



Charles N. Kahn III
President and CEO

June 16, 2023

Melanie Fontes Rainer
Director
Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 515F
Washington, DC 20201

Re: HIPAA Privacy Rule to Support Reproductive Health Care Privacy; 88 Fed. Reg. 23506 (RIN 0945-AA20) (April 17, 2023)

Dear Director Fontes Rainer:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying public and privately held hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's and cancer services.

The FAH appreciates the opportunity to provide the Office for Civil Rights (OCR) with feedback on the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy Proposed Rule*. The FAH and its members are committed to maintaining the confidentiality of patients' health information and agree with OCR in its statement that "a relationship of trust between individuals and health care providers" is essential to the proper functioning of our health care system. The FAH offers the below comments and recommendations on the Proposed Rule, which are focused on operational questions and the best ways to reduce the burden on hospitals and other health care providers so that they can focus limited time and resources on providing health care. Our comments focus on:

- State versus federal rules;
- Operational challenges;

- Educational needs; and
- Enforcement and compliance date.

State Versus Federal Rules

The FAH supports OCR's goal of preserving trust in the provider to patient relationship and appreciates the purpose-based approach taken in the Proposed Rule that is consistent with the structure of the HIPAA Privacy Rule itself. However, the FAH is very concerned that the Proposed Rule would place hospitals, health systems and other regulated entities in the position of navigating conflicting state and federal laws and rules, including being in the position of having to determine whether care that may have been provided by others, including in other states, was provided lawfully.

Specifically, in proposed changes to Section 164.502, OCR would prohibit regulated entities from using or disclosing protected health information (PHI) for a criminal, civil, or administrative investigation into or proceeding against any person (including health care providers) in connection with seeking, obtaining, providing, or facilitating reproductive health care in certain circumstances. OCR also proposes to prohibit regulated entities from using or disclosing PHI to identify any person (including health providers) to initiate such an investigation or proceeding in certain circumstances, which include:

- When the reproductive health care is provided outside of the state where the investigation or proceeding is authorized and where such health care is lawfully provided.
- When the reproductive health care is protected, required, or authorized by Federal law, regardless of the state in which such health care is provided.
- When the reproductive health care is provided in the state in which the investigation or proceeding is authorized and is permitted by the law of that state.

OCR proposes to define "reproductive health care" broadly to mean: "care, services, or supplies related to the reproductive health of the individual." Given the changing nature of state and federal laws and guidance related to reproductive health care, it will be extremely challenging for a given hospital or health system to determine whether an individual's medical record contains the information outlined in the proposed prohibition. These challenges are even more significant in the federally supported era of information sharing, where a hospital or health system may have received and incorporated into a patient's record information about care provided in other settings, including in other states. Similarly, regulated entities will face difficulties in making these determinations in communities where bordering states have divergent laws. Therefore, the FAH believes it is unrealistic to ask regulated entities to determine whether an individual patient's record meets the specific circumstances outlined in the Proposed Rule and recommends that OCR leave those determinations up to a court of law, for example through a court order, subpoena, or other alternative, efficient legal process that is enforceable by a court of law, unless otherwise authorized by the individual. This will ensure that the courts, which have expertise in these legal matters, instead of health care entities, make the determination regarding the lawfulness of the reproductive services.

OCR also proposes to define a new term, "*Public health*," as used in the terms "public health surveillance," "public health investigation," and "public health intervention," [to mean] population-level activities to prevent disease and promote health of populations. Such activities do not include uses and disclosures for the criminal, civil, or administrative investigation into or

proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care, or for the identification of any person in connection with a criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care." The FAH commends OCR for clarifying that public health purposes are not to be used to request information for the prohibited purposes but asks OCR to clarify that reporting of individual-level data to public health agencies is permitted as part of these public health activities.

Operational Challenges

The FAH appreciates the goal of OCR's Proposed Rule but has significant concerns about the operational challenges that will face regulated entities should the rule be finalized.

Identifying reproductive health care information: Given the proposed broad definition of reproductive health care and the vast array of information contained in most medical records, it will be very challenging for hospitals and health systems to determine whether a given individual's record contains reproductive health care information, which could take the form of a diagnosis, procedure, medication, or supply. In addition to specific reproductive health diagnoses and procedures that may be relatively easy to identify using search tools, medical records include clinical notes, diagnostic images, and a host of other unstructured data that could also convey information about reproductive health care. While electronic health records and release of information systems can potentially be updated to support some automated search tools, identifying all relevant information would require an onerous and unrealistic manual review. Even then, there are likely to be data elements that could speak to reproductive health care in unexpected places, such as pregnancy status provided in the context of an advanced imaging test or cancer infusion treatment.

Attestation: OCR proposes to require a regulated entity to obtain a signed "attestation" from a record requestor when: (i) the request is for PHI potentially related to reproductive health care; and (ii) the request is for one of the following purposes: health oversight activities; judicial and administrative proceedings; law enforcement purposes; and to coroners or medical examiners. OCR outlines a set of information that must be included in an attestation and states that the attestation may be electronic but may not be combined with any other document.

As noted above, it is unfair to expect regulated entities to make a determination of when an attestation is needed, and it would be very burdensome to do so. Therefore, the FAH recommends that if OCR chooses to finalize the proposed prohibition, OCR should require an attestation for every request for PHI related to stated purposes of concern (health oversight activities; judicial and administrative proceedings; law enforcement purposes; and to coroners or medical examiners). This universal approach to attestations would put the requestor, rather than the regulated entity, in the position of determining whether the purpose of the request is lawful and would obviate the need to determine if requested records contains PHI potentially related to reproductive health care.

To support regulated entities, OCR must make it clear that regulated entities are expected to take attestations at face value and will be held harmless in the event of a false attestation. Regulated entities should not be expected to monitor how a requestor that provides an attestation subsequently uses the medical records provided. Similarly, the FAH asks OCR to clarify that the proposed prohibition will only apply to the activities of a regulated entity in response to a request

for information that meets the conditions of the prohibition. For example, inappropriate use of information after a compliant disclosure or the disclosure of data originating with a regulated entity but shared by a third party (such as a health information exchange or third-party app developer) should not be considered the responsibility of the regulated entity.

In addition, the FAH urges OCR to develop and widely disseminate model attestation language for regulated entities to adopt. As discussed further below, OCR must also educate the law enforcement community about the proposed prohibition and the need for attestations.

Notice of Privacy Practices: OCR proposes to require regulated entities to update their notice of privacy practices to include a plain language description of the new prohibition. The FAH supports the need to ensure that individuals understand their rights and protections under HIPAA. However, given the burden of updating notices and training staff on the needed changes, the FAH urges OCR to develop and widely disseminate model language for regulated entities to adopt. To reduce burden and limit the need for consecutive changes to the NPP, OCR also should consider finalizing as part of this rulemaking its earlier proposal to eliminate the requirement to obtain an individual’s written acknowledgment of receipt of a direct treatment provider NPP and instead require that the NPP be publicly available through a regulated entity’s website and patients be provided information on how to access the NPP. (See the [Proposed Modifications to the HIPAA Privacy Rule](#) published in the Federal Register on January 21, 2021).

Educational Needs

As noted above, given significant concerns about the Proposed Rule, if OCR finalizes its proposals, we strongly recommend that OCR engage in a range of activities to educate both the law enforcement community and regulated entities about the rule.

Given that the proposed prohibition would principally affect access to PHI requested by law enforcement and judicial authorities, OCR should work with those communities at both the federal and state levels to communicate any change in policy, including the need for these entities to make attestations about the purpose of their requests for medical records. Educational efforts for law enforcement would need to go well beyond updating the [existing guidance](#) on OCR’s website so that regulated entities are not doubly burdened by both implementing the proposed prohibition and having to explain it to state and local authorities when they request medical records.

Enforcement and Compliance Date

Enforcement: Given the many operational challenges outlined above, it is possible that regulated entities could inadvertently and unintentionally overlook and share reproductive health care information in response to a medical record request for a prohibited purpose. Consequently, it is critical that OCR use discretion in enforcing the proposed prohibition. Regulated entities should be permitted to rely on a “good faith” standard without being subjected to enforcement activities. In the event that a regulated entity faces enforcement activities, they should focus on educating, not penalizing, the regulated entity.

Compliance Date: OCR seeks comment on its proposed compliance date of 180 days after the effective date (60 days after publication of the final rule). Given the complexity of the

proposals and the operational challenges outlined above, we urge OCR to extend the compliance date to 360 days after the effective date. This timeframe would allow regulated entities time to analyze the final rule, work with EHR and release of information vendors to update software, develop workflows to implement the requirements, train release of information staff, and conduct other operational steps. A longer compliance timeframe would also allow OCR time to conduct activities to support regulated entities. Specifically, OCR could (i) develop additional educational materials, model attestations, and model language for the notice of privacy practices to support regulated entities; and (ii) work with the Department of Justice and state governments to educate the law enforcement community on the new provisions, including the attestation requirements.

The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership as OCR works to balance the benefits and burdens of the HIPAA Privacy Rule. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Kuntz". The signature is fluid and cursive, with a long horizontal stroke extending to the right.