



June 16, 2023

Mr. Lester Coffey
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, SW
Washington, DC 20201

RE: RIN 0945-AA20: HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Submitted via www.regulations.gov for [RIN 0945-AA20](https://www.regulations.gov/document/2023-06-16/1)

Dear Mr. Coffey:

The American Pharmacists Association (APhA) is pleased to submit comments on the Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) request for comments titled "HIPAA Privacy Rule to Support Reproductive Health Care Privacy." APhA supports the intent of this proposal to prohibit the use or disclosure of protected health information (PHI) and urges HHS to ensure there are no conflicts between federal and state disclosure laws or regulations for covered entities, including our nation's pharmacies.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

[Preemption of State Laws](#)

HHS' proposed prohibition of the use or disclosure of reproductive-related PHI would preempt any contradicting state laws in all cases where the reproductive health care:

- (1) is provided outside of the state where the investigation or proceeding is authorized and that is lawful in the state in which such health care is provided;
- (2) is protected, required, or authorized by Federal law, regardless of the state in which such health care is provided; or

(3) is provided in the state in which the investigation or proceeding is authorized and that is permitted by the law of that state.

APhA recommends that HHS provide clear guidance to pharmacists and other covered entities to ensure there is no confusion on how to respond to contradictions between state laws related to use or disclosure of PHI and this proposed rule.

Disclosures Required by the Privacy Rule – Patient’s Right to Access PHI

HHS’ proposal states that “regulated entities are expected to continue to comply with and disclose protected health information (PHI) in response to an individual's request for access to their own PHI or a request to disclose PHI as part of an investigation of compliance with the HIPAA Rules.”

Additionally, HHS asserts that an individual's right of access to their own PHI cannot be denied based on the individual patient’s intended use of their own PHI.

APhA agrees that a patient’s right to access their own reproductive health care PHI from their pharmacist should not be denied.

HHS is also seeking comments on the following considerations:

1. The effects of individuals' concerns about the potential disclosure of their PHI to law enforcement or others on their willingness to confide in their health care providers.
2. The effects of individuals' withholding information about their health from their health care providers.
3. The effects of health care providers' concerns about potential criminal, civil, or administrative investigations into or proceedings against them or their patients in connection with the provision of lawful reproductive health care on the completeness and accuracy of medical records and continuity of care.

APhA supports stronger protections for patients’ reproductive health care information. However, as health care providers, we have concerns that patients seeking lawful reproductive health care may choose to withhold vital health information from their pharmacists due to fear of inappropriate use or disclosure of their PHI. If a patient withholds this information, this may prevent a pharmacist’s ability to appropriately counsel patients on potential drug-to-drug interactions.

Under APhA’s House of Delegates policy “... APhA opposes legal actions against pharmacies, pharmacists, and pharmacy personnel that provide patient access to, or information regarding, reproductive health care services that are within the pharmacist scope of practice.”¹ APhA requests HHS work with federal policymakers and stakeholders to protect pharmacists' authority to exercise their professional judgment to ensure that patients’ reproductive health care PHI remains protected and their care is not disrupted due to continued confusion following the *Dobbs* decision, the ongoing appeals of the *Alliance for Hippocratic Medicine vs. FDA* case, and conflicting state and federal laws and regulations.

¹ APhA House of Delegates Policies 2023, <https://www.pharmacist.com/About/Leadership/HOD/2023-Policy-Updates>

HHS is also seeking comment on whether this proposal should apply broadly to any health care, rather than limiting it to reproductive health care PHI; whether they should prohibit or limit uses or disclosures of “highly sensitive PHI” for certain purposes; and if HHS should define “highly sensitive” PHI.

APhA does not believe this proposal should apply to all health care PHI. However, APhA recommends HHS consider circumstances when other types of stigmatized health care, such as treatment of substance use disorder that could potentially become criminalized as “highly sensitive PHI.”

C. Section 164.509—Uses and Disclosures for Which an Attestation Is Required (Proposed Heading)

HHS is proposing a new requirement for covered entities, that would include pharmacists and pharmacies, to obtain an attestation from an individual requesting the use and/or disclosure of reproductive health care records as a condition for permitted uses and disclosures. HHS’ proposal would require pharmacists to obtain a signed and dated written statement from the individual requesting the PHI to ensure the use or disclosure of the information would not be for a prohibited purpose.

HHS states this attestation would apply when the request for PHI is potentially related to reproductive health care, [as defined in proposed 45 CFR 160.103](#). HHS states “an attestation would not be required when an individual is making the request does not seek PHI potentially related to reproductive health care.” HHS also states “if [a] request would require a regulated entity [including pharmacists/pharmacies] to disclose PHI potentially related to reproductive health care, a regulated entity would have to first obtain an attestation from the individual making the request to ensure that the PHI would not be used or disclosed for a prohibited purpose.”

APhA believes the [proposed attestation requirements](#) will place an additional administrative burden on pharmacists who are already navigating conflicting state and federal laws related to reproductive health care. Additionally, this [language](#) is confusing for pharmacists to determine when an attestation would be required. **APhA requests HHS clarify this language in the final rule to clearly define when obtaining an attestation would be required for an individual seeking reproductive health care PHI.**

APhA appreciates HHS is considering developing a model attestation template, however, **we respectfully request clarity on how a new attestation requirement will be implemented.** APhA also appreciates the agency will not require covered entities, including pharmacies, to investigate the validity of an attestation provided by an individual requesting the use of or disclosure of PHI.

D. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity To Agree or Object Is Not Required

Section 164.512 contains standards for use and disclosure of PHI for which an authorization to agree or object is not required. Permission for uses and disclosure are not required by HIPAA but balance

the privacy interests of individuals and the interests of communities by making certain information available for certain public health, health care oversight, and research purposes. APhA's House of Delegates supports public policies that protect the patient's privacy yet preserve access to personal health data for research when the patient has consented to such research or when the patient's identity is protected.² Accordingly, we support HHS's intent to ensure that reproductive health PHI continues to be protected and disclosed appropriately, especially due to continued confusion with conflicting state and federal laws and regulations. APhA's House of Delegates supports public policies that protect the patient's privacy yet preserve access to personal health data for research when the patient has consented to such research or when the patient's identity is protected.³

HHS' proposal also believes it may be necessary to modify these [rules](#) to reflect the changes proposed in this rule that would place new conditions on certain uses and disclosures permitted in addition to the newly proposed attestation requirement. **APhA has concerns how this proposed rule and the attestation requirement may impact clinical researchers who would need access to reproductive health care data to conduct clinical research studies and we recommend HHS clarify how these proposed changes could affect clinical research for reproductive health care.**

Conclusion

APhA appreciates the opportunity to provide feedback on OCR's request for comments titled "HIPAA Privacy Rule to Support Reproductive Health Care Privacy." APhA supports the agencies intent to protect reproductive health care PHI. As HHS finalizes this rule, APhA respectfully requests OCR consider the administrative burdens this proposed rule will place on our nation's pharmacists while also ensuring patients' private reproductive health care records remain protected. While the proposed rule states "[t]he Department assumes that costs affecting pharmacies are incurred at each pharmacy and drug store establishment and each PSAO," there is no clear estimate of the specific affects to our nation's pharmacists and pharmacies. Accordingly, APhA recommends OCR survey and assess our nation's pharmacies to accurately quantify the financial impact of this proposed rule. If you have any questions, or need any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Acting Head of Government Affairs
American Pharmacists Association

² APhA House of Delegates Policy Manual, <https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=XbMYZdOuE1E%3d>