The Network
for Public Health Law

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June 1, 2023

U.S. Department of Health and Human Services
Office of Civil Rights
Attention RFC, RIN 0945-AA20
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: RFC, RIN 0945-AA20

This letter provides the Network for Public Health Law's comments in response to the Office for Civil Rights (OCR), Department of Health and Human Services (HHS) Request for Comments (RFC) seeking public input on the regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as that law has been modified from time to time. The Network supports the proposed regulations and provides the following comments to expound on further suggestions and support.

Background

The Network is a national nonprofit organization that works to advance the use of law and policy to improve lives and make communities safer, healthier, stronger, and more equitable. Through the provision of non-partisan legal technical assistance, resources, and training, the Network collaborates with a broad set of partners across sectors to expand and enhance the use of practical legal and policy solutions. For over a decade, the Network has helped public health officials, policymakers, researchers, health care providers, and advocates across the country understand and advance evidence-based laws, policies, and regulations to improve health outcomes in communities. Through meticulous research and analysis, Network attorneys provide legal expertise and guidance on an array of critical public health issues, including health data privacy and reproductive health care access.

Network attorneys are recognized as HIPAA subject matter experts, having provided substantial legal support to state and local public health authorities (PHAs) regarding HIPAA compliance. Such support has included providing legal technical assistance to PHAs on individual HIPAA questions, authoring legal resources on HIPAA, and developing and presenting webinars on HIPAA topics. These attorneys also have substantial experience providing legal opinions on, and operationalizing compliance with, HIPAA and its Privacy, Security, and Breach Notification Rules, in a public health agency setting.

The Network has also worked for years on numerous legal issues influencing health equity, including maternal health and access to health care among many others. In anticipation of the tremendous public health and health equity challenges that would emerge following the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* (June 2022), which overturned 50 years of precedent and eliminated federal constitutional abortion rights, the Network accelerated our work in reproductive health and equity.[i] Network attorneys are developing a growing body of resources, webinars, and professional presentations to address the serious legal questions and health equity issues

emerging across the U.S. in the absence of *Roe v. Wade*. The Network has provided legal technical assistance to dozens of practitioners, officials, policy leaders, and care providers regarding the impacts and aftermath of *Dobbs,* clarifying and assessing the new U.S. reproductive health legal landscape in constitutional law, data privacy, and other arenas.

The critical importance of HHS' proposed rulemaking is highlighted by the sheer reality of reproductive health in the U.S. post-*Dobbs*. Reproductive health-related civil and criminal consequences pose a barrier to achieving health equity and health justice. As noted by Professor Michele Goodwin,[ii] among others, attempts to criminalize reproductive health outcomes predominantly impact pregnancy-capable individuals of color and those experiencing low incomes. In an increasingly polarized and highly volatile landscape post-*Dobbs*, protecting the privacy of reproductive health information is paramount to preventing inequitable enforcement of state laws criminalizing health care access.

Comments

We have organized our comments by section of the HIPAA Rules. Our comments address several specific and general questions posed by OCR/HHS (the Department) in the RFC, including:

- IV.A.4.a. "Whether the definitions the Department proposes to adopt are appropriate."
- IV.A.4.c. "Whether the Department should provide examples of 'reproductive health care' in regulatory text, or it is sufficient to provide extensive discussion of the examples in preamble?"
- IV.A.4.d. "Whether it would be helpful for the Department to define any additional terms. If so, please propose a definition and support for the definition and rationale."
- IV.B.4.e. "Whether the proposed prohibition in section IV.B.2. is sufficiently narrow so as to limit harmful uses or disclosures (such as for investigating individuals who have obtained, or health care providers who have provided, lawful health care primarily because they obtained or provided the lawful health care)…. If not, please explain and provide examples."
- IV.C.3.r. "Whether the proposed attestation requirement in section IV.C. would address all relevant types of permitted uses and disclosures under the Privacy Rule."
- IV.D.4.d. "The way in which regulated entities currently receive and address requests for PHI when requested pursuant to the Privacy Rule permissions at 45 CFR 164.512(d) (uses and disclosures for health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (uses and disclosures about decedents to coroners and medical examiners)."
- IV.E.4.ii. "Whether it would benefit individuals for the Department to require that covered entities include a statement in the [Notice of Privacy Practices (NPP)] explaining that when PHI is disclosed for a permitted purpose to an entity other than a covered entity (*e.g.,* disclosed to a non-covered health care provider for treatment purposes), the recipient of the PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply."

45 CFR § 160.103
Definitions

We support the addition of the definitions of "public health" and "reproductive health care" as well as the amended definition of "person." The additional definitions balance the need for health records to be appropriately shared with the enhanced privacy concerns that reproductive health care records raise.

The Network supports the clarifying definition for "public health" which will ensure that jurisdictions cannot use their public health agencies to probe private health care decisions. Investigating patient medical decisions is not a traditional public health activity and while it should not be necessary for OCR to unequivocally state that in its proposed rules, the Network supports such a strong statement given current legislative and judicial action. In Texas, the Health and Human Services Commission is empowered with enforcing the "Abortion Complication Reporting Requirements" and the Commission is mentioned throughout SB8, the "Fetal Heartbeat Bill." Public Health agencies must remain active in protecting and promoting the life and wellness of their constituents, not in investigating their personal health care decisions. With trust in public health in question following the COVID-19 pandemic, for states to potentially use their public health agencies to probe into private medical decisions would further erode that trust. The Network supports the clarification that public health may not be used to harass individuals who have made the choice to terminate pregnancies.

Additionally, we encourage the Department to provide examples of "reproductive health care" in regulatory text to provide greater clarity to patients, regulated entities, and their legal counsel. While the Department intends for the definition of "reproductive health care" to be read broadly, without examples of the broad range of services intended to fall under that definition, regulated entities may not understand the Department's true intent, especially as time passes.

Changes to Definition of Health Oversight Agency to Exclude Investigations and Prosecutions Relating to Reproductive Health Care

Inspectors general and similar agencies typically fall within the definition of health oversight agency. However, some inspectors general may consider themselves in some instances to be law enforcement officials since they enforce certain laws. The line between these two types of activity—health oversight and law enforcement—may be difficult or even impossible to define. An investigation into potential fraud and abuse, for example, could potentially uncover activity unrelated to fraud or abuse that is nevertheless contrary to state law, such as laws relating to reproductive health. To this end, we believe the Department should consider expressly stating that the definition of health oversight does not include investigations and prosecutions relating to reproductive health. We encourage the Department to add an additional definition of "Health Oversight" to 45 CFR § 160.103 or amend the definition of "Health Oversight Agency" in 45 CFR § 164.501. The goal of the additional, or amended, definition would be to align the health oversight activities/agencies language with the proposed public health activities/agencies language to ensure that health oversight agencies do not misuse their investigatory powers. The language could mirror the definition proposed for "public health" in 45 CFR § 160.103,

> 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.

45 CFR § 164.502
Uses and disclosures of protected health information: General rules.

We support the addition of a new category of prohibited uses and disclosures concerning reproductive health care records. The Department has long recognized and promoted innovative public policies surrounding PHI and addressed novel challenges to the security and privacy of health records. As noted in the preamble, the Department has previously published rules that prohibit certain health plans from using or disclosing genetic information for underwriting purposes as well as prohibiting the sale of PHI.

Since the Supreme Court's decision in *Dobbs*, states have regulated reproductive health care with little federal intervention. Some states, such as California, Connecticut, Delaware, Illinois, Massachusetts, New Mexico, New Jersey, New York, and Washington, and the District of Columbia, have passed laws that seek to shield those records from out-of-state prosecutors and investigators. However, health care information, like patients, frequently crosses state lines. Many state health information exchanges are interoperable across jurisdictions. This interoperability facilitates care for patients but may also create gaps through which patient records cannot be shielded.[iii] A federal solution that preempts state law is necessary to better protect the privacy of reproductive health records regardless of which state an individual happens to seek care in.

We applaud the Department for clearly and unequivocally stating, "[u]nder the Constitution, an individual cannot be barred from traveling from one state to another to obtain reproductive health care." Further, we agree with the Department's assessment that the proposed prohibition, by barring uses or disclosures of PHI where the data would be used to support an investigation or proceeding relating to lawful reproductive health care, would discourage providers and patients from intentionally leaving gaps or inaccuracies in medical records due to fears about how the information may be used. These clear policy positions will support jurisdictions and providers that are daily fighting misinformation and fear surrounding reproductive health care.

However, there is one area that this prohibition does not touch and that is educational records maintained by school nurses who see adolescent patients in schools but who are not covered entities, as that term is defined at 45 CFR § 160.103. While we understand that educational record privacy is outside the Department's purview, we encourage the Department to work with its sister agency to protect the reproductive health records held by schools that are not HIPAA covered entities. Adolescents are among the most vulnerable patients in need of reproductive health care as they are under-resourced and often unable to make their own medical decisions. If a student chooses to speak to a school nurse regarding reproductive health concerns, the nurse's records could be subject to inspection by the student's parents as health records become part of a student's educational record, which is open to inspection upon request by that student's parent/guardian. Whereas, under HIPAA, if a minor consents to reproductive health care permissibly under state law and does not use their guardian's health insurance, their records would be confidential under HIPAA. We encourage cross-agency conversation to fill in the gaps left by the Family Educational Rights and Privacy Act (FERPA) and secure reproductive health care privacy for minors as appropriate.

As the Department has used this Notice of Proposed Rule Making to fill in the gaps left by state law in an age of interoperability, we encourage the Executive Branch to go further to ensure that all reproductive health records are subject to rigorous privacy standards.

45 CFR § 164.509
Uses and disclosures for which an attestation is required.

We support the addition of an attestation requirement in a new section 45 CFR § 164.509 as an additional administrative safeguard to bolster privacy of Protected Health Information (PHI) relating to reproductive health. Following the *Dobbs* decision, reproductive health data can no longer be treated as equivalent to any other PHI. Elevated protections, like those provided through the attestation requirement, will better address the increased potential for misuse of reproductive health data. The attestation requirement would provide much needed protection for health information after an initial permitted disclosure, limiting subsequent disclosures. We agree that this requirement will enhance protection in circumstances in which the uses or disclosures of an individual's PHI have the greatest potential to support adverse legal action relating to lawful reproductive health care.

Attestations are a feature of some recent state laws designed to bolster privacy protections of reproductive health information. For example, on April 5, 2023, New Mexico enacted Senate Bill 13, which bars submission of out-of-state subpoenas in connection with interstate investigations or proceedings relating to legal reproductive health care delivered in New Mexico unless the request is accompanied by an attestation, signed under penalty of perjury, that the proceeding is based on a claim that would also be recognized under New Mexico law. Similarly, Illinois passed House Bill 4664 in January 2023, requiring that subpoenas seeking documents relating to lawful reproductive health care or a claim that would interfere with a person's rights to reproductive health care under Illinois law must be accompanied by an attestation, also signed under penalty of perjury, that the requests fall under a valid exemption to the general prohibition against disclosure.

We believe that an attestation requirement in 45 CFR 164.509 would, in many instances, provide an appropriate additional safeguard against subsequent disclosures, especially where the initial disclosure may be to a non-covered entity. If used correctly, the provision would promote privacy of PHI by requiring a new attestation for each use and disclosure. We agree that members of historically underserved and marginalized groups are more likely to be the subjects of investigations and proceedings related to lawful reproductive health care.[iv] The attestation requirement promotes equity by increasing privacy protections for the groups most vulnerable to adverse legal actions.

We believe HHS has identified appropriate contexts in which the attestation would provide additional safeguards: disclosures for health oversight activities; for judicial and administrative proceedings; for law enforcement purposes; or about decedents to coroners and medical examiners. As discussed below, these contexts present increased risk for misuse or violation of the respective provision permitting uses and disclosures.

45 CFR § 164.512(d)
Health Oversight

Some health oversight agencies perform a variety of functions—not all of which fall within the definition of health oversight activity at 45 CFR 164.501—including functions akin to law enforcement. For example, an inspector general may investigate fraud and abuse, provide general oversight over the health care system, and enforce civil rights law—all health oversight activities by definition—but may also conduct unrelated investigations centered around public employees' actions, including public sector health care providers, public health employees, health officials, and board of health members. This creates the potential for oversight agencies to access PHI for permitted purposes under 45 CFR 164.512(d) but subsequently use the information for law enforcement activities such as investigations and prosecutions relating to reproductive health. Furthermore, because a health oversight agency is unlikely to be a covered entity, it would likely not be subject to the Privacy Rule with respect to the PHI

it obtains for health oversight and therefore is not subject to HIPAA with respect to these redisclosures of PHI.

Furthermore, since a disclosure of PHI for health oversight under 45 CFR 164.512(d) does not currently require any satisfactory assurances or other procedural protections, an oversight agency obtaining protected health information under 45 CFR 164.512(d) is not currently required to provide any agreement to not re-use or re-disclose the PHI in a manner inconsistent with 45 CFR 164.512(d) or beyond the scope of the health oversight activity for which it was obtained. We believe the proposed attestation requirement would appropriately limit the use and disclosure of PHI to the initial, permitted purpose.

45 CFR § 164.512(e)
Judicial and Administrative Proceedings

We agree that permitted uses and disclosures of PHI for administrative proceedings pursuant to 45 CFR § 164.512(e) must not include uses and disclosures relating to investigations and proceedings involving an individual's choice to seek reproductive health care. However, we believe the existing procedural protections set forth in 45 CFR 164.512(e) provide adequate safeguards, obviating the need for a separate attestation document.

In administrative proceedings, PHI is often disclosed to and used by entities that are not subject to the HIPAA Privacy Rule Rules, such as law firms or pro se litigants. Furthermore, the government is frequently a party in proceedings. Because the government performs many different functions, there is a potential for subsequent use or disclosure outside of the judicial or administrative proceeding for which the PHI was legitimately used or disclosed.

Nevertheless, 45 CFR 164.512(e) already includes several procedural protections designed to safeguard PHI against unauthorized uses and disclosures. Owing to the existing complexity of the Privacy Rule and administrative burden placed on records custodians, we encourage the Department to consider expanding existing procedural protections within 45 CFR 164.512(e) to better protect reproductive health information rather than requiring a separate attestation document.

For example, where a use or disclosure is currently permitted in judicial and administrative proceedings pursuant to a court order, the Privacy Rule could require that court orders include express language prohibiting uses and disclosures in investigations and proceedings relating to reproductive health. Similarly, where the rule currently permits uses and disclosures in response to a subpoena, discovery request, or other lawful process, where the request is accompanied by satisfactory assurances, the Privacy Rule could require that the satisfactory assurances similarly include additional protections. For example, where the current rule permits the use of a qualified protective order to provide satisfactory assurances, the Privacy Rule could require that the qualified protective order include additional language prohibiting uses and disclosures in investigations and proceedings relating to reproductive health care.

45 CFR § 164.512(f)
Law Enforcement

We agree that law enforcement is an appropriate category for requiring an attestation to prevent use and disclosure of PHI related to reproductive health. Law enforcement agencies are generally not covered entities, so once PHI is released to law enforcement, even for a legitimate purpose, it is no longer subject to the Privacy Rule. An attestation would require a law enforcement official to make clear that the use of disclosure is not for a prohibited purpose,

such as for investigations or proceedings relating to an individual seeking reproductive health care.

45 CFR § 164.512(g)
Medical Examiners and Coroners

Likewise, we agree that medical examiners and coroners constitute an appropriate category for requiring an attestation to prevent improper use and disclosures of reproductive health data. These entities generally are not covered by HIPAA, but nonetheless access PHI that can be used in investigations and proceedings. Determination of a cause of death is relied upon by law enforcement, prosecutors, juries, and judges. It is important that PHI collected for legitimate use cannot be seized and used inappropriately. We agree with the Department regarding the pivotal role that a fetal autopsy may play as evidence for police and prosecutors, which is particularly important in the context of pregnancy loss. There are many misconceptions and biases about pregnancy risks and harms that necessitate particular care when handling related data. The attestation requirement appropriately emphasizes how this data can be used, even where the PHI refers to an individual who is deceased.

45 CFR § 164.512
Uses and disclosures for which an authorization or opportunity to agree or object is not required.

For the reasons set forth above, we support modifying 45 CFR § 164.512 to require attestations or similar procedural protections for disclosures of PHI for health oversight activities; for judicial and administrative proceedings; for law enforcement purposes; or about decedents to coroners and medical examiners.

45 CFR 164.512(f)(1)(ii)(C)
Clarifying Requirements for Administrative Requests

We support clarifying that, under 45 CFR 164.512(f)(1)(ii)(C), a disclosure to law enforcement in response to an administrative request is permitted only if the administrative request is of a type that requires a response by law. There has long been confusion over what constitutes a valid "administrative request," and the absence of a definition of the term within the rules has led to ambiguity. Where there is ambiguity or room for misinterpretation in the rules, there is potential for non-compliance. What's more, employees of law enforcement agencies are unlikely to receive HIPAA training because those agencies are not covered entities and so law enforcement officials may be unaware of HIPAA's requirements for uses and disclosures of PHI.

We agree with the Department that some covered entities could misinterpret—and may already have misinterpreted—the requirements for an administrative request and may apply the provision in a manner inconsistent with the intent of the Privacy Rule. This has the potential to introduce intentional and unintentional misuse. We therefore fully support clarification that a valid administrative request is one for which the law requires a response.

45 CFR § 164.520
Inclusion of new prohibition and attestation requirement in notice of privacy practices

We support increasing transparency to the public about what a covered entity may do with PHI, through changes to the required elements of a valid NPP. The proposed modification to 45 CFR § 164.520 may help to alleviate some of the increased fear that has arisen following *Dobbs*. For example, increased public awareness of the prohibition on uses and disclosures in investigations and proceedings relating to reproductive health care and the attestation requirement, via inclusion in the NPP, may increase individuals' confidence that information they share with their health care providers will remain

confidential. As a result, they may feel more comfortable seeking needed care and disclosing all relevant details to their provider.

45 CFR § 164.520

Inclusion of statement regarding subsequent disclosures in notice of privacy practices

We also support including an explicit statement in the NPP explaining that when PHI is disclosed for a permitted purpose to an entity that is not covered, the recipient will not be bound by the proposed prohibition on uses and disclosures in investigations and proceedings relating to reproductive health care. Most people are under- or uninformed about HIPAA protections. In particular, most people do not understand which entities are covered, the scope of HIPAA's applicability, or how HIPAA does or doesn't apply to subsequent disclosures. Adding language to the notice will help alleviate some of the confusion and lack of knowledge about protections particularly regarding disclosures to entities not covered by HIPAA.

Further, the Privacy Rule currently requires a valid authorization to release PHI under 45 CFR 164.508(c)(2)(iii) to include a statement explaining that PHI disclosed pursuant to the authorization may be subject to subsequent disclosure. Adding a similar statement to the NPP would be similarly appropriate and would promote individual's understanding of their rights under HIPAA and the limitations of HIPAA's protections. We believe an individual with a better understanding of the potential uses and disclosures of their protected health information will make more informed decisions as to their protected health information.

Respectfully submitted,

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[i] *Reproductive Health and Equity*, NETWORK FOR PUB. HEALTH L., https://www.networkforphl.org/resources/topics/reproductive-health-and-equity/ (last visited May 18, 2023).
[ii] MICHELE GOODWIN, POLICING THE WOMB: INVISIBLE WOMEN AND THE CRIMINALIZATION OF MOTHERHOOD (Cambridge University Press 2020).
[iii] CARLEEN M. ZUBRZYCKI, THE ABORTION INTEROPERABILITY TRAP, YALE L. J., https://www.yalelawjournal.org/forum/the-abortion-interoperability-trap (October 18, 2022).
[iv] *See* GOODWIN, POLICING THE WOMB: INVISIBLE WOMEN AND THE CRIMINALIZATION OF MOTHERHOOD.