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June 16, 2023

Melanie Fontes Rainer
Director, Office for Civil Rights
U.S. Department of Health and Human Services
Attention: HIPAA and Reproductive Health Care Privacy
Hubert H. Humphrey Building, Room 515F
200 Independence Avenue, SW
Washington, DC 20201

Re: HIPAA Privacy Rule to Support Reproductive Health Care Privacy (RIN Number 0945-AA20)

Dear Director Fontes Rainer:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking entitled “HIPAA Privacy Rule to Support Reproductive Health Care Privacy,” 88 *Fed. Reg.* 23506 (April 17, 2023). We appreciate the Department’s efforts to amend provisions of the Privacy Rule to strengthen privacy protections for individuals’ protected health information (PHI) related to reproductive health care.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC’s U.S. membership and expanded its reach to international academic health centers. Learn more at aamc.org.

AAMC member health systems and hospitals have been leaders in ensuring that patient information is protected and are committed to ensuring use of such information is consistent with federal and state privacy laws. Teaching health systems and hospitals are invested in the transformation to delivering value-based health care and recognize the role of health information

exchange and patient engagement in that effort. The AAMC supports policies to improve patient engagement in their care and remove obstacles to efficient care coordination and case management while preserving the privacy of patients' PHI.

The AAMC commends the HHS Office for Civil Rights (OCR) for its efforts to strengthen privacy protections for individuals' PHI related to lawful reproductive health care. These protections are especially important at this time since state restrictions and enforcement actions related to reproductive health care after the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*¹ make it more likely that information could be used or disclosed in a way that chills access to lawful health care. After the *Dobbs* decision, we have heard concerns that civil, criminal, and administrative investigations of lawful reproductive health care have interfered with access to high quality health care and physician-patient relationships. Physicians, nurses, and other qualified personnel must be able to work directly with their patients to make decisions about the most appropriate care. Physicians, nurses, and other health care professionals should not fear criminal and civil prosecutions for ensuring the health and well-being of their patients when providing lawful care.

Overall, the AAMC supports the goal of HHS's proposed amendments to the HIPAA privacy rule that will enhance provider-patient relationships through heightened privacy protections for information regarding lawful care, though we note below the serious practical obstacles for health care providers to comply with the proposed rule as it is currently written. As described in the rule, the fear of highly sensitive information being released can lead to mistrust. If individuals believe that their PHI may be disclosed without their knowledge or consent to be used in criminal, civil or administrative investigations or proceedings against them or others based on receipt of lawful reproductive health care, they may be less open about their symptoms and medical history and refrain from providing critical information to their health care providers. This will make it difficult for providers to determine an accurate diagnosis and manage the patient's care. Lawful medical care should not result in adverse legal consequences for patients and providers.

Prohibited Uses and Disclosures

We support the proposal in the rule to establish a new purpose for which disclosures are prohibited in certain circumstances—that is, “for the use or disclosure of PHI for the criminal, civil, or administrative investigation of or proceeding against an individual, regulated entity, or other person for seeking, obtaining providing or facilitating reproductive health care.” We support the proposal to prohibit these disclosures when the reproductive health care: 1) is provided outside of the state where the investigation or proceeding is authorized and is lawful; 2) is protected, required, or authorized by Federal law regardless of the state where provided; or 3) is provided in the state where the investigation or proceeding is authorized and that is permitted by the law of that state. We agree that in these circumstances, the state lacks any substantial interest in seeking the disclosure.

¹ 597 U.S., 142 S. Ct 2228 (2022) (n. 19-1392) (June 24, 2022).

HHS seeks comments on whether this proposal should be limited to reproductive health care or apply more broadly to other types of “highly sensitive PHI.” **AAMC supports expanding this proposal to other types of “highly sensitive PHI,” such as patients with HIV, patients receiving pre-exposure prophylaxis (PrEP), patients with substance use disorders, and patients receiving gender affirming care.** A growing number of lawmakers have enacted or are considering laws to prohibit certain gender-affirming treatments for youths and to impose penalties on physicians and other health care professionals who provide this care. The AAMC endorses the widely accepted view of the professional medical community that in some cases gender-affirming care is medically necessary and that decisions about appropriate treatment should be made between a physician and patient. PHI about gender affirming care or other sensitive care that is lawful should not be used to target patients, their families, physicians, and other health care professionals in civil and criminal proceedings.

Attestations

We support the requirement that requestors of the PHI for certain types of permitted uses and disclosures (i.e., health care oversight, judicial and administrative proceedings, law enforcement purposes, and coroners and medical examiners) provide covered entities with an attestation to the fact that they are not seeking to use the information to investigate or penalize the lawful provision of health care. This requirement balances the patient’s privacy rights with the government’s need for health information for certain purposes in proceedings.

The final rule should make it clear that providers are not required to investigate and determine the validity of an attestation if the statements in the attestation are objectively reasonable. In addition, the rule should finalize the provision that a requester that knowingly falsifies an attestation to obtain individually identifiable health information could be subject to criminal penalties. The rule proposes that the attestation would require a regulated entity to cease use or disclosure of PHI if the regulated entity developed reason to believe that the representations contained within the attestation were materially false, leading to uses or disclosures for a prohibited purpose. It goes on to state that there could be criminal liability for such disclosure. We urge HHS to clarify that a provider would be liable for a requestor’s inappropriate use of the PHI only if the provider has actual knowledge that the requestor will use the information for a prohibited use.

HHS specifically asks whether requesters of PHI should be required to name the individuals whose PHI they are requesting or whether it would be sufficient to request PHI for a class of individuals that are described. To minimize cost and burden, the AAMC recommends that requests be individualized.

HHS requests comment on whether use and disclosure for the prohibited purpose described should be allowed with a valid authorization from the patient. The AAMC opposes allowing use and disclosure for a criminal, civil, or administrative investigation for seeking, obtaining, providing, or facilitating lawful care, even with a valid authorization from the patient. We agree with HHS’s concern that law enforcement and other entities may coerce patients into sharing their medical information. As a result, permitting use or disclosure of this PHI based on a patient’s authorization may threaten patient safety and put providers in jeopardy.

Compliance Challenges

While we support the overall approach in the rule, we urge HHS to make some changes because of the significant obstacles to complying with the rule as proposed. It is extremely difficult for covered entities and business associates to know if a given record contains reproductive health information since this information could be incorporated throughout medical records, which are often very large and complex. The additional time it would take to review records for structured and unstructured data, in dozens and sometimes hundreds of sub-sections of a medical chart, would lead to significant delays in processing record requests. Further, many types of PHI may not initially appear to be related to an individual's reproductive health yet may in fact reveal information about an individual's reproductive health. For example, pregnancy tests are routinely administered before a surgical procedure to ensure that surgeons and anesthesiologists can identify any potential risks of proceeding with surgery and identify alternative treatment options. Additionally, the existence of hypertension or gestational diabetes could indicate that the individual is pregnant, causing that information in the record to potentially be considered reproductive health care. Again, it would take medical record clerks significant time to review records requests for information that might qualify to trigger the NPRM's requirement.

Unlike psychotherapy notes, reproductive health information is not easily defined or segregated. Additionally, electronic health record (EHR) systems do not currently enable providers to segment reproductive health care, at least in a manner that is not overly burdensome and cost prohibitive.² If providers decide to make costly updates to their EHR systems to allow segmenting of certain data elements on reproductive health care, they would be creating barriers for care coordination.

Against these challenges, providers would have the burden of evaluating the full scope and context of the PHI requested to determine whether it could reveal information about the individual's reproductive health. Because reproductive health care is included throughout the medical record, and often difficult to identify amongst many subsections of large medical records, providers may inadvertently miss the reproductive health information, putting themselves at risk for non-compliance with this new HIPAA rule. To avoid that issue, providers may err on the side of requesting attestations in cases where there may not be reproductive health information, and thereby put themselves at risk for non-compliance with Information Blocking rules under the 21st Century Cures Act or other laws and regulations.

While it is helpful that the rule proposes that regulated entities would be required to obtain an attestation from persons requesting PHI that is "potentially related to reproductive health care," (emphasis added) operational challenges will still exist. Providers will still have the burden of evaluating the full scope and context of the PHI requested to determine whether it could reveal information about the individual's reproductive health.

² See "Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019, "Health Information Technology Advisory Committee (Feb. 19, 2020), p. 37
https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf

This puts providers in an untenable position. **Therefore, we recommend that the final rule be amended to require that all requests for PHI under 45 CFR section 164.512 (d) through (g) (i.e., for health care oversight, judicial and administrative proceedings, law enforcement purposes, and coroners and medical examiners) be supported by an attestation that the information will not be used or disclosed in connection with a criminal, civil, or administrative investigation or proceeding based on an individual's seeking, obtaining, providing, or facilitating reproductive health care that is lawful in the jurisdiction in which it is provided.**

Furthermore, the rule puts the onus on the provider to determine if the care was provided under circumstances in which it was lawful to do so. A provider in the state of the individual's residence that may receive PHI concerning reproductive health care provided to the individual out-of-state would need to be aware of the laws of the other state to determine if the care was lawful. **Given the rapidly changing state laws about reproductive health care, it will be extremely difficult for a provider to determine if reproductive health care delivered in another state at various points of time, was lawful.** Not every covered entity would have the resources to research the laws in all 50 states and territories to make these determinations. We urge HHS to take steps to alleviate this burden on providers.

To reduce the burden on regulated entities implementing the proposed attestation, HHS states it is considering developing a model attestation that would be voluntary. **We strongly encourage HHS to develop an attestation template.** Having a model template will make it much easier for covered entities to comply with the attestation requirements.

Preemption of State Laws

HHS states that the provisions in the rule would preempt any state laws that are contrary. Specifically, the rule states that it would prohibit disclosure of PHI for a law enforcement investigation of reproductive care that is lawful, even in response to a court order, such as a search warrant. Such disclosure, despite the court order, would be a violation of the Privacy Rule and would subject the regulated entity to a potential investigation and civil monetary penalty. While we agree that HIPAA preempts state law, we are concerned that providers may be put in a difficult position of facing penalties for violating federal privacy regulations or sanctions for not complying with state law enforcement directives. Therefore, the AAMC recommends HHS make resources available when this rule is finalized to assist physicians and other providers in understanding their rights under this rule, and how to respond when enforcement actions under state laws contradict the policies set forth in this rule. **We urge HHS not to penalize physicians that are placed in difficult positions by law enforcement entities in the states.**

OCR Should Revise its December 22 Online Tracking Guidance

The HHS issued guidance regarding the use of online tracking technologies in December 2022.³ It is our understanding that this guidance may have been created, in part, to address some of the

³ See, United States Department of Health and Human Services, Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates (Dec. 1, 2022) <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html>

same privacy concerns about reproductive health as this proposed rule. However, the guidance defines PHI too broadly to include all IP addresses. Such a broad definition will hinder access to credible and reliable health information. Therefore, we strongly urge HHS to revise this guidance, which may no longer be necessary if the provisions in this HIPAA proposed rule on reproductive care are finalized.

Increasingly, individuals are using the Internet to search and find out information about health care. It is critical that individuals using the Internet obtain health information that is accurate and from trustworthy sources. Teaching health systems and hospitals provide important, credible information on their websites to assist patients as they seek this information. Through their websites and apps, they provide information to individuals throughout the country, including in underserved areas that may not have access to this information.

Under the online tracking guidance, an IP address is protected even if the consumer is not actually seeking medical care. This policy applies HIPAA protections when consumers search for general health information on websites about vaccines, symptoms of an illness, office hours, facility locations, credentials and experience of physicians, and other topics on a teaching hospital and health systems website. In many cases, these individuals browsing the website are not patients, but rather are individuals simply seeking information.

We urge the OCR to make it clear that IP addresses alone do not individually identify an individual as a patient. If the OCR chooses to protect IP addresses, then we recommend that the protection only apply to IP addresses provided via webpages that are password-protected, such as patient portals, or that include actively completed webforms, such as appointment request webpages. These types of webpages and protected websites are more likely to contain PHI that we agree should be protected. These changes to the guidance would enable teaching hospitals and health systems to provide health information and education to their communities, while protecting patient privacy. We would welcome the opportunity to discuss our concerns about this guidance with you further.

Conclusion

The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org.

Sincerely,



Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO