



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

December 3, 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: Privacy and Security in Health Data Access



Previous reports have focused on this area:
Beyond HIPAA, Data Collection and Use during a PHE
2019
2022

HIPAA Right of Access Initiative enforcement priority
2019
One of the largest volumes of complaint categories

PCS SC
Project Proposal in Privacy and Security in Health Data Access
Q3 2024

Expert Panels
Privacy and Security in Health Data Access
HIE
Public Health
Human Services
Q3 2024

Hold Additional panel briefings that focus on the patient and provider
Draft a letter of recommendation for approval by Full Committee
Q1/2 2025 and beyond

Summary of Concerns from P&S in Health Data Access Panel----HIE, Public Health and Human Services



- Lack of regulations around health data apps----may need a national campaign to educate consumers, app developers, healthcare providers about what can occur when your health data is stored on an app that may not be covered by HIPAA.
- P&S issues around the secondary uses of BAs, especially when they are in a network environment, and they are sharing data with many additional groups that may not be protecting the privacy and security of the health data as it flows.
- How HIPAA interacts with other regulations and the patchwork of state laws that health care providers, public health entities and others must decipher when sharing PHI—no compendium of all laws.
- The need for a national privacy law (consistency).
- What to do when we hear from many that “nothing is private anymore” or that people are giving up on privacy?

Summary of Concerns from Panel on P&S in Health Data Access----HIE, Public Health and Human Services



- The reidentification of data ----lack of trust.
- Consent Management---very important for healthcare, social services, and public health information to have a streamlined consent management process.
- Lack of an infrastructure in public health, social services, behavioral health to exchange and use data and being able to integrate data with healthcare (back and forth).
- The need for specificity and clarity of the privacy rule when sharing PHI with public health authorities.
- 42 CFR Part 2 is still impeding the sharing of Substance Use Disorder (SUD) data since it still requires consent.

Additional Areas to be Addressed



- Covered Entities (CEs) confirming the validity of identity and assertion of purpose of use.
- Minimum standard for consent, authorization or identity for use or disclosure of PHI (NIST assurance levels)
- Standards for apps to ensure PHI is protected
- Ensure appropriate authentication and authorization without impeding timely and equitable access to medical records.
- Auditing and enforcement provisions for violations in the areas listed above
- Penalties or consequences for non-covered parties for misuse of consent, authorization, or identity when PHI are disclosed? (including fraud, breach in transit)
- General education and outreach for consumers on how to share or access data, being informed about the privacy and security risks of downloading a medical record on their personal device or from their patient portal etc.
- Problems CE's face in honoring requests for PHI
- Difficulties patients face getting access to their PHI

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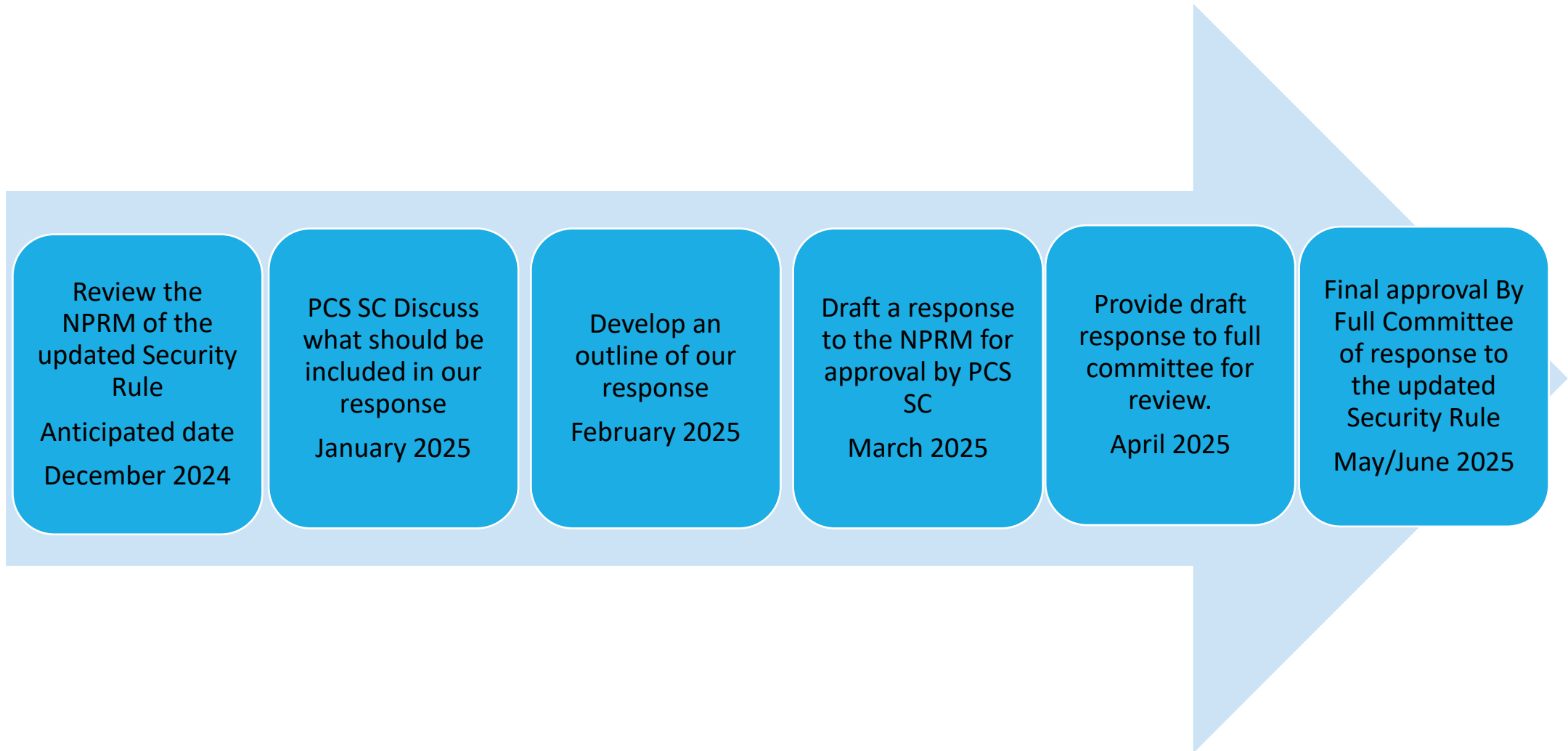
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Response to updated HIPAA Security Rule



Review the
NPRM of the
updated Security
Rule
Anticipated date
December 2024

PCS SC Discuss
what should be
included in our
response
January 2025

Develop an
outline of our
response
February 2025

Draft a response
to the NPRM for
approval by PCS
SC
March 2025

Provide draft
response to full
committee for
review.
April 2025

Final approval By
Full Committee
of response to
the updated
Security Rule
May/June 2025

Civil Monetary Penalties (CMPs)---Q3 2025



- The objective is to decipher and categorize the RFI responses received from RFI on April 6, 2022. *RFI on Recognized Security Practices and Sharing Civil Money Penalties and Monetary Settlements with Harmed Individuals Under the HITECH Act* in relation to the following questions:
 - What Constitutes Compensable Harm with Respect to Violations of the HIPAA Rules?
 - Should potential or future harm be compensable?
 - Should OCR allow individuals to include actual and perceived harm?
 - Should harm be presumed in certain circumstances? Should the Department recognize as harm the release of information about a person other than the individual who is the subject of the information (e.g., a family member whose information was included in the individual's record as family health history) for purposes of sharing part of a CMP or monetary settlements?

Civil Monetary Penalties (CMPs)---Q3 2025



- Should there be a minimum total settlement or penalty amount before the Department sets aside funds for distribution?
- How should harmed individuals be identified?
- How should they be notified that they may be eligible for distributions?
- What goals should the Department prioritize when selecting a distribution model?
- Finally, the Department requests comment on any additional factors or information the Department should consider in developing a proposed methodology to share a percentage of CMPs and monetary settlements with harmed individuals.

Future Focus Area—Accounting of Disclosures---Q3 2025



- 2011 HITECH Act directed the Dept to modify the Privacy Rule to require that an accounting of disclosures include disclosures made for Treatment, Payment and Health Care Operations (TPO) purposes through an EHR during the three years before the request.
- In 2018 the Office for Civil Rights (OCR) published an RFI with questions centered on several themes to address care coordination, one of which was accounting of disclosures
- Over 1300 comments received
- Many expressed industry burden regarding accounting of disclosures

Accounting of Disclosures 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

Privacy and Security of Telehealth Exploration— Q4 2025



- To assure that the health information that is transmitted is protected and secure.
- Determine priorities for privacy and security regulations around telehealth.
- OCR to provide more information
- Panel Briefings/Environmental Scan
- Information to support development and advice on this topic.
- HIPAA and Telehealth
 - <https://www.hhs.gov/hipaa/for-professionals/special-topics/telehealth/index.html>

Summary of Proposed Topics



Topic	Dates
Privacy and Security in Health Data Access	Q3 2024 – Q2/3 2025
Response to HIPAA Security Rule	Q4 2024 – Q2 2025
Civil Monetary Penalties	Start Q3 2025
Accounting of Disclosures	Start Q3 2025
Telehealth P&S	Start Q4 2025



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Questions & Discussion