



CENTER *for* HEALTH LAW
and POLICY INNOVATION
HARVARD LAW SCHOOL

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Melanie Fontes Rainer
Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building 509F
200 Independence Ave
SW Washington, DC 20201

Attn: HIPAA and Reproductive Health Care Privacy NPRM (HHS-OCR-0945-AA20)

Dear Director Fontes Rainer,

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) applauds the Department of Health and Human Services Office for Civil Rights for its commitment to health information privacy. We appreciate this opportunity to provide comments regarding HHS-OCR-0945-AA20.

CHLPI advocates for reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with or at risk for chronic illness. Our program originated in the late 1980s as a provider of direct legal services to people living with HIV. It follows that we are long-time advocates for robust, consent-centric privacy protections—especially when dealing with highly personal and sensitive information that implicates an individual’s safety, freedom from violence and discrimination, and ability to trust in the health care system.

We firmly believe that strengthening this country’s central health information privacy framework to better safeguard reproductive health care privacy is critical. The Health Insurance Portability and Accountability Act (“HIPAA”) and the protections that are and are not afforded thereunder directly impact access to legal, lifesaving, high-quality health care. In this proposed rule, the Department of Health and Human Services (“HHS”) seeks to modify the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”) issued pursuant to HIPAA. Specifically, HHS proposes to restrict certain use and disclosure permissions for protected health information (“PHI”) pertaining to reproductive health care, such as in certain criminal, civil, or administrative investigations.

Throughout this letter, we have focused our comments on recommendations and considerations that we hope will further our shared goals.

1. Proposed Amendments to Section 160.103—Definitions

We support HHS’s clarification of the definition of “Person” and the new definition of “Reproductive Health Care.” We also support HHS’s attention to how terms used in Section 11178(b) of the Social Security Act are interpreted but argue that further action is urgently needed. Abortion reporting—even for a public health purpose as proposed by the NPRM—can severely undermine public health.

Abortion reporting to health departments may require health care providers to include information sufficient to re-identify individuals that receive the reportable care. The [South Carolina Department of Health and Environmental Control’s Report of Induced Termination of Pregnancy](#), for example, mandates detailed reporting of a patient’s age, county of residence, race and ethnicity information, and previous pregnancies. In [Texas](#), mandatory information for reporting includes a patient’s date of birth, county of residence, and marital status. And in [Georgia](#), mandatory information includes patient date of birth, address, and race and ethnicity information.¹

The ease and threat of patient re-identification from these kinds of variables was recently captured by a district court judge in Kentucky:

Hundreds of Kentucky zip codes have a population of less than 1,000. The Commonwealth is 50.7% female, 87.5% white, 8.5% Black or African American, 1.6% Asian, 2% two or more races, and 3.9% Hispanic or Latino. Where these pieces of information are reported in combination for a particular patient, along with other personal information such as previous pregnancies, and are of public record, [health care facilities] are at risk of disclosing protected health information that could be used to identify patients. . . . Records held by [the department of health] are subject to inspection by citizens of the Commonwealth. Forms submitted to [the department of health] with protected health information could be considered public records. The Court finds that it would be possible to ascertain the identity of patients if the information required by [the reporting form] were published²

In addition to public record act concerns, information reported to public health departments is vulnerable to data breaches. State health departments are common targets of data breaches. According to [breach reports](#), 20,815 individuals were affected in a hacking incident recently reported by the Iowa Department of Health and Human Services. Other agencies reporting security incidents to the Office of Civil Rights in the first four months of 2023 alone include the Two Rivers Public Health Department (April 14, 2023), the California Department of Health Care

¹ Georgia forms require providers to report extensive personally identifiable information notwithstanding state regulations that prohibit the form from directly naming individuals. See Ga. Comp. R. & Regs. r. 511-5-7.

² *Planned Parenthood Great Northwest, Hawaii, Alaska, Indiana, and Kentucky, Inc. v. Cameron*, 2022 WL 3973263 (W.D.Ky., 2022) (vacated and remanded following the promulgation of regulations that prohibit identifying information from being included as part of reporting).

Services (March 14, 2023), the Jefferson County Health Department (January 13, 2023), and the Minnesota Department of Human Services (January 11, 2023).

Finally, once in the hands of a health department, information may be disclosed further to law enforcement for purposes of investigating or punishing a person for seeking, obtaining, providing, or facilitating reproductive health care. Health departments vary in their motivation to object to a subpoena, the resources available to fight a subpoena, and/or the knowledge and training to understand their rights and responsibilities when faced with a subpoena.

HHS emphasizes that “disclosures to public health authorities permitted by the Privacy Rule must be limited to the ‘minimum necessary’ to accomplish the public health purposes and that, in many cases, regulated entities need disclose only de-identified data to meet the public health purpose.” But this requirement is currently misunderstood, willfully misinterpreted, and poorly enforced. The following example is illustrative of our concern.

CHLPI has spent the past year providing technical assistance to a health clinic that is a sub-recipient of funds to provide Ryan White Treatment Modernization Act Part B services (the “Clinic”). The Clinic has been in a prolonged battle with its state department of health (the “State Health Department”) over a proposed data sharing agreement to be executed by the parties. The State insists on receiving robust, personally identifiable data on Ryan White clients receiving care from the Clinic. The Clinic rightfully argues that it should be able to provide de-identified data—the minimum necessary for Ryan White program monitoring and management purposes.³

Several factors limit the ability of the Clinic to fight the health department: (1) HHS [permits](#) regulated entities to rely on a health department’s judgment as to the minimum amount of information needed to accomplish its purpose and the State Health Department has leaned heavily on this flexibility to run roughshod over the concerns of the Clinic; (2) in our experience, federal regulators may be deferential to the proclaimed data needs of a health department without sincere or rigorous inquiry into the connection between personally identifiable data sought and a legitimate public health purpose, thereby leaving no clear recourse for wary health care providers;⁴ and (3) the State Health Department has significant power over the Clinic because the Clinic receives Ryan White funding through the health department—funding that enables the Clinic to provide essential, life-preserving services—but the State Health Department has conditioned funding on agreement to these overly inclusive data sharing provisions.

³ In many other jurisdictions, the department of health collects only de-identified data from its Ryan White sub-recipients for the same purported purpose of monitoring agency contracts. See e.g., Boston Public Health Commission, e2Boston: Data Sharing and Eligibility (Apr. 7, 2021), <https://perma.cc/G9JQ-TBU5> (“In order to monitor agency contracts, the above identifiable information may also be de-identified to become accessible to the [Ryan White Services Division of the Boston Public Health Commission] as the Ryan White Part A Recipient, their program and administrative staff or consultants, and RDE Systems, the organization providing the software and technical support for the e2Boston system.”).

⁴ To date, the Clinic has been informed that “RWHAP recipients are permitted to request personally identifiable information from their subrecipients for oversight purposes” without any apparent limitations or legitimate inquiry into necessity pursuant to 45 C.F.R. §§ 75.101(b), and 75.352(b).

With respect to disclosures for public health purposes, we recommend the following additional actions in furtherance of HHS's goals:

- HHS should clarify that HIPAA's minimum necessary standard preempts the inclusion of HIPAA identifiers in abortion monitoring and surveillance activities. Moreover, HHS should clarify the circumstances in which the minimum necessary standard ever permits anything more than the provision of de-identified data to health departments.
- HHS should ensure that all of its operating components, including those that work closely with state departments of health (e.g., the Health Resources and Services Administration, the Centers for Disease Control and Prevention) are active partners in holding state departments of health accountable to HIPAA's minimum necessary standard.
- HHS should create and maintain a dedicated process for regulated entities to elevate concerns and file complaints against state, county, or local departments of health. The process should be transparent, allowing such entities to know the status of their complaints at any point in time, and efficient, avoiding long delays that can further burden regulated entities. To ensure accountability, complaint metrics and correction plans should be made available to the public in a timely manner.

2. Proposed Amendments to Sections 164.502, 164.509, and 164.512—Uses and Disclosures

Overall, we support HHS's proposed amendments to Sections 164.502, 164.509, and 164.512. We believe they will have a positive impact on access to health care, care quality, and health equity. **Our responses to specific requests for comment regarding reproductive health care privacy are as follows:**

Should the proposed requirement in section IV.C. apply as a condition of any additional permitted uses and disclosures that could be used to request uses and disclosures of PHI for a prohibited purpose?

- We think it is important that, for disclosures for treatment purposes, attestation is required where the third party is not regulated by HIPAA. Not all health care providers are subject to HIPAA. Moreover, in [previous proposed rulemaking](#) and [guidance](#), HHS has emphasized that regulated entities may disclose a patient's PHI to unregulated social services entities for treatment purposes. Accordingly, this form of permitted disclosure leaves pregnant people especially vulnerable to actions that circumvent the NPRM's proposed prohibition on use and disclosure.

Would a model attestation be useful for regulated entities? If so, what other information should be included within such model attestation to improve regulated entities' understanding of the proposed attestation requirements, if adopted?

- A model attestation would support rapid, clear, and consistent implementation of the new rules. Consistent with HIPAA standards governing business associate agreements and data use agreements, requesters should have to attest that they will not use or disclose information in a manner that is not expressly provided for in the attestation. The attestation should also commit requesters to destroying or returning information in a timely manner.

Should requesters of PHI be required to name the individuals whose PHI they are requesting, or is describing a class of individuals whose PHI is requested sufficient?

- In furtherance of the minimum necessary standard and data minimization best practices, requesters should be required to name the individuals whose PHI they are requesting. This additional protection helps to ensure that requests are intentional, well thought-out, and reasonable in scope.

Additionally, while the focus of the NPRM is on safeguarding reproductive health care privacy, HHS requests feedback on whether and how to protect other forms of highly sensitive health information.

We urge HHS to eliminate existing permissions for regulated entities to disclose PHI to law enforcement without patient authorization *except* in very limited, clearly enumerated circumstances in which the alleged criminal conduct is wholly unrelated to the person's health status (e.g., to report a crime committed on the premises where the victim is a member of the regulated entity's workforce).

Health-related information is among the most sensitive types of information that can exist about an individual. Furthermore, the situations in which the ability to deliver high quality health care is undermined because of potential uses of health information against an individual patient cannot effectively be enumerated. The following examples are illustrative of areas of concern— but they are not the only ones.

- HIV prevention, care, and treatment depends on complete, accurate, and timely information (regarding, e.g., viral load). But HIV prevention and response efforts are undermined by the fact that health care provider records, other medical records, and health departments are sources of health information that may be used in HIV-related prosecutions.⁵ The negative impacts of HIV criminalization on HIV testing and other

⁵ See, e.g., Sero Project, *The National HIV Criminalization Survey, 2021* (2023), <https://perma.cc/CYM2-2VDX> (documenting negative impacts of HIV criminalization laws including decreasing trust in public health professionals,

health-promoting activities are exacerbated by the fact that HIV criminalization laws in many jurisdictions are outdated and do not take into account current scientific and medical evidence.⁶

- Pregnant people using substances should be encouraged to access support and care systems, and to provide complete and open information to their health care providers. However, [as emphasized by this administration’s Office of National Drug Control Policy \(ONDCP\)](#), “many pregnant women with SUD are reluctant to engage in SUD treatment for fear of mandatory referrals to child welfare, resulting in their child being removed from the home and placed in foster care.” Disclosures for purposes of criminalization and other punitive actions of information relating to drug use disclosed to health care providers, drug testing by health care providers, and drug treatment of pregnant people—whether or not this information is revealed to a health care provider as part of reproductive health care services—deter vulnerable pregnant people from essential health care.⁷
- Robust protections are also critical for the health and safety of transgender and gender diverse individuals and those who care for them. Transgender and gender diverse people routinely face discrimination and stigma in health care and other settings.⁸ Potential disclosure of health information can increase fears of engaging with the health care system for necessary, life-saving medical treatment.⁹ Additionally, states continue to propose and pass legislation restricting youth access to gender-affirming care, including

limiting information sharing with health care providers, and making it harder for AIDS service organizations to conduct open work on HIV disclosure).

⁶ See, e.g., Chris Beyrer and Robert Suttle, *Living with HIV isn’t a crime. Why is the United States treating it like one?*, The New York Times (Aug. 26, 2019), <https://perma.cc/YCG7-KPW3> (describing applications of the law “contrary to scientific evidence” and efforts to “ensure that the significant advances in HIV science are taken into account in HIV-related legal cases”); ChangeLab Solutions, *HIV Criminalization Legal and Policy Assessment Tool* (2022), <https://perma.cc/GU2B-HCSV> (“The scope, characteristics, and application of HIV criminalization laws vary substantially among jurisdictions. These variations include the extent to which such laws adhere to current evidence-based best practices such as the US Department of Justice’s recommendations on aligning HIV-specific criminal laws with scientifically supported factors.”)

⁷ See, e.g., Sarah CM Roberts and Amani Nuru-Jeter, *Women’s perspectives on screening for alcohol and drug use in prenatal care*, 20 *Womens Health Issues* 193 (2010) (“Most women were averse to having drug . . . use identified and were mistrustful of providers’ often inconspicuous efforts to discover drug use. Women expected psychological, social, and legal consequences from being identified, including feelings of maternal failure, judgment by providers, and reports to Child Protective Services. Women did not trust providers to protect them from these consequences. Rather, they took steps to protect themselves. They avoided and emotionally disengaged from prenatal care, attempted to stop using substances that could be detected by urine tests before prenatal care visits, and shared strategies within social networks for gaining the benefits of prenatal care while avoiding its negative consequences.”).

⁸ Fenit Nirappil, *For trans people, medical visits can be more traumatizing than healing*, The Washington Post (Mar. 24, 2023), <https://perma.cc/WG8S-3JTK>.

⁹ See, e.g., Colleen Schrappen, *Parents of patients at St. Louis transgender center fear privacy breaches, file complaints*, St. Louis Post-Dispatch (Mar. 20, 2023), <https://perma.cc/E3C3-E32H>; H. Thompson, *Patient Perspectives on Gender Identity Data Collection in Electronic Health Records: An Analysis of Disclosure, Privacy, and Access to Care*, 1 *Transgender Health* 205, 210 (2016).

through the criminalization of parents/guardians and providers who assist youth in obtaining such evidence-based medical care.¹⁰ Providers have faced threats of violence¹¹ and families have faced child abuse investigations.¹²

HHS has an important opportunity in this rulemaking to eliminate the egregious violation of trust that occurs any time the act of accessing legal health care is weaponized against individuals.

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Thank you again for your commitment to protecting access to health care, preserving the patient-provider relationship, and strengthening health information privacy. We would be happy to work with HHS in furtherance of these shared goals. Please e-mail Rachel Landauer (rlandauer@law.harvard.edu), Maryanne Tomazic (mtomazic@law.harvard.edu), and Erika Hanson (ehanson@law.harvard.edu) with any questions.

Sincerely,



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on behalf of

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¹⁰ See, e.g., L. Dawson, J. Kates, & M. Musumeci, *Youth Access to Gender Affirming Care: The Federal and State Policy Landscape*, Kaiser Family Foundation (June 2022), <https://perma.cc/7Z2T-X3US> (noting a 2022 Alabama law making it a felony for an individual to assist a transgender minor to receive puberty blockers, hormone therapy, and surgical intervention, a 2021 Arkansas law prohibiting health care providers from making referrals for minors seeking certain gender affirming treatment, and a 2021 Texas gubernatorial directive calling for penalties for parents and health care providers that assist youth in accessing certain gender-affirming care); Movement Advancement Project, *Bans on Best Practice Medical Care for Transgender Youth* (May 2023), <https://perma.cc/A6FW-E5DP> (“19% of transgender youth (ages 13-17) live in states that ban best practice medication and surgical care for transgender youth.”).

¹¹ Letter from American Academy of Pediatrics, American Medical Association, and Children’s Hospital Association to Attorney General Merrick Garland (Oct. 3, 2022), <https://perma.cc/BCS4-8EEV> (“From Boston to Akron to Nashville to Seattle, children's hospitals, academic health systems, and physicians are being targeted and threatened for providing evidence-based health care. These attacks have not only made it difficult and dangerous for institutions and practices to provide this care, they have also disrupted many other services to families seeking care.”); Susan Sudborough, *Boston Children’s Hospital received another bomb threat, police say all clear*, Boston.com (Nov. 16, 2022), <https://perma.cc/AT3E-CVBL> (“The email said the sender had placed bombs at Boston Children’s Hospital and made threats against the hospital’s doctors. . . . The sender said they were targeting the hospital because they opposed its Gender Multispecialty Service (GeMS) program. The program provides gender-affirming care, including hormone blockers and hormone therapy, to transgender and non-binary youths.”)

¹² Caitlin Gibson, *Texas is home. The Briggie family and their trans child are fighting for it.*, The Washington Post (April 10, 2023), <https://perma.cc/B86M-U7G4> (reporting at least 15 families that were investigated for child abuse).