

June 20, 2023

Melanie Fontes Rainer, JD
Director of the Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Dear Director Fontes Rainer:

On behalf of the undersigned organizations representing physicians and partners in women's health and the health of individuals seeking obstetric and gynecologic services, we appreciate the provisions outlined in the Department of Health and Human Services (HHS) Office of Civil Rights (OCR) proposed rule entitled *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*. As the leading voices for obstetrician-gynecologists, we feel particularly passionate about ensuring these provisions are high-quality and executed effectively to reaffirm confidence in the critical health care that obstetrician-gynecologists provide to their patients. We look forward to working with HHS and OCR to further protections for obstetrician-gynecologists and their patients.

In the wake of the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, millions of individuals' access to abortion care has been put in jeopardy. As of April 2023, [14 states](#) have banned abortion completely with many more imposing restrictions. The radically altered legal landscape for reproductive health care, including vast swaths of the country with near-total abortion bans, has intensified an environment of fear for patients that they will be criminalized or scrutinized for their pregnancy decisions and outcomes. This fear can delay or deter individuals from seeking needed health care, resulting in worse health outcomes. Now more than ever, trust in the health care system along with protected health information (PHI) of patients and their medical records is crucial to protecting patient-provider relationships.

Definitions

In this proposed rule, OCR is revising or clarifying certain definitions related to the provisions included within this proposed rule. Amongst these definitions is clarification that the terms "disease or injury", "birth", "death", and "health tracking efforts" are not specifically defined. This lack of clarification could result in misuse of these data to criminalize patients and their physicians. As such, **our organizations would recommend clarifying the terms "disease or injury", "birth", "death", and "health tracking efforts" to prevent the possibility of criminalization of patients and physicians and to only include those circumstances covered under public health surveillance, investigation, or intervention as identified by the Privacy Rule.**

We appreciate OCR's effort to clarify the appropriate uses of public health activities related to reproductive health care and limiting disclosures of this type of data for this purpose to the minimum necessary standard. **We urge finalizing these proposals as written.**

Uses and Disclosures of PHI

Amongst the provisions of this proposed rule, OCR is focusing efforts on creating a new category of prohibited uses and disclosures of PHI to strengthen privacy protections for individuals' PHI covered under HIPAA. OCR notes that this proposal is meant to address investigations or proceedings brought against any person seeking, obtaining, providing, or facilitating lawful reproductive health care under the circumstances in which it is provided. It is also meant to address use or disclosure of PHI to identify a person for the purpose of initiating such an investigation or proceeding. **We support the creation of this new category of prohibited uses and disclosures of PHI to shore up protections for physicians and their patients.**

OCR is proposing to add a requirement that regulated entities must obtain an attestation from the person requesting the use or disclosure. The attestation would be a signed and dated statement attesting that the use or disclosure would not be for a prohibited purpose as detailed in the proposals above. We appreciate the steps OCR is taking to ensure reproductive health care information is not inappropriately used or disclosed, especially for the purposes of legal and civil investigations, especially in the current legal environment. An attestation-based method of ensuring use and disclosure of reproductive health care PHI is an important step in protecting patients and physicians. However, we also believe attestations may not go far enough to fully protect patients and physicians from bad actors. As such, **we urge OCR to finalize the inclusion of the attestation-based method with the addition of baseline investigatory requirements, not to be conducted by the physician, to ensure the representation within the attestation is true.** Doing so will instill even further confidence in the process to protect the patient's reproductive health care PHI while balancing the need to reduce physician administrative burden and remove any liability for use of data from the physician.

In this proposed rule, OCR notes they are concerned that given the current legal landscape, regulated entities may believe they are permitted to make disclosures of PHI when it is believed that persons who provide or facilitate access to reproductive health care are perpetrators of abuse, neglect, or domestic violence. For this reason, they are proposing to add language to clarify that the permission to use or disclose PHI in reports of these crimes does not permit uses or disclosures based primarily on the provision or facilitation of reproductive health care to the individual. **We recommend OCR finalize this proposal as written.**

Notice of Privacy Practices for PHI

With these new provisions, OCR is concerned that the current Notice of Privacy Practices (NPP) requirements may not provide individuals with the confidence that a revised Privacy Rule would prohibit the use or disclosure of their PHI and thus may avoid accessing important reproductive health care. As such, OCR is proposing to require that a covered entity separately describe each type of use or disclosure prohibited and must do so in sufficient detail for an individual to understand the prohibition and the proposed attestation requirement. **We appreciate this consideration and recommend finalizing this proposal as written.**

Other Recommendations

Within this proposed rule, OCR included a couple of requests for comment. Below is our feedback regarding these requests for comment and other recommendations not discussed in the proposed rule.

- Create a model attestation for use by regulated entities, ensuring that minimum standards are maintained.

- Require a requestor provide a signed declaration made under penalty of perjury that their request does not violate the prohibitions detailed in this proposed rule.
- Clarify the standards of the potential for states to apply for an exception to preempt the federal regulations and consider strengthening these standards wherever possible or remove the potential for exceptions entirely.
- Develop consumer and provider educational resources to better communicate the impact of these new regulations and how they can be implemented in a regulated entity's workflow in the case they are finalized.

Thank you again for your leadership on this issue, we look forward to working with HHS and OCR to strengthen protections for physicians and their patients.

Sincerely,

American College of Obstetricians and Gynecologists
American Association of Gynecologic Laparoscopists
American Society for Reproductive Medicine
American Urogynecologic Society
Society of Family Planning
Society for Maternal-Fetal Medicine