

October 4, 2024

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Re: Comments on Notice of Proposed Rulemaking on Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability, RIN 0955-AA06

The Center for Reproductive Rights (“the Center” or “CRR”) respectfully submits the following comment on the Notice of Proposed Rulemaking (“the proposed rule” or “NPRM”) on Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (“HTI-2”).¹

Since 1992, CRR 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.

We appreciate the opportunity to provide feedback on the proposed rule published by the Department of Health and Human Services’ (“the Department’s” or “HHS’s”) Office of the National Coordinator for Health Information Technology (“ONC”). ONC’s commitment to improving health information exchanges, while also taking into consideration the changing health access landscape, is laudable. CRR aims to provide the perspective of our clients, who include patients and care providers, to help ensure the finalization of a rule that advances ONC’s mission and ensures the safety and security of patients and providers facing stigma, harassment, and even criminalization for seeking and providing reproductive care.

Reproductive health care, including abortion, is essential health care and a human right. Nonetheless, since the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health*

¹ Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability, 89 Fed. Reg. 63948 (proposed Aug. 5, 2024) (to be codified at 45 CFR pts. 170, 171, and 172), <https://www.govinfo.gov/content/pkg/FR-2024-08-05/pdf/2024-14975.pdf> [hereinafter *HTI-2*].

Organization,² which overturned the federal constitutional right to an abortion, law enforcement agencies, and even civilians in many states, actively pursue opportunities to harass and criminalize people who seek reproductive care. It is clear that ONC recognizes this difficult landscape and the proposed rule demonstrates a commitment to addressing these challenges. Patients should be able to trust their health care providers, and protecting sensitive health information is one key aspect of protecting and promoting the patient-provider relationship and ensuring access to quality care.

The *Dobbs* decision has had a devastating impact on abortion access in an already challenging landscape. Even prior to *Dobbs*, patients were being forced to travel across state lines to obtain abortion care because their home states severely limited access.³ Post-*Dobbs*, abortion bans have made abortion care unavailable across entire regions.⁴ As of this writing, 13 states have made abortion care illegal, and 12 states are extremely vulnerable to bans and lack legal protections for abortion.⁵ As a result, thousands of individuals are unable to obtain abortions in their state of residency, and patients and providers across the country live in fear of criminal repercussions for obtaining, providing, or facilitating abortion care, even when and where it remains legal. Many patients must not only travel hundreds of miles to obtain care in states where abortion is still legal, but also fear criminal penalties in their home states for seeking that care.

While we acknowledge the benefits of information sharing for facilitating patient care, the *Dobbs* decision requires rethinking many longstanding health care assumptions, including that information sharing among providers is always positive. There are circumstances in which information sharing is not in a patient's best interest. Patients, especially those in states that ban or severely limit access to reproductive care, may be fearful that anyone who can access their medical records will potentially report them to authorities for obtaining care. The ready availability of a patient's medical history due to current interoperability rules and technological limitations compounds the risk that patients who access reproductive care may face whenever they seek out a health care provider.

The Center supports a strong rule that facilitates interoperability technology and also boldly prioritizes patients, providers, and those who facilitate reproductive health care. Although the proposed rule narrows the scope of health information that must be disclosed to avoid provider penalties by delineating regulatory exceptions, there are still potential loopholes through which sensitive health information may fall into the wrong hands. The Protecting Care Access, Privacy, and Infeasibility Exceptions are all valuable tools that advance ONC's goals, yet it is vital that ONC address remaining gaps; we appreciate the opportunity to provide feedback on ways to strengthen the exceptions' protections.

² 597 U.S. 215 (2022).

³ Isaac Maddow-Zimet & Kathryn Kost, *Even Before Roe Was Overturned, Nearly One in 10 People Obtaining an Abortion Traveled Across State Lines for Care*, GUTTMACHER INST. (Jul. 21, 2022), <https://www.guttmacher.org/article/2022/07/even-roe-was-overturned-nearly-one-10-people-obtaining-abortion-traveled-across>.

⁴ *Id.*

⁵ See *After Roe Fell: Abortion Laws by State*, CTR. FOR REPROD. RIGHTS, <https://reproductiverights.org/maps/abortion-laws-by-state/> (last visited Sept. 26, 2024).

I. The Protecting Care Access Exception, which supports the implementation of the HIPAA Privacy Rule, is a necessary addition to the Information Blocking Rule, and can be expanded further to adequately protect reproductive health data.

CRR previously emphasized the need for exceptions to information blocking that grant providers the ability to protect reproductive health care information from wrongful disclosure in our comments on the Disincentives for Information Blocking Rule.⁶ We are excited to see that the proposed rule has taken this suggestion and aims to empower providers to exercise caution before disclosing sensitive health information. The Protecting Care Access Exception “limits sharing of a patient’s [Electronic Health Information] potentially related to reproductive health care in order to protect that patient [or providers or people who facilitate care] from potential exposure to legal action.”⁷ The Protecting Care Access Exception is a vital safeguard because it empowers health care providers to decline to share any data that could expose a patient’s reproductive health history, without fear of civil monetary penalties. While this exception addresses many of our concerns, we ask that ONC consider additional feedback to further strengthen the exception’s protections.

- a. ONC should include the HIPAA Privacy Rule’s definition of “reproductive health care” in the final rule.

ONC proposes the addition of the HIPAA Privacy rule’s definition of “reproductive health care” (codified at 45 CFR 160.103) to the information blocking provision of the proposed rule.⁸ As attacks on reproductive care increase, it is vital to codify a comprehensive, evidence-based definition of reproductive health care in rulemaking. “Reproductive health care” as defined in the HIPAA Privacy Rule adequately describes the type of care, and information related to that care, that should be protected. Additionally, including this definition ensures alignment of various initiatives across HHS; shared language and understanding help to advance the overall goal of promoting efficient and effective health care. Finally, inclusion of this definition strengthens the Protecting Care Access exception by linking the exception directly to the HIPAA Privacy Rule. This is especially important to ensure that providers are aware of their ability to not disclose patient information, even while the HIPAA Privacy Rule is being challenged in the courts.

- b. ONC should replace the exception’s good faith standard with an alternative that presumes additional deference to a provider’s determination.

The Protecting Care Access Exception relies on a provider’s good faith belief that disclosure of reproductive health care information could expose a person who seeks, obtains, provides, or

⁶ Ctr. for Reprod. Rights., *Comments on Notice of Proposed Rulemaking on 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (RIN 0955-AA05)* (Dec. 22, 2023), <https://reproductiverights.org/wp-content/uploads/2024/05/21st-Century-Cures-Act-Center-Comment-Dec-2023.pdf>.

⁷ Office of the Nat’l. Coordinator for Health Info. Technology, Dep’t. of Health & Human Servs., *Information Blocking Exceptions 2*, https://www.healthit.gov/sites/default/files/page/2024-07/HTI-2_ProposedRule_Information_Blocking_Exceptions_Factsheet_508.pdf / (last visited Sept. 26, 2024).

⁸ *HTI-2* at 63633 (“Because we propose in this rule an exception that relies on the “reproductive health care” definition in 45 CFR 160.103, we also propose to add to § 171.102 the following: “Reproductive health care is defined as it is in 45 CFR 160.103.”).

facilitates reproductive health care to legal action as a consequence. Although ONC acknowledges that a good faith belief does not require accuracy (but does limit the risk of false claims), we believe that this requirement imposes unnecessary risk on individuals who may not understand the legal nuance of a good faith standard. ONC offers an alternative proposal where HHS may presume an actor's belief met the standard unless evidence is found establishing that the actor's belief did not meet the standard. We strongly prefer this alternative standard because it empowers providers to make decisions that protect patients without fear of baseless accusations of intentional interference. Additionally, the alternative standard allows providers to keep the provision of care at the forefront of their work, rather than spending valuable resources on evaluating compliance with a nuanced area of the law. Affirming providers in their knowledge and expertise promotes a stronger provider-patient relationship while also advancing ONC's mission of exchanging health information to promote general health care.

- c. ONC should revise its preamble language regarding the lawfulness of reproductive health care to better align with the proposed rule's broad goals.

Under the Protecting Care Access Exception, a provider must believe that a patient has “[o]btained reproductive health care . . . [i]nquired about or expressed an interest in seeking reproductive health care . . . or [h]as any health conditions . . . for which reproductive health care is often sought, obtained, or medically indicated.”⁹ ONC expands upon this in the preamble and specifies that any reproductive health care should have been lawfully obtained to qualify under the exception.¹⁰ We encourage ONC to reconsider this language.

On its face, the proposed rule simply requires that a patient have obtained or inquired about reproductive health care; there is no requirement in the regulatory text that the obtained or inquired about care be lawful. We support the regulatory text language because requiring lawfulness unfairly narrows the scope of patient information that can be protected. Abortion access is in constant flux nationwide, making it difficult for patients and providers to keep track of what and where care may be “lawful.” Additionally, many people self-manage their abortions, often in states where clinical abortion is otherwise banned or criminalized. Determining whether care in these situations is lawful can be complicated. Requiring providers to consider the “lawfulness” of a patient's care before determining whether or not they can disclose information is unnecessary and will only complicate implementation of this rule.

Furthermore, the lawfulness of care should not be a priority for providers whose jobs are to ensure health access. People who seek reproductive care, including abortions, are no less deserving of safety, dignity, and protection than those who seek all other types of health care. People should be empowered to get the health care they need when they need it, without fear that their providers will feel compelled to disclose the information to third parties, even third parties acting ostensibly for good by promoting health information technology. By including an affirmative presumption of “lawfulness” in the preamble, ONC risks the disclosure of reproductive health information that should otherwise be protected, especially for patients,

⁹ *Id.* at 63804.

¹⁰ *Id.* at 63634.

providers, and facilitators in the country’s most vulnerable regions. ONC should consider these broader circumstances and revise the preamble language to remove the expectation of lawful care and allow for broader interpretation of the rule’s language.

II. The suggested revisions to the Infeasibility Exception address the challenges of data segmentation and empower providers to establish clear internal policies and procedures for withholding information where it is impossible to adequately segment reproductive health information.

The proposed rule amends the Infeasibility Exception to give providers more autonomy and authority to deny information requests based on the limitations of their recordkeeping systems. We support this change because our clients have indicated that segmenting reproductive health care data is extremely difficult, since existing electronic health record software does not allow for portions of data to be easily segmented across data fields. To protect patient information and comply with a disclosure request, providers must dedicate significant time and resources to adequately redact sensitive information before disclosure. Excessive provider burden should not be the goal of the information blocking rule, and ONC’s proposed revision to this exception is a welcome change.¹¹

Furthermore, we interpret the proposed rule as empowering providers to establish organizational policies which may systematically deny information requests due to broad segmentation limitations. Importantly, by explicitly cross referencing the existing Privacy Exception and the newly proposed Protecting Care Access Exception,¹² the proposed rule suggests that organizations can establish disclosure policies that align with the most restrictive condition currently codified.¹³ By allowing providers to enact uniform policies that outline their inability to segment data with reproductive health implications, and thus justify their nondisclosure, providers can prioritize the important work of caring for patients.

III. The suggested revision to the Privacy Exception will ensure patient preferences for health information disclosure are prioritized.

The Privacy Exception currently only protects providers who fail to disclose patient information based on patient preference if the disclosure is not required by law.¹⁴ We agree with ONC’s reasoning that the current language fosters situations where “actors may be unwilling to consider granting individuals’ requests for restrictions, or may prematurely terminate some or all requested restrictions” out of fear of information blocking penalties or disincentives.¹⁵

¹¹ *Id.* at 63803.

¹² 45 CFR § 171.204(a)(2)(ii).

¹³ *HTI-2* at 63623 (“In addition, citing § 171.202 in the proposed revision to subparagraph (ii) of § 171.204(a)(2) would expand explicit application of the § 171.204(a)(2) segmentation condition to certain situations where an actor subject to multiple laws with inconsistent preconditions adopts uniform privacy policies and procedures to adopt the more restrictive preconditions (as provided for under the Privacy sub-exception Precondition Not Satisfied, see § 171.202(b)(3) as currently codified).”).

¹⁴ 45 CFR § 171.202(e).

¹⁵ *HTI-2* at 63622.

We support removing the “not required by law” language as proposed in this rule because patient preferences on health care information should always be the priority when providers are faced with an information disclosure request.

IV. We recommend that HHS launch an implementation and enforcement timeline that aligns information sharing requirements with existing technological developments.

We wholeheartedly support the addition and clarification of information blocking exceptions that prioritize patient privacy. ONC has demonstrated a commitment to these protections and the proposed rule is a significant step in that direction. However, we reiterate that the technology to actually operationalize systematic redaction and segmentation of data implicating reproductive health does not exist. In fact, under HTI-1, ONC set the required date for the new “patient requested restrictions” certification criterion in § 170.315(d)(14) as January 1, 2026. This means that for the next year and a half, there are no technological requirements to operationalize patient requests. Given the critical need to align information blocking enforcement with supportive technology, we suggest ONC and the Office of the Inspector General begin investigations into information blocking no earlier than January 1, 2027 if the provider claims they are protected under the Protecting Care Access, Privacy, or Infeasibility Exceptions (giving providers at least one year to integrate the new patient requested restrictions technology into their practices). Additionally, ONC should ensure that operationalizing data segmentation is an immediate priority for software developers. This could be done by offering financial incentives for health information technology developers that make changes immediately to categorically protect the flow of reproductive health data under the exceptions. Standardized and default technological functions will promote efficient practices that help to ensure compliance with this rule and other information sharing laws.

V. Conclusion

We appreciate the opportunity to comment on this NPRM, and we commend ONC for taking vital steps to protect reproductive health data while also promoting the open exchange of health information. Nonetheless, we urge ONC to consider additional changes in the final rule based on our comments. If ONC/HHS require any additional information about the issues raised in this letter, please contact Vidhi Bamzai, Federal Policy Counsel, at VBamzai@reprorights.org.

Signed,

The Center for Reproductive Rights