

June 16, 2023

VIA ELECTRONIC SUBMISSION

Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW, Mary E. Switzer Building
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (RIN 0955-AA03)

Dear Dr. Micky Tripathi:

The Center for Reproductive Rights (“CRR”) appreciates the opportunity to comment on the notice of proposed rulemaking (“NPRM”), Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, published April 18, 2023.¹

Since 1992, the Center for Reproductive Rights has used the power of law to advance reproductive rights as fundamental human rights worldwide. Our litigation and advocacy over the past 30 years have expanded access to reproductive health care around the nation and the world. We have played a key role in securing legal victories in the United States, Latin America, Sub-Saharan Africa, Asia, and Eastern Europe on issues including access to life-saving obstetric care, contraception, safe abortion services, and comprehensive sexuality information. We envision a world where every person participates with dignity as an equal member of society, regardless of gender; where individuals are free to decide whether or when to have children and whether or when to get married; where access to quality reproductive health care is guaranteed; and where every person can make these decisions free from coercion or discrimination.

Interoperability generally allows medical records to be shared across state lines and among covered entities in order to facilitate care coordination. This NPRM would enable a certified health information technology (“IT”) user to implement a process to restrict data from use or disclosure in response to a patient request. This data restriction process would help operationalize the HIPAA Privacy Rule’s “right to request a restriction” on uses and disclosures of protected health information (“PHI”).

I. Operationalizing patient requested restrictions is crucial because of the stigma, discrimination, and retaliation that patients may face for accessing reproductive health care.

The NPRM policies on patient requested restrictions come at a critical time, as patients and providers who obtain or provide abortion care are increasingly criminalized and privacy concerns are mounting. This NPRM was released right on the heels of an updated HIPAA Privacy Rule

¹ Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. 23746 (proposed Apr. 18, 2023) (to be codified at 45 CFR pts. 170, 171), .

specific to reproductive health, and this NPRM preamble explicitly recognizes that reproductive health has historically been stigmatized.²

While we acknowledge the benefits of interoperability for facilitating patient care, the United States Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*³ requires rethinking many longstanding health care assumptions, including that information sharing between providers is always positive.⁴ In fact, interoperability may have troubling effects on abortion care, and there are circumstances in which information sharing is not in a patient’s best interest. For example, research shows that unnecessary reporting by health care providers is frequently the driver for the criminalization of pregnant people.⁵ Such reporting can have a detrimental effect on the patient-provider relationship and may result in fewer people seeking health care.

Reproductive health care data can be gathered from billing, laboratory, imaging, and medication records. Beyond care providers, this information may be available to laboratories, pharmacies, payers, and patient-managed apps, because “documenting anywhere is equivalent to documenting everywhere.”⁶ This is particularly problematic given the disparate state laws regarding the criminalization of reproductive health care.

For example, if a patient who has an out-of-state abortion in a haven state receives any subsequent medical care in a restrictive state, abortion-related or not, it is likely that the patient’s entire medical record will be available to providers in the restrictive state.⁷ And while the HIPAA Privacy Rule on reproductive health care attempts to protect the PHI of patients who received lawfully provided care out of state, there is enormous variation in how in-state providers, particularly those hostile to abortion, will treat that information. The free flow of reproductive health data through an interconnected technological ecosystem, notwithstanding the HIPAA Privacy Rule, “risks harassment, litigation, and devastation for patients,” including potentially being subject to investigation and prosecution.⁸ Already, we have heard stories from patients whose medical records automatically populated at a health care provider’s facility in a hostile state and who subsequently faced harassment and intimidation from that provider based on abortion care the patient received previously in another state. Importantly, a 2022 study found

² *Id.* at 23791.

³ 213 L. Ed. 2d 545, 142 S. Ct. 2228 (2022).

⁴ See Raman R. Khanna, et al., *Protecting Reproductive Health Information in the Post-Roe Era: Interoperability Strategies for Healthcare Institutions*, 30 J. AM. MED. INFORMATICS ASS’N. 161, 162 (2022).

⁵ Laura Huss, Farah Diaz-Tello, & Goleen Samari, *Self-Care, Criminalized: August 2022 Preliminary Findings, If/When/How* (2022), <https://www.ifwhenhow.org/resources/self-care-criminalized-preliminary-findings/> (finding that thirty-nine percent of adult cases came to the attention of law enforcement through health care providers).

⁶ See Raman R. Khanna, et al., *Protecting Reproductive Health Information in the Post-Roe Era: Interoperability Strategies for Healthcare Institutions*, 30 J. AM. MED. INFORMATICS ASS’N. 161, 162 (2022).

⁷ Carleen M. Zubrzycki, *The Abortion Interoperability Trap*, 132 YALE L.J. 197, 200 (2022), https://www.yalelawjournal.org/pdf/F7.ZubrzyckiFinalDraftWEB_6jsh8oxp.pdf. Zubrzycki, *The Abortion Interoperability Trap*, 132 YALE L.J. 197, 200 (2022), https://www.yalelawjournal.org/pdf/F7.ZubrzyckiFinalDraftWEB_6jsh8oxp.pdf.

⁸ *Id.* at 227.

that more than one-third of criminal investigations regarding ending a pregnancy were initiated by health care providers (39%).⁹

ONC seeks comment on the usefulness for patients of the technological capabilities proposed in this NPRM. Because of the tremendous risk of stigma, discrimination, and retaliation, including investigation and prosecution, that patients may face from some covered entities for accessing reproductive and other stigmatized health care, we support the operationalization of patient requested restrictions, which will be an important safety tool for patients.

II. We support technological changes to health information technology that implement the HIPAA Privacy Rule’s right to request a restriction.

The NPRM makes significant progress toward empowering individuals to keep certain data, including abortion care data, confidential. We enthusiastically support technology facilitating the ability to protect the flow of reproductive health data, and segmenting data for patient requests is an excellent start. We understand that health IT users are not obligated to honor a patient’s request to segment certain data, but this NPRM means they will at least have the technical ability to do so.

ONC seeks comment on whether the proposal should include additional functions to better support compliance with the HIPAA Privacy Rule. We propose the addition of technological functions that facilitate the ability to categorically protect the flow of reproductive health data. This should be the default so that health IT users do not have to go through the burdensome process of segmenting data by individual. It is far from clear that voluntarily protecting patients from data sharing threats will be a priority for health IT users such as providers, who are dealing with many demands.¹⁰ In fact, the penalties of the information blocking rule, which prohibits interfering with, preventing, or materially discouraging access, exchange, or use of electronic health information, push toward erring on the side of sharing medical records with other medical providers.¹¹ Additionally, this approach places the burden on abortion patients, who are disproportionately likely to come from marginalized communities and are less likely to have the time or resources to affirmatively seek segmentation.¹² One potential solution would be for electronic health record vendors to create pop-ups requiring doctors to verify that reproductive health-related records are necessary.¹³

We also support better functionality for patients to easily opt out of data sharing. While the NPRM notes that patient requests could be made through an internet-based method, we are concerned that the proposed Trusted Exchange Framework and Common Agreement (“TEFCA”)

⁹ Laura Huss, Farah Diaz-Tello, & Goleen Samari, *Self-Care, Criminalized: August 2022 Preliminary Findings, If/When/How* (2022), <https://www.ifwhenhow.org/resources/self-care-criminalized-preliminary-findings/>.

¹⁰ Carleen M. Zubrzycki, *The Abortion Interoperability Trap*, 132 YALE L.J. 197, 225 (2022), https://www.yalelawjournal.org/pdf/F7.ZubrzyckiFinalDraftWEB_6jsh8oxp.pdf.

¹¹ *Id.* at 214.

¹² *See generally*, Christine Dehlendorf, Lisa H. Harris & Tracy A. Weitz, *Disparities in Abortion Rates: A Public Health Approach*, 103 AM. J. PUB. HEALTH 1772, 1773 (2013) (discussing causes of comparatively higher abortion rates among women of lower socioeconomic status and women of color).

¹³ Carleen M. Zubrzycki, *The Abortion Interoperability Trap*, 132 YALE L.J. 197, 222 (2022), https://www.yalelawjournal.org/pdf/F7.ZubrzyckiFinalDraftWEB_6jsh8oxp.pdf.

condition for the “manner” exception may make this difficult in practice. The new condition in proposed § 171.301(c) states that “[t]he actor is not required to offer the [electronic health information] in any alternative manner.”¹⁴ This suggests that patients may have a difficult time accessing their data to determine if any concerning data is in their record, such as an out-of-state abortion. Simultaneously, the encouragement to participate in TEFCA increases the risk that there are many more covered entities with access to the data. We encourage ONC to consider ways to make TEFCA more patient-centric, as opposed to provider- and payer-centric, and support technological updates that give patients more access to their data and meaningful opportunities to opt out of data sharing.

III. We urge ONC to consider additional rulemaking or clarifications that make patient requested restrictions a functional and meaningful option.

- a. ONC should expand information blocking exceptions, or at the very least provide additional guidance on the scope of current exceptions.

The information blocking provisions in 45 C.F.R. pt. 171 state that actors can default to not sharing data without running afoul of the requirements if a patient requests to have certain data blocked, but it must be requested by an individual each time before a health IT user can act. We encourage ONC to expand the information blocking exception to expressly allow for policies that restrict patient data where there is a likelihood of multiple patients making the same request, or it involves sensitive health data. As an example, hospitals could adopt policies that categorically protect information related to abortion procedures.¹⁵

In the alternative, ONC could provide guidance that such policies do not violate the information blocking rule. This guidance could clarify that pregnancy and abortion care are appropriate “grounds to refuse” and can be excluded under the existing exception for when disclosure might cause harm to a person reflected in the data.¹⁶ Common examples where this is currently invoked include HIV care and mental health, and reproductive health care is similarly sensitive.

- b. ONC should reconsider its inclusion of pregnancy status in the United States Core Data for Interoperability (“USCDI”) Version 3.

ONC recently included pregnancy status as one of its “health status” data elements in version 3 of the USCDI standards, which will result in health information exchange networks having substantially more data on pregnancy status.¹⁷ The potential statuses are pregnant, not pregnant, or pregnancy status unknown. Changes in pregnancy status could be an indication of abortion. The intention is to capture pregnancy-related data in a standardized way to improve research and quality measurement, as well as help patients avoid teratogenic medications, but this addition does not account for the increased criminalization of reproductive health and pregnancy-related

¹⁴Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. at 23872.

¹⁵ Carleen M. Zubrzycki, *The Abortion Interoperability Trap*, 132 YALE L.J. 197, 223 (2022), https://www.yalelawjournal.org/pdf/F7.ZubrzyckiFinalDraftWEB_6jsh8oxp.pdf.

¹⁶ 45 C.F.R. § 171.201 (2023).

¹⁷ Daniel M. Walker, et al., *Interoperability in a Post-Roe Era: Sustaining Progress While Protecting Reproductive Health Information*, 328 JAMA 1703, 1703 (Nov. 1, 2022).

care. While it is important for health IT to be able to capture pregnancy status, it is equally important that data not be automatically sent when it has the potential to cause patient harm. We encourage ONC to reconsider this addition in light of *Dobbs*, recognizing that the benefits may still outweigh the potential harms. At a minimum, ONC should consider delaying the automatic sharing of pregnancy status until patient requested restrictions are fully operationalized.

- c. ONC should reconsider the implementation date for the patient requested restrictions certification criterion.

The new “patient requested restrictions” certification criterion in § 170.315(d)(14) would be required for the Privacy and Security Framework by January 1, 2026.¹⁸ This means that for the next two and half years, there are no technological requirements to operationalize these patient requests. Given the critical need to put these protections in place, we suggest an earlier requirement date of January 1, 2024. Alternatively, ONC could provide incentives for health IT developers to make this change imminently. ONC should ensure that operationalizing patient requested restrictions is an immediate priority for software developers.

Conclusion

We appreciate the opportunity to comment on this NPRM, and we commend ONC for taking these vital steps to operationalize patient requested restrictions under the HIPAA Privacy Rule. We urge ONC to consider additional changes in the final rule based on our comments. If ONC requires any additional information about the issues raised in this letter, please contact Liz McCaman Taylor, Senior Federal Policy Counsel, at LTaylor@reprorights.org.

Signed,

The Center for Reproductive Rights

¹⁸ Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. at 23822.