June 16, 2023

The Honorable Xavier Becerra
Secretary
U. S. Department of Health and Human Services
Attention: HIPAA and Reproductive Health Care Privacy NPRM
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RIN Number 0945–AA20, Comments submitted electronically via www.regulations.gov

Dear Secretary Becerra:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the HIPAA Privacy Rule to Support Reproductive Health Care Privacy. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation’s biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

AMIA supports efforts by the U. S. Department of Health and Human Services (HHS) to revise 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 for Economic and Clinical Health Act of 2009 (HITECH Act), to implement protections limiting uses and disclosures of protected health information (PHI) for certain purposes where the use or disclosure of information is about reproductive health care that is lawful under the circumstances. Specifically, AMIA supports the scope of the proposal to provide strong protections against 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, as well as the identification of any person for the purpose of initiating such an investigation or proceeding.
As a community of leading professionals at the intersection of health and information technology, we are concerned about the privacy considerations regarding access of PHI and health information technology to investigate and prosecute individuals and the health care professionals entrusted with their care. AMIA supports privacy-protective policies governing the use of health and health-related information so that highly sensitive information receives additional privacy protection from disclosure that would impinge on the rights of individuals, interfere with fostering a patient-provider relationship where all health care needs may be discussed openly and without fear, or compromise the professional integrity of informatics faculty and staff. There is precedent for “special protections” to treat and limit access to some categories of highly sensitive PHI, as with mental health notes,[6,7] and those discussing HIV care[8] and adolescent privacy protections.[9,10] We support HHS efforts to add special protections for reproductive health care PHI.

Need for Clarification of Privacy Protections for Reproductive Health Care

Electronic health records (EHRs) and related patient portals represent the major repository of confidential health information in the United States. Such records, however, are subject to release for certain purposes, including via subpoena for legal proceedings. We agree with the HHS stance that clarification is needed to provide guidance and direction for regulated entities about permitted and prohibited disclosures of PHI.

Patient-Provider Relationship

AMIA strongly agrees with the HHS emphasis on protecting a positive, trusting relationship between individuals and their health care providers as essential to an individual’s health and well-being. We agree that the prospect of releasing highly sensitive PHI can result in medical mistrust and the deterioration of quality health care and a functional health care system. We believe prosecutorial misuse of health data has grave consequences for the sanctity and trust inherent in the therapeutic and fiduciary relationship between patients and their healthcare providers. Violating this trust will cause immediate and future harm for all parties and their families – not just those receiving care for reproductive health.

Attestation

Under the proposed rule, regulated entities would be required to collect an attestation from the person or entity seeking the PHI, that such use or disclosure of the PHI is not for a prohibited purpose. The attestation requirement would apply when the PHI is potentially related to reproductive health care and is requested for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and disclosures to coroners and medical examiners. The regulated entity would have to collect an attestation from the requesting entity through a signed and dated written statement that the use or disclosure of such PHI would not be for a prohibited purpose. The attestation would only apply to each use or disclosure, thereby requiring a new attestation every time a request is made. This would place significant burden on regulated entities to comply with this provision.
Additionally, AMIA is very concerned that the proposed rule places an even larger burden on regulated entities to not disclose the PHI if the regulated entity believes the attestation is “materially false.” Health care providers should not be placed in the position to determine if an attestation is untrue, misleading or deceptive. At a minimum, HHS must provide a model attestation with clearly stated penalties for submitting a false attestation.

**Notice of Privacy Practices**

We support the HHS proposal to require modifications to the Notice of Privacy Practices (NPP) to ensure that individuals are aware of any finalized regulations regarding protections against uses and disclosures of PHI where the use or disclosure of information is about reproductive health care that is lawful under the circumstances. Modifications to the NPP to address the attestation requirement should only be made if HHS releases a model attestation. Otherwise, non-uniform agreements and various provider approaches to describing the attestation requirements will only create confusion for patients.

**Public Health Surveillance**

AMIA agrees with HHS that the Privacy Rule’s permissions to use and disclose PHI for the “public health” activities of surveillance, investigation, or intervention do not include criminal, civil, or administrative investigations into, or proceedings against, any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, nor do they include identifying any person for the purpose of initiating such investigations or proceedings.

**EHR Technical Considerations**

AMIA appreciates HHS’ stated recognition that reproductive health information is not easily defined or segregated in the medical record. AMIA would like to underscore the Department’s understanding that today’s clinical documentation and health IT do not provide regulated entities with the ability to segment certain PHI such that regulated entities could afford specific categories of PHI special protections, without significant cost and burden on such entities.

As this is an evolving area of regulation, we support the HHS intent for the proposed purpose-based prohibition on disclosure of information. However, this purpose-based prohibition will not alleviate the need for EHR modifications to provide further safeguards for this sensitive data. A proactive, considered, and deliberate approach to safeguarding digital health data is a prerequisite to safe care for all. Work by HL7[1] to develop a data segmentation for privacy standard that supports the patient-provider relationship has been implemented successfully.[2] Efforts now underway by Shift[3] build upon earlier work to advance granular patient privacy across a range of circumstances with unique challenges, e.g., mother/infant, adolescent, older adult, and mental health information. Continuous stewardship of safeguards for sensitive data, including that of reproductive health, is required for the safe and effective use, reuse, and exchange of EHR data.
Affected Individuals

AMIA notes the HHS statement that ‘the Department believes that the population of individuals potentially affected by the proposed rule is approximately 74 million overall, representing nearly one-fourth of the U.S. population, including approximately 6 million pregnant women and girls annually and an unknown number of individuals facing a potential pregnancy or pregnancy risk.’ The HHS chart supporting this estimate is based on “Females of Potentially Childbearing Age. AMIA suggests that the number of individuals potentially affected by the proposed rule is much larger than estimated. Any individual who was ever of child-bearing age is at risk should their records be accessed and disclosed. In addition, this NPRM affects the family members of affected patients.

HHS might also consider adding transgender, nonbinary, and gender-expansive people who experience pregnancy to the estimate of affected individuals or otherwise acknowledge the impact population is known to be greater than this estimate, even if not currently well defined [5].

Overall, more consideration should be given to the population of who would be considered affected individuals. Would it stop at patient and provider? There needs to be further clarification regarding vendors serving as the conduit for information exchange. Would the software developers be held liable for breaches?

Thank you for your consideration of these comments. If you have questions or require additional information, please contact Reva Singh, JD, AMIA Vice President of Public Policy, at rsingh@amia.org.

Sincerely,

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