



June 16, 2023

Director Melanie Fontes Rainer  
Office for Civil Rights  
US Department of Health and Human Services  
Washington, D.C. 20201

Dear Director Fontes Rainer,

On behalf of the Healthcare Information and Management Systems Society ([HIMSS](#)), we are pleased to provide written comments to the Notice of Proposed Rule Making for [HIPAA Privacy Rule to Support Reproductive Health Care Privacy](#) (2023-07517). HIMSS appreciates the opportunity to leverage our members' expertise to share feedback on the importance of patient privacy relating to reproductive healthcare.

HIMSS is a global advisor and thought leader and member-based society committed to reforming the global health ecosystem through the power of information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology driven by health equity. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision. HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include more than 125,000 individuals, 480 provider organizations, 470 non-profit partners, and 650 health services organizations. Our global headquarters is in Rotterdam, The Netherlands and our Americas headquarters in Chicago, Illinois.

HIMSS supports the work completed thus far across the Department of Health and Human Services (HHS) to protect patients' privacy. This rule will promote access to lawful, safe healthcare services, while ensuring patients' healthcare information is kept private. It is essential that we take all necessary steps to ensure patients' personal health information is kept private and secure within an interoperable health ecosystem. There is nothing more personal to an individual than their health information.

In the wake of the US Supreme Court decision overturning *Roe v. Wade*, there is distrust in the healthcare system's ability to protect personal health information. HIPAA's protections need to remain robust to help protect the privacy of patient information, especially for the most vulnerable.

HIMSS believes it is critical to support the establishment of policies that ensure privacy, data protection, and secure information exchange and to eliminate the potential misuse of patient information. Advancing the state of information privacy across the health sector should be supported to protect the confidentiality, integrity, and

availability of patient information and other sensitive information and ensure the continued and effective delivery of safe, secure patient care and coordination of care.

HIMSS offers the following comments regarding the proposed requirements:

### **Expanding the Proposal**

*Should the proposed prohibition be applied broadly to any healthcare, rather than limiting it to reproductive health care?*

The proposal should be expanded to any healthcare services, rather than limiting it to reproductive care. Healthcare information should not be used unfairly against the patient or individuals coordinating with the patient. Determining who has access and the reasons they have access to data should be the same, irrespective of the types of data. This also reduces the operational challenges of distinguishing between reproductive care versus other types of care.

Notwithstanding this, we also recognize that there are times when law enforcement needs to have access to protected health information for reasonable purposes so long as such purposes do not interfere with legal healthcare services, such as legal reproductive services. The government should consider a process of capturing an attestation from the requesting law enforcement agency that the information will not be used unfairly against patients or individuals coordinating with patients.

### **Highly Sensitive PHI**

*Should HIPAA be amended to prohibit or limit uses or disclosures of "highly sensitive PHI" for certain purposes?*

HIPAA should not be amended to prohibit or limit uses or disclosures of "highly sensitive PHI" for certain purposes. This is highly burdensome and sometimes operationally impossible to segregate the "highly sensitive PHI" from other PHI. OCR should coordinate with the ONC and their HTI-1 [proposed rule](#), which includes a focus on operationalizing data segmentation. At this point, additional work is needed to make data segmentation a reality for all systems.

### **Definitions**

HIMSS concurs with OCR's proposal to make the definition of reproductive healthcare consistent across all media. A consistent, as well as broad definition, is critical to protect patients. To ensure clarity, OCR should include a broad definition of reproductive healthcare in the regulatory text, not only in the preamble guidance. It should be specific and list examples of reproductive healthcare; however, the list of examples should not be exclusive. The method will improve protection of data privacy, improve clarity and aim to prevent states from defining reproductive healthcare in different ways, thus creating inconsistent approaches to data protection.

HIMSS identified that data associated with gender affirming care for transgender individuals is absent from the definition of reproductive healthcare. This should be included in the definition, to protect this vulnerable population and to ensure consistency and clarity of what types of data are to be protected.

## Attestation and Education

HIMSS understands the reason for OCR's proposal to require covered entities to obtain a signed attestation that the health information will not be used to investigate or punish patients seeking or obtaining reproductive health services. We recommend including a model attestation as referred to in the NPRM, along with substantial education, to make it easier to operationalize this requirement. We also recommend that OCR provide additional guidance on the attestation implementation requirements and how a covered entity will be judged in determining the credibility of attestation in addition to a safe harbor to protect covered entities who act in good faith from penalty.

In addition to the model attestation, we recommend revising the [HIPAA Privacy Rule: A Guide for Law Enforcement](#) to be compliant with this rule, as well as include the model attestation and a description of the prohibition indicating that law enforcement will need such an attestation for a covered entity or business associate to respond to certain requests for protected health information. OCR could consider creating similar documents for the other covered entities who need to comply, such as for courts, health oversight agencies, coroners, and medical examiners, to clarify expectations and to make compliance easier. OCR should also collaborate with the Department of Justice to develop and promulgate education on the expectations for anyone requesting or fulfilling attestation, including law enforcement.

As it stands in the proposed rule, the attestation is only required if reproductive healthcare information is involved in the requested data. It may be burdensome for individuals to review the information and identify whether reproductive healthcare information is included. Reproductive health information could be in many different types of records; for example, when a patient receives imaging services, they are asked about pregnancy status. Additionally, some business associates, such as cloud services providers, may not have a reasonable means of knowing whether information that they maintain includes reproductive health care information. Therefore, we recommend that the attestation is required for all requests for protected health information by health oversight agencies, courts, law enforcement officials, coroners, and medical examiners, not only for when there is reproductive healthcare data included.

To the extent that HHS finalizes the attestation requirement to only apply to requests for reproductive healthcare information, we expect that there will be many instances in which a covered entity or business associate violates HIPAA by disclosing protected health information in response to a request that is not accompanied by an attestation without knowing that such protected health information includes reproductive healthcare information. In such circumstances, we believe that it is appropriate for a covered entity or business associate to be able to receive the benefit of the affirmative defense at 42 U.S.C. § 1320d-5(b)(2) and 45 C.F.R. § 160.410(b)(2) if it takes appropriate action within 30 days of discovery of the mistake.

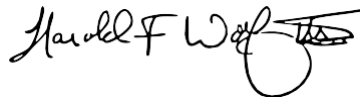
We recommend that OCR clarify the actions that a covered entity or business associate may take within 30 days of discovering an erroneous disclosure of information relating to reproductive healthcare information so that the entity will be deemed to have corrected the violation for purposes of the statutory and regulatory affirmative defense. For example, OCR may clarify that a covered entity or business associate is deemed to

have corrected the violation if, within 30 days of discovery, the covered entity or business associate requests return of the protected health information.

In addition to substantial education requested for the covered entities, HIMSS recommends transparency and education for the patient community with culturally relevant methods. This will improve trust and therefore can lead to higher willingness to access healthcare services.

HIMSS thanks OCR for the opportunity to provide input on this important proposed rule. HIMSS would be happy to facilitate discussions between OCR and HIMSS subject matter experts and we look forward to continuing our partnership with OCR and acting as a resource for the agency. Please feel free to contact [Alana Lerer](#), Senior Government Relations Manager, with questions or for more information.

Sincerely,

A handwritten signature in black ink that reads "Harold F. Wolf III". The signature is written in a cursive style with a large, stylized "W" and "F".

Harold F. Wolf III, FHIMSS  
President & CEO