



National Committee on Vital and Health Statistics  
Advising the HHS Secretary on National Health Information Policy

# **NCVHS Subcommittee on Privacy, Confidentiality and Security (PCS) Update**

**April 11-12, 2024**

# Building on Our Recent Work



**2019**

**2019 Health Information Privacy Beyond HIPAA: A Framework for Use and Protection**

**2022**

**Recommendations to Strengthen Cybersecurity in Healthcare**

**2023**

**Response to NPRM on HIPAA Privacy Rule to Support Reproductive Health Privacy**

**2022**

**Recommendations regarding PCS Considerations for Data Collection and Use During a PHE**

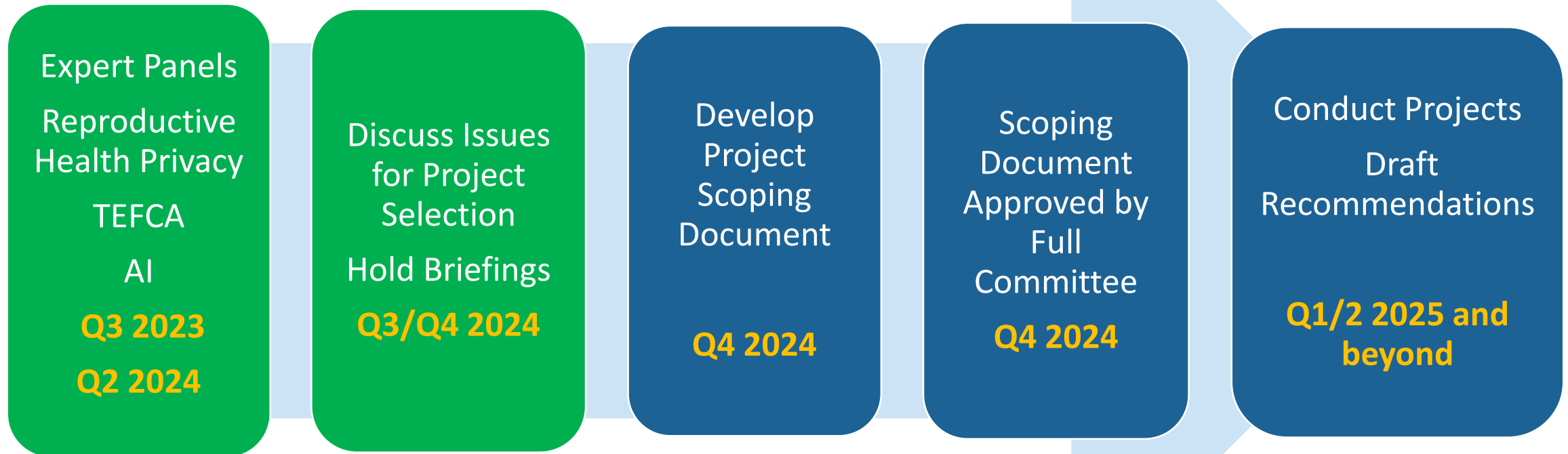
**2022**

**Environmental Scan—Ongoing and Emerging Issues in Privacy & Security in a Post COVID-19 Era**

**2023**

**Recommendations to Strengthen the Security Rule**

# Our Journey: Past, Present, Anticipated Future



# Future Focus Areas--Reproductive Health Information Privacy and Security



- NPRM released on April 12, 2023 to strengthen the Privacy Rule protections by prohibiting the use or disclosure of PHI to identify, investigate, prosecute, or sue patients, providers and others involved in the provision of legal reproductive health care, including abortion.
- Public comment period closed on June 16, 2023
- HHS received ~25,900 comments

23506 Federal Register / Vol. 88, No. 73 / Monday, April 17, 2023 / Proposed Rules

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Office of the Secretary  
45 CFR Parts 160 and 164  
RIN 0945-AA20

**HIPAA Privacy Rule To Support Reproductive Health Care Privacy**

**AGENCY:** Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.  
**ACTION:** Notice of proposed rulemaking; notice of Tribal consultation.

**SUMMARY:** The Department of Health and Human Services (HHS or “Department”) is issuing this notice of proposed rulemaking (NPRM) to solicit comment on its proposal to modify the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology

by any of the following methods. Please do not submit duplicate comments.  
To participate in the Tribal consultation meeting, you must register in advance at <https://www.zoomgov.com/meeting/register/vJltf-2hqD8jHfdtmYaUoWidy9odBZMYQ4Q>.

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov> by searching for the Docket ID number HHS-OCR-0945-AA20. Follow the instructions at <http://www.regulations.gov> for submitting electronic comments. Attachments should be in Microsoft Word or Portable Document Format (PDF).
- *Regular, Express, or Overnight Mail:* You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA and Reproductive Health Care Privacy NPRM, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue

Docket ID number HHS-OCR-0945-AA20.  
**FOR FURTHER INFORMATION CONTACT:** Lester Coffey at (202) 240-3110 or (800) 537-7697 (TDD).  
**SUPPLEMENTARY INFORMATION:** The discussion below includes an Executive Summary, a description of relevant statutory and regulatory authority and history, the justification for this proposed regulation, a section-by-section description of the proposed modifications, and a regulatory impact analysis and other required regulatory analyses. The Department solicits public comment on all aspects of the proposed rule. The Department requests that persons commenting on the provisions of the proposed rule label their discussion of any particular provision or topic with a citation to the section of the proposed rule being addressed and identify the particular request for comment being addressed, if applicable.  
I. Executive Summary  
A. Overview

<https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-to-support-reproductive-health-care-privacy>

# Key Proposed Privacy Rule Amendments



1. Prohibit using or disclosing PHI for a criminal, civil, or administrative investigation into or proceeding against any person for
  - Seeking
  - obtaining
  - providing\*
  - facilitating\*reproductive health care in certain circumstances
2. Prohibit regulated entities from using or disclosing PHI to identify any person to initiate such an investigation or proceeding (same restrictions)
3. Require a signed attestation that requests for PHI are not for a prohibited purpose
  - where PHI is *potentially related to* reproductive health care

# Proposed Attestation Requirement



- Require CE (or its BA) to obtain a signed attestation if the PHI is requested for any of the following purposes:
  - Health oversight activities
  - Judicial and administrative proceedings
  - Law enforcement purposes
  - Use by coroners or medical examiners
- Attestation may be electronic
- Attestation may not be combined with another document



- HHS specifically invited the Committee to comment and cited past work of the committee on sensitive health information.
- NCVHS Comment Letter – NPRM on HIPAA Privacy Rule to Support Reproductive Health Privacy







- HHS should consider not making a distinction between care provided that is **illegal v. legal**.
- HHS should consider prohibiting disclosures for investigations involving ***any health care***, not just reproductive health care,
  - or consider reworking the definition of “reproductive health care” to include specific, encompassing, and clear terms.



# NCVHS Comments on Attestations



- HHS should consider requiring **attestations for *all* requests for PHI**, rather than limiting the requirement to requests potentially related to reproductive health care
  - definition is so broad, in practice it would encompass all PHI, *or*
  - consider reworking the definition of “reproductive health care”
    - to include specific, encompassing, and clear terms, and
    - provide examples of diverse types of reproductive health care.
  
- HHS should consider requiring that attestations include a **pledge not to redisclose** the records to another party for any of the prohibited purposes named in the attestation

# Other NCVHS Comments



- HHS should consider clarifying uses of PHI for “public health” to ensure the privacy rule does not produce unintended consequences.
- HHS should consider addressing relationship of Privacy Rule to health information access and exchange, including in telehealth, telemedicine, medical devices, apps, wearables, interoperability, information blocking, and TEFCA.
- HHS should consider specifying plain language for the CE Notice of Privacy Practices that is clear and understandable to all patients.
- HHS should examine the definition of “de-identified data” and consider NCVHS’s 2017 recommendations on the topic.

# Extend to other healthcare entities



- Patient's phone app not used as part of a covered entity/covered practice
- Geofencing across healthcare facilities--location data--user's privacy may be at risk
- Tracking non-prescription data such as prenatal vitamins, pregnancy tests
- Data analytics to predict pregnancies
- Telehealth/Telemedicine

# Documentation and coding gaps



- Healthcare providers are not always documenting reproductive health information for fear of prosecution
- Relevant clinical codes for miscarriages and ectopic pregnancies, include the word “abortion” in the code description---physicians do not include these codes for fear of prosecution or litigation.

# Professional repercussions



- Signed statements delays treatment for potentially life-threatening conditions; erodes trust in the profession of OB/GYN
- Residents not entering the OB/GYN profession

# Reproductive Justice and Racial Inequities



- Focus on people most impacted by the Dobbs decision
  - Medical mistrust of providers and healthcare system
  - Strengthen privacy protections now so that needed healthcare is obtained
- Concern about protection of gender-affirming care
  - Strengthened protections and a whole-government approach needed

# Next Steps



- Review HHS Final Rule anticipated in Spring 2024
- Prioritize areas not included in Final Rule as well as what was not included in our response to NPRM
- Formulate a project scope outline
- Develop recommendation letter to include areas lacking in Final Rule



# Future Focus Area—Accounting of Disclosures



- 2011 HITECH Act directed the Dept to modify the Privacy Rule to require that an accounting of disclosures include disclosures made for TPO purposes through an EHR during the three years before the request.
- In 2018 OCR published an RFI that included 53 questions asking whether and how the Department could modify the HIPAA Rules to support care coordination, case management and promote value-based care, while preserving the privacy and security of PHI.

# Future Focus Area—Accounting of Disclosures



Questions centered on several key themes to address care coordination, one of which was accounting of disclosures

- RFI sought information about implementing the requirement of the HITECH Act to include disclosures by a covered entity for TPO through an EHR in an accounting of disclosures.<sup>[70]</sup>
- Over 1300 comments received
- Many expressing industry burden regarding accounting of disclosures

- HHS issued NPRM “Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement,” Jan 21, 2021, to modify the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under HIPAA and HITECH
- Based on the comments received in response to the 2018 RFI and the history of proposed rulemaking the Department intends to address this requirement in future rulemaking.

# Examples of Comments



*Patients who do ask for an accounting of disclosures under current law often reverse course when they learn what an accounting of disclosures report would contain. Instead, what these patients typically are seeking is an investigation into whether a specific user of the EHR inappropriately viewed their record.*

*Patients already have a right to understand how their information is used for TPO. Patients also have a right to know if their information has been used inappropriately through breach notification provisions. Patients additionally have recourse through the complaint process if they believe their PHI has been misused. **A new requirement for CEs to use EHRs to provide an accounting of disclosures would provide little or no benefit for patients while increasing burdens on health care providers.***

*There are already a number of ways in which patients are informed about how their information is used and disclosed by a CE, including the NPPs. Further, patients are more interested in knowing whether a specific violation has occurred and getting detailed information in response to a specific inquiry and investigation by the hospital's privacy and compliance staff. Patients value these investigations because they provide information about specific violations and what appropriate disciplinary and other measures were taken to ensure that violations do not reoccur. These processes and procedures already are in place and are aimed at ensuring patients receive the information they feel they need and value most.*

***An additional mandate to provide an access report would not add value to patients and would place unnecessary administrative burden on hospitals.....***

# Next Steps



- PCS SC discussed with OCR and this continues to be an area of interest and outstanding HITECH requirement that needs to be closed off
- Next steps:
  - Review comments received from 2018 RFI and 2021 NPRM
  - Discuss further with OCR
  - Hold briefings from industry for more input

# Future Focus Area-Privacy and Security in AI— Next Steps



Focus on practical application of AI in Healthcare and Big Tech

- Review the previous briefings and other research etc.
- Consider meeting with other agencies (OCR, NIST, CISA etc.) to explore questions
- Create a project scope outline

# Future Focus Area-P&S of Health Data Exchange Through TEFCA: Personal and Public Health Data Sharing—Next Steps



- Decipher input from expert panelists
- Make part of the Beyond HIPAA Joint Project Scope or a separate project?
- Joint PCS and Standards Subcommittees Project ?
- Determine next steps



# Future Focus Area—Beyond HIPAA



Build off the Committee’s Beyond HIPAA work published in 2019. A key excerpt from that report that will inform the work:

*“Today’s health information environment is a complex digital ecosystem comprised of countless “non-covered” entities that handle, process, and use some form of health information for a broad range of purposes. These entities include health app developers, device manufacturers, genetic companies, private disease and treatment registries, social media, marketing and analytic organizations, retail outlets, and more. If they are outside of HIPAA, they have a variety of limited obligations to protect the privacy of the health information subjects. They are not subject to the uniformity that patients now expect from the HIPAA rules. Today, safeguards for individually identifiable health information too often are weak or nonexistent.”*



## Two Focus Areas to Begin

- Privacy and Security of Health Data Exchange Through TEFCA: Personal and Public Health Data Sharing
  - Gain a better understanding of how health data will be shared through TEFCA between covered entities and non-HIPAA entities
- Reproductive Health Information Privacy and Security
  - Reproductive health information housed on health apps, public health data, other healthcare entities that house reproductive health information as explained earlier

# Our Journey: Past, Present, Anticipated Future



Expert Panels  
Reproductive  
Health Privacy

TEFCA

AI

**Q3 2023**

**Q2 2024**

Discuss Issues  
for Project  
Selection

Hold Briefings  
(Accounting of  
Disclosures)

**Q3/Q4 2024**

Develop  
Project  
Scoping  
Document

**Q4 2024**

Scoping  
Document  
Approved by  
Full  
Committee

**Q4 2024**

Conduct Projects  
Draft  
Recommendations

**Q1/2 2025 and  
beyond**



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## Questions & Discussion