS BAA or data use agreement (DUA) is not required. Therefore, GDIT requests that NCVHS include the following in the comment letter: "We are seeking an informed definition of what is considered 'reproductive healthcare.'" In addition, GDIT recommends that NCVHS not mention the HITECH Act.

Janice Karen, Director of Policy, Technology, and Innovation, Massachusetts Health Data Consortium

Janice Karen stated that the HHS Office of the National Coordinator for Health Information Technology (ONC) Information Blocking Rule and CMS Interoperability and Patient Access Rule addressed privacy and placed data privacy protections under the FTC for third-party applications. In addition, the FTC does not have oversight over nonprofit organizations.

Ms. Karen asked whether the Committee has discussed the impact of requiring attestation for all PHI requests on FHIR-compliant APIs—both those currently mandated by regulation that are meant to be a floor and additional exchanges optionally implemented that go beyond those minimums. NCVHS's language during this meeting suggests an intent to recommend that all requests for PHI should require an attestation; therefore, NCVHS could consider revising the language regarding FHIR-compliant APIs.

Closing Remarks and Adjourn—Ms. Monson, Chair

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

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

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Chair Date