

October 4, 2024

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

Submitted via Regulations.gov.

RE: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule (RIN 0955-AA06)



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The American Civil Liberties Union (ACLU) is pleased to submit these comments on the Notice of Proposed Rulemaking by the Office of the National Coordinator (ONC) regarding updates to ONC's information blocking regulations (NPRM).¹ As one of the nation's premier defenders of civil rights and civil liberties, the ACLU has long championed both reproductive and privacy rights.

In that vein, the ACLU has supported robust privacy protections for our medical information,² recognizing that unwarranted or excessive disclosures of patient information "will chill vulnerable patients from accessing care, by undermining their trust and potentially exposing them to risky encounters with police, the family regulation system, or other government interventions."³ Privacy protections are particularly critical where states have criminalized and otherwise targeted healthcare, as "[u]ndermining privacy protections in health care leads to a breakdown in trust between providers and patients, and to adverse health outcomes."⁴

The ACLU supports the aspects of the NPRM that would strengthen patient privacy, especially when the legal risk for patients, providers,

¹ Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability, Notice of Proposed Rulemaking, 89 Fed. Reg. 63498 (Aug. 5, 2024), [here](#).

² ACLU, Memorandum on Medical Records Privacy (Mar. 7, 2001), [here](#).

³ Comment of the ACLU at 3, Modification to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6446 (May 6, 2021), [here](#).

⁴ Comment of the ACLU, HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 88 Fed. Reg. 23506 (June 16, 2023), [here](#).



and others could chill or even threaten care. In particular, the proposed “Protecting Care Access Exception” provides valuable clarity and flexibility to healthcare providers and health information technology (IT) providers to protect patients and healthcare providers, supplementing existing federal and state protections.

In these comments, the ACLU contends:

- The proposed Protecting Care Access Exception will create crucial flexibility for healthcare and healthcare IT providers, supplementing existing protections.
- Three aspects of the proposed “threshold condition” provide robust protections and should be maintained or strengthened.
- The patient protection and care access conditions are appropriately structured.
- The proposed Protecting Care Access Exception should extend to gender affirming care, and ONC should consider adding other types of health information to the exception.
- The new “requestor preferences exception” and updated “individual request” sub-exception will meaningfully advance privacy protections for healthcare.

I. The Proposed Protecting Care Access Exception Will Create Crucial Flexibility for Healthcare and Healthcare IT Providers, Supplementing Existing Protections

A. The Proposed Exception Would Increase Flexibility in Managing Reproductive Health Information in Response to Increased Attacks on Reproductive Healthcare

The proposed Protecting Care Access Exception would expand flexibility for healthcare and healthcare IT providers while still broadly maintaining the purposes underlying ONC’s existing information blocking rule. The information blocking rule is intended to improve the quality of healthcare, ensure continuity of care, and foster a “more effective marketplace, greater competition, and increased consumer choice.”⁵ The information blocking rule furthers those goals by prohibiting any practices that constitute “information blocking,” with key exceptions.

⁵ 89 Fed. Reg. 63498, 63500 (Aug. 5, 2024).



Under the current rule, any practice that constitutes “information blocking” would be subject to a variety of penalties. “Information blocking” is any practice by a healthcare provider, certain healthcare IT providers, and others⁶ that “is likely to interfere with access, exchange, or use of electronic health information,”⁷ subject to exceptions.⁸ However, if a practice is *required* by law, it is not “information blocking.”⁹ The net effect of this exclusion is that the information blocking rule would *require* disclosures where other laws such as the Health Insurance Portability and Accountability Act (HIPAA) would merely permit them, unless an exception applies.¹⁰

The NPRM would establish a new Protecting Care Access Exception that would provide healthcare providers and health IT providers flexibility in determining to withhold healthcare information. Under the proposed exception, healthcare providers, healthcare IT providers, and other “actors” would have discretion to withhold electronic health information based on a “good faith belief” that exchange of the information could result in persons “seeking, obtaining, providing, or facilitating reproductive health care” to be placed at “risk of being potentially exposed to legal action.”¹¹ The blocking must be implemented pursuant to an organizational policy or on a documented,

⁶ The current information blocking rule is applicable to “actors,” defined as “a health care provider, health IT developer of certified health IT, health information network or health information exchange.” 45 C.F.R. § 171.102.

⁷ 45 C.F.R. § 171.103(a). The practice must also meet a knowledge element that varies with the type of actor. *Id.* § 171.103(b). “Electronic health information” is a subset of protected health information under HIPAA, to the extent it is included in the “designated record set” that a patient is entitled to access. *Id.* § 171.102 (citing 45 C.F.R. §§ 160.103, 164.501).

⁸ 45 C.F.R. §§ 171.200–171.303.

⁹ 45 C.F.R. § 171.103(a).

¹⁰ 89 Fed. Reg. 63498, 63629 (Aug. 5, 2024) (“[A] HIPAA covered entity or business associate is not required by the HIPAA Privacy Rule to make a use or disclosure that the rule merely permits. . . . It is the implication of the ‘information blocking’ definition . . . that would cause an actor to be concerned about, for instance, refusing to disclose EHI indicating reproductive health care for permissible purposes . . .”).

¹¹ 89 Fed. Reg. 63498, 63804 (Aug. 5, 2024) (to be codified at 45 C.F.R. § 171.206(a)(1)).



case-by-case basis and must be no more extensive than necessary, in addition to other related requirements.¹²

The proposed exception is a crucial supplement to existing protections, as states hostile to reproductive healthcare increase legal attacks on healthcare providers and others for providing or facilitating reproductive healthcare.¹³ For example, 13 states have enacted total bans on abortion, eight have pre-viability bans,¹⁴ and others have attempted to curtail other professional and constitutional rights, including the ability for medical professionals to make out-of-state referrals, for individuals to travel out of state, or educators to teach about reproductive healthcare.¹⁵ As the NPRM recognizes, the proposed exception is distinct from the existing exceptions, none of which are focused on an evaluation of legal risk created by the exchange of health information.¹⁶

As detailed below, new state and federal protections have been established to meet the rising attacks on reproductive rights. However, the proposed exception provides meaningful flexibility beyond that offered by both those new protections and the information blocking rule's current exceptions—particularly where healthcare providers or other entities are not sharing health information directly with law enforcement, but instead with a permissible intermediary within the healthcare system, who may redisclose the information to third

¹² 89 Fed. Reg. 63498, 63804 (Aug. 5, 2024) (to be codified at 45 C.F.R. § 171.206(a)(2)). The “good faith belief” and other requirements listed here are described in the NPRM as the “threshold condition.” The remaining requirements, which must be satisfied in the alternative, are included in the “patient protection” and “care access” conditions, respectively.

¹³ See Letter from Hon. Raúl Labrador, Idaho Attorney General, to Hon Brent Crane (Mar. 27, 2023), [here](#); Anna Claire Vollers, *Helping a Minor Travel for an Abortion? Some States Have Made It a Crime*, Idaho Capital Sun (Aug. 26, 2024), [here](#).

¹⁴ Allison McCann & Amy Schoenfeld Walker, *Tracking Abortion Bans Across the Country*, N.Y. Times (Sept. 30, 2024), [here](#); Guttmacher, *State Policy Trends 2023* (Dec. 19, 2023), [here](#) (counting 14 total bans and seven pre-viability bans).

¹⁵ ACLU, Planned Parenthood Great Northwest, Hawai'i, Indiana, Kentucky v. Labrador (Apr. 6, 2023), [here](#); The Lawyering Project, *Matsumoto v. Labrador (Idaho)* (Feb. 7, 2024), [here](#); ACLU, *Idaho Federation of Teachers v. Labrador* (Aug. 7, 2023), [here](#).

¹⁶ 89 Fed. Reg. 63498, 63629 (Aug. 5, 2024) (“Currently, however, there are no exceptions in 45 CFR part 171 that are designed to accommodate concerns an actor may have about a patient’s, health care provider’s, or other person’s risk of potential exposure to legal action . . .”).



parties.¹⁷ This threat is not merely hypothetical—45 percent of criminal cases involving adults’ self-managed abortion between 2000 and 2020 were reported by healthcare providers or other care providers.¹⁸

B. Existing Laws Provide Important Protections for Reproductive Healthcare, but Potentially Leave Some Circumstances Unaddressed or Unclear

The proposed exception would supplement existing protections at the state and federal level. In general, the variety of protections at the state and federal level address information sharing in specific contexts or by specific entities and may leave conduct in other scenarios or by other entities unaddressed. Consequently, as described below, the proposed exception may help supplement existing protections in the HIPAA Privacy Rule, state shield laws, state health privacy laws, state electronic health record segmentation requirements, and the current exceptions to the information blocking rule.

First, the **HIPAA Privacy Rule** may not reach secondary uses of protected health information by permissible recipients. HIPAA regulates the collection, use, and disclosure of protected health information by covered entities (healthcare providers, healthcare plans, and healthcare clearinghouses),¹⁹ with two required exceptions and at least a half dozen permitted exceptions,²⁰ including for treatment and healthcare administration.²¹ The recent update to the Privacy Rule imposes two primary limitations on sharing protected health information: (1) it prohibits disclosure of protected health information for purposes of investigating or prosecuting individuals seeking, facilitating, or providing lawful reproductive healthcare, and (2) it requires an attestation for requesting protected health

¹⁷ 89 Fed. Reg. 63498, 63629 (Aug. 5, 2024) (“[T]he HIPAA Privacy Rule permits a HIPAA covered entity to disclose an individual’s PHI to a health care provider who is not a HIPAA covered entity for treatment activities. Once PHI is in the possession, custody, or control of an entity that is not regulated under the HIPAA Privacy Rule, the information is no longer protected by the HIPAA Privacy Rule.”).

¹⁸ Laura Huss et al., *If/When/How, Self-Care, Criminalized* 30 (2023), [here](#).

¹⁹ 45 C.F.R. § 164.500.

²⁰ 45 C.F.R. § 164.502(a)(2) (required disclosures to individuals and the Department of Health and Human Services).

²¹ 45 C.F.R. § 164.504(c)(2).



information potentially related to reproductive healthcare under four exceptions to HIPAA.²²

Those protections, however, may still leave some circumstances unaddressed, particularly where HIPAA would permit the initial transfer or exchange of protected health information. For example, as the NPRM observes, HIPAA permits sharing protected health information with other healthcare entities (who may not be HIPAA-covered) to provide treatment; unless an exception applies, the information blocking rule may require that transfer.²³ If that initial transfer is for purposes of healthcare treatment, it may not trigger the new HIPAA reproductive privacy rule, perhaps even when the transferring entity believes the possibility of redisclosure or secondary uses creates some legal risk.

Likewise, some transferring entities are covered by the information blocking rule but *not* by HIPAA. Those entities “may be concerned about potential information blocking consequences” if they deny a transfer of information for purposes which would have otherwise been prohibited by HIPAA,²⁴ such as for investigating lawful reproductive healthcare.

Similarly, **state shield laws** may not address sharing among private entities, especially healthcare providers. For purposes of this comment, “state shield laws” refers to state laws that restrict the state judicial or executive branches from complying with legal process from other states related to investigations, prosecutions, and other legal proceedings related to protected healthcare.²⁵ Under a shield law, “a state judge could be prohibited from domesticating an out-of-state subpoena seeking location data showing that an individual visited an abortion

²² 45 C.F.R. § 164.502(a)(5)(iii); 45 C.F.R. § 164.509(a).

²³ 89 Fed. Reg. 63498, 63629 (Aug. 5, 2024).

²⁴ 89 Fed. Reg. 63498, 63628 (Aug. 5, 2024).

²⁵ Jake Laperruque et al., Center for Democracy & Technology, Two Years After Dobbs at 1 (2024), [here](#) [hereinafter, “Two Years After Dobbs”]. The Guttmacher Institute defines “shield” laws slightly more broadly as those that more generally “protect health care providers and in some instances, volunteers and patients, from legal or professional consequences” in abortion-restricting states. Guttmacher, *State Policy Trends 2023* (Dec. 19, 2023), [here](#). The Guttmacher definition would also encompass additional laws that regulate how private entities may respond to legal process regarding lawful reproductive healthcare; those types of laws are analyzed in this comment as “state health privacy laws.”



clinic, or local police could be prohibited from aiding extradition of a doctor to a state where they've been criminally charged with performing unlawful abortions.”²⁶

For example, Vermont law prohibits state courts from ordering testimony or producing documents in any out-of-state “abusive litigation” involving reproductive healthcare or gender affirming care.²⁷ It also prohibits state agencies from cooperating with out-of-state investigations or proceedings for the “provision, seeking or receipt of, or inquiring about” reproductive healthcare or gender affirming care.²⁸ Approximately 20 states have passed shield laws.²⁹ Because shield laws often focus primarily on state actors, they often do not address one of the key harms addressed by the proposed exception—sharing information with (primarily private) entities within the healthcare system, particularly those outside HIPAA’s protections.³⁰

Protections offered by **state health privacy laws** may likewise not reach sharing within the healthcare system. As used in this comment, “health privacy law” refers to laws that restrict the sharing of health information by *private* entities. Following *Dobbs*, state health privacy laws have followed diverse models, roughly falling into three groups:

- Generally applicable health privacy laws that restrict the collection, sharing, and sale of consumer health information across private entities—including not just healthcare providers, but also consumer applications and services.³¹

²⁶ Two Years After *Dobbs* at 1–2.

²⁷ Vt. Stat. Ann. tit. 12, § 7304.

²⁸ Vt. Stat. Ann. tit. 12, § 7306.

²⁹ Guttmacher, *State Policy Trends 2023* (Dec. 19, 2023), [here](#) (counting 22); Two Years After *Dobbs*, *supra* note [] at 2 (counting 19).

³⁰ 89 Fed. Reg. 63498, 63629 (Aug. 5, 2024).

³¹ Conn. Gen. Stat. §§ 43-524(f), 42-526; Nev. Rev. Stat. § 603A.400–603A.550; Wash. Rev. Code §§ 19.373.005–19.373.900. Moreover, it is not clear currently whether the provisions of these statutes limit disclosure in response to legal process. Compare Nancy Libin et al., *New Washington Law Has Broad Implications for Protecting Consumer Health Data*, Davis Wright Tremaine LLP (Apr. 28, 2023), [here](#) (“[T]he Act does not specifically address law enforcement access to [consumer health data].”), with Andreas Kaltounis, *Washington State’s New Shield Law, Part of Washington’s ‘Choice-Defending Agenda,’ Modifies Obligations Related to Other States’ Criminal*



- Laws that aim to protect the privacy of sensitive health information by restricting the ability of healthcare providers, healthcare plans, or related entities to share information related to reproductive healthcare and, occasionally, gender affirming care, sometimes focusing on their ability to respond to out-of-state legal process.³²
- Laws that aim to protect the privacy of sensitive health information by restricting the ability of other privacy entities, most commonly electronic communication service providers, to respond to out-of-state legal process.³³

Broadly speaking, these laws tend to focus on responses to legal process related to criminalization of reproductive health care or in legal proceedings more generally, meaning that many do not address sharing within the healthcare system. Further, several of the laws either expressly do not cover protected health information under HIPAA or permit transfer of health information for treatment,³⁴ creating the possibility that the current information blocking rule would compel sharing of reproductive health information in those circumstances.

Related laws requiring **segmentation of electronic health records** will be complemented by the proposed exception. Two states have passed such laws: California requires that reproductive health information and information related to gender affirming care be segregated from transfers of health information; Maryland has imposed segmentation requirements for reproductive health information.³⁵ Other states are working on similar legislation. While those laws focus on *types* of information that must be segmented and withheld, the proposed exception provides a complementary set of protections based on the consequences of sharing information.

and Civil Process, BakerHostetler (Apr. 17, 2023), [here](#) (“[Washington’s law] prohibits most sharing of covered data by regulated entities with any third party without affirmative consent (including sharing with law enforcement, unless the data relates to a criminal violation recognized under Washington state or federal law).”).

³² *E.g.*, Cal. Civ. Code §§ 56.108, 56.109; Del. Code Ann. tit. 10, §3926A; Me. Rev. Stat. tit. 22, § 1711-C(8) (L.D. 227 2024); N.M. Stat. Ann. § 24-35-4–24-35-6.

³³ Cal. Penal Code §§ 1546.5(c), 13778.3(f); N.Y. Gen. Bus. Law § 394-f(2); Wash. Rev. Code § 7.115.020(d).

³⁴ Del. Code Ann. tit. 10, §3926A(d); Me. Rev. Stat. tit. 22, § 1711-C(8)(D).

³⁵ Cal. Civ. Code § 56.101(c)(1)(C); Md. Code Ann., Health-Gen. § 4-302.5



Similarly, some entities have sought to avoid the information blocking rule by segregating reproductive health information and maintaining it in paper records;³⁶ the proposed exception would allow those entities to avoid sharing reproductive health information without resorting to maintaining them in paper form.

Finally, the current **exceptions to the information blocking rule** do not accommodate concerns about legal risk. As the NPRM states, “Currently, however, there are no exceptions in 45 CFR part 171 that are designed to accommodate concerns an actor may have about a patient’s, health care provider’s, or other person’s risk of potential exposure to legal action”³⁷ Three existing information blocking exceptions are potentially the most relevant here, but each may not reach the circumstances addressed by the proposed exception. Likewise, several of the exceptions or sub-exceptions either require or effectively require individualized assessments or individual requests. This individualized approach limits the exceptions’ suitability for addressing widespread attacks on reproductive healthcare and creates practical obstacles of practitioners in the field:

- First, practices that are **required by law** are exempted from the definition of “information blocking.”³⁸ As described above, existing legal restrictions on the use of health information can benefit from the additional protections offered by the proposed exception. For example, the HIPAA Privacy Rule may preclude sharing of protected health information for prohibited purposes of criminal, civil, or administrative investigations or proceedings related to obtaining, providing, or facilitating reproductive healthcare.³⁹ The Privacy Rule, however, would not reach circumstances where the initial disclosure was not for a

³⁶ Raman Khanna et al., *Protecting Reproductive Health Information in the Post-Roe Era: Interoperability Strategies for Healthcare Institutions*, 30 J. Am. Med. Inform’n Ass’n 161–66 (2023), [here](#); Carleen M. Zubrzycki, *The Abortion Interoperability Trap*, Yale Law Journal (Oct. 18, 2022), [here](#); Nik Popli & Vera Bergengruen, *Lawmakers Scramble to Reform Digital Privacy After Roe Reversal*, Time (July 1, 2022), [here](#).

³⁷ 89 Fed. Reg. 63498, 63629 (Aug. 5, 2024).

³⁸ 45 C.F.R. § 171.103(a); Micky Tripathi, *Supporting Information Privacy for Patients, Now and Always*, HealthITbuzz (May 13, 2024), [here](#).

³⁹ 45 C.F.R. § 164.502(a)(5)(iii).



prohibited purpose, such as treatment,⁴⁰ even if the disclosing actor has a good faith belief that the disclosure may create legal risk for a patient or provider related to lawful reproductive healthcare.

- Second, the **preventing harm exception** may not cover the legal risk contemplated by this rule. As relevant here, the preventing harm exception applies to determinations on “an individualized basis” that the exchange of information is “likely to endanger the life or physical safety of the individual or another person.”⁴¹ ONC has interpreted this phrase to not cover “non-physical harms,”⁴² and it may consequently not reach the legal harms contemplated by the proposed exception. Likewise, the requirement that the harm be determined on “an individualized basis” may make it a burdensome means for protecting against widespread legal risk;⁴³ for example, a reproductive healthcare provider that treats numerous out-of-state patients may not have the capacity to assess each patient’s individual risk of harm.⁴⁴
- Third, the **privacy exception**’s various sub-exceptions likely do not apply to legal risk.⁴⁵ Instead, those sub-exceptions cover: failure to satisfy preconditions under relevant privacy laws, IT developers’ adherence to organizational privacy policies, denial

⁴⁰ 89 Fed. Reg. 32976, 33012 (Apr. 26, 2024) (“Where a person requesting PHI identifies a legal basis for the request beyond the mere act of a person having sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which it was provided, the prohibition at 45 C.F.R. § 164.502(a)(5)(iii) would not apply.”).

⁴¹ 45 C.F.R. §§ 171.201(c)(1), (d)(4) (citing § 164.524(a)(3)(i)). Section 171.201(d)(4) addresses harms from the exchange of EHI generally; the remaining types of harms identified in § 171.201(d)(1)–(3) address interfering with access by the patient or their legal representative and are less relevant to the concerns addressed by the proposed exception and these comments.

⁴² 85 Fed. Reg. 25642, 25824 (May 1, 2020).

⁴³ 45 C.F.R. § 171.201(c)(1). The preventing harm exception includes an alternative type of risk, one “aris[ing] from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.” *Id.* § 171.201(c)(2). Although that type of risk does not require an individualized assessment, it is less relevant here.

⁴⁴ Dallas Morning News, *New Mexico to Build Abortion Clinic Serving Texas, Other Neighboring States* (Sept. 9, 2024), [here](#); Jolie McCullough, *At a New Mexico Abortion Clinic, Calls Flood in from Texas and Wait Time for Appointments Grows*, Texas Tribune (July 1, 2022), [here](#).

⁴⁵ 45 C.F.R. §§ 171.202.



of individual access under HIPAA, and implementing an individual's request not to share health information.⁴⁶ Those first three sub-exceptions do not easily cover concerns about legal risk. Further, as described at length above, existing privacy laws and their preconditions may not cover a variety of situations that merit concerns about legal risk. The fourth sub-exception—implementing individual requests—may be burdensome to utilize as the request must come from the individual, may not be premised on “any improper encouragement or inducement of the request by the actor,”⁴⁷ and must be inherently implemented on a case-by-case basis.

These exceptions are meaningful, but the ACLU agrees that additional clarity and flexibility are needed for actors to address the legal risk posed by attacks on reproductive healthcare and, in some instances, avoid the need for individual assessments or requests.

C. The Proposed Exception Would Provide a Crucial Supplement to and Increased Flexibility Around Existing Protections

The proposed exception would meaningfully supplement those existing protections in three crucial respects.

First, the focus of the proposed exception—legal risk—appropriately complements the concerns addressed by other protections. The HIPAA Privacy Rule, for example, is focused on the purpose for requesting health information—namely, its use in investigating or prosecuting those “seeking, obtaining, providing, or facilitating reproductive health care.”⁴⁸ Similarly, many state shield and state privacy laws address situations where the health care provider, electronic communications provider, or other private entity is responding to legal process. The proposed exception cuts to the heart of and complements those concerns by allowing actors to assess the ultimate underlying risk, even if the immediate request is not for a prohibited purpose or accompanied by legal process.

Second, and relatedly, the proposed exception would provide actors greater flexibility in protecting health information by allowing

⁴⁶ 45 C.F.R. §§ 171.202(b)–(e).

⁴⁷ 45 C.F.R. §§ 171.202(e)(1).

⁴⁸ 45 C.F.R. § 164.502(a)(5)(iii)(A).



information to be withheld even if other protections do not apply or their ultimate legal application is unclear. For example, the proposed exception would provide helpful flexibility in the following situations:

- A healthcare provider in a state where reproductive care is legal provides treatment to a resident of a state where it is not. The patient's primary healthcare provider is located in the state where reproductive healthcare is not legal. If the primary care provider does not engage in covered transactions and is not a covered entity, it may nonetheless receive the treatment information under the information blocking rule and HIPAA's exception for healthcare operations. Since it is not a covered entity, the primary healthcare provider would not be prohibited by the HIPAA Privacy Rule from providing the information to law enforcement. However, the proposed exception would allow the originating provider to assess the underlying legal risk to the patient and those involved in the provision of their care. Under the proposed exception, the original provider may be able to avoid sharing the treatment information under the information blocking rule.
- Similarly, a state health privacy law may prohibit disclosures of information in a proceeding or investigation into reproductive healthcare. That law, however, may not clearly apply to a proceeding where law enforcement claims the investigation is premised on child endangerment, child abuse, kidnapping, or some other, seemingly unrelated, crime or tort. The proposed exception would alleviate the need for information blocking actors to identify a legal prohibition that *requires* the information blocking and instead would allow such actors to only assess potential legal risk more broadly. The proposed exception provides clarity by alleviating the burden of referencing existing laws to determine if the information blocking is *required*.

Third, as described above, several of the relevant exceptions or sub-exceptions effectively permit implementation only on an individualized case-by-cases basis.⁴⁹ Individualized exceptions are poorly suited for addressing the widespread risks from attacks on reproductive

⁴⁹ 45 C.F.R. § 171.201(c)(1) (as relevant here, the preventing harm exception requires determination of risk on an "individualized basis"); *id.* §171.202(e) (request must come from the individual).



healthcare. The proposed exception would provide an alternative approach that permits broader administration, particularly for practitioners in the field.

The complimentary nature of the proposed exception and the increased flexibility it offers are meaningful protections for reproductive privacy. It will allow actors an additional tool in protecting individuals who obtain lawful reproductive healthcare from unwarranted legal risk and invasions of privacy.

II. Three Aspects of the Proposed “Threshold Condition” Provide Robust Protections and Should Be Maintained or Strengthened

The proposed Protecting Care Access Exception includes a “threshold condition,” which stipulates that the actor may only block information based on a “good faith belief” that “the person(s) seeking, obtaining, providing, or facilitating reproductive health care are at risk of being potentially exposed to legal action that could arise as a consequence of particular access, exchange or use of specific” electronic health information.⁵⁰ At least three dimensions of the threshold condition provide robust protections and should be preserved or in some instances strengthened.

A. The Threshold Condition Appropriately Defines “Good Faith Belief” as Subjective

First, ONC proposes that an actor need to have a subjective “good faith belief” that the patient, provider, or other facilitators are at legal risk.⁵¹ ONC’s adoption of a *subjective* standard is appropriate. The proposed exception’s strength lies in the flexibility it grants actors; this flexibility supplements existing protections, such as those provided by the HIPAA Privacy Rule, which requires *objective* assessments by regulated entities.⁵² Limiting the proposed exception’s protections to

⁵⁰ 89 Fed. Reg. 63498, 63633 (Aug. 5, 2024).

⁵¹ 89 Fed. Reg. 63498, 63633 (Aug. 5, 2024).

⁵² 45 C.F.R. § 164.502(a)(5)(iii)(B) (requiring a “reasonable determination” that healthcare was lawful); 45 C.F.R. § 164.509(b), (d) (requiring “reasonable” reliance on attestations); *accord* 89 Fed. Reg. 32976, 33031 (Apr. 26, 2024) (noting that “a reasonable person standard is inherently objective”).



an objective reasonableness standard would unnecessarily limit the supplementary protections it provides.

Further, a subjective standard appropriately balances privacy and law enforcement interests at stake here.⁵³ The Supreme Court has observed in the speech context that a subjectiveness standard avoids a “chilling effect” that stems from uncertainty about how the “legal system” will assess actors’ behavior.⁵⁴ In contrast, an objective standard, which “turn[s] only on how reasonable observers would construe a statement in context,” would require actors to protect health information, not based on their own beliefs regarding legal risk, but based on how a court or agency would assess their behavior *post hoc*.⁵⁵ This would undesirably “chill” the very protections the proposed exception seeks to establish.

However, to fully realize the protections of a subjective “good faith belief” standard, ONC should establish a presumption that the actor’s belief meets this standard. This places the burden on the Department of Health and Human Services to produce “evidence that the actor’s belief did not meet the standard at all relevant times,”⁵⁶ rather than requiring the actor withholding reproductive health information to show they acted in good faith.

ONC also solicits feedback on whether the terms “belief” or “honest belief” should be substituted as the appropriate standard. The crucial element is that the belief be subjective, and we believe that either “honest belief” or “good faith belief” convey that meaning and are roughly synonymous.⁵⁷ However, in either case, ONC should explicitly state that the “good faith” or “honest” belief is indeed subjective.

⁵³ 89 Fed. Reg. 32976, 33012–13 (Apr. 26, 2024) (“[T]he prohibition applies only where individuals’ privacy interests outweigh the interests of law enforcement, and private parties afforded legal rights of action, in obtaining individuals’ PHI for the non-health care purpose of investigating or imposing liability for reproductive health care that was not lawful”)

⁵⁴ *Counterman v. Colorado*, 600 U.S. 66, 75 (2023).

⁵⁵ *Id.* at 78.

⁵⁶ 89 Fed. Reg. 63498, 63633 (Aug. 5, 2024).

⁵⁷ Good Faith, *Black’s Law Dictionary* (12th ed. 2024) (defining “good faith” as “honesty in belief or purpose”).



B. The Threshold Condition Takes an Appropriately Broad View of “Legal Action,” Which Should Be Further Expanded

Second, the threshold condition takes an appropriately broad view of the term “legal action.” The NPRM proposes to define “legal action” as including civil, criminal, or administrative investigations, actions, or proceedings “when initiated or pursued against any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.”⁵⁸ This scope of “legal action” recognizes the breadth of processes that governmental entities may use to impose penalties on patients, providers, and other facilitators. The definition also largely parallels the scope of proceedings covered by the HIPAA Privacy Rule.⁵⁹

However, HIPAA also covers uses of protected health information to *identify* any person for such investigations or proceedings,⁶⁰ and the proposed exception should adopt similar coverage. Mere efforts to identify individuals, shy of a formal investigation or proceeding, can chill healthcare access and patient trust to the same degree as formal investigations and proceedings.

C. The Threshold Condition Allows for Continuing Advances in Segmentation of Medical Records

Third, the proposed approach to segmentation appropriately recognizes that, while segmentation capabilities are rapidly advancing, not all reproductive health-related information may be capable of segmentation at this time.⁶¹ The ACLU supports ONC’s proposal to expressly reference the Protecting Care Access Exception in the segmentation condition of § 171.204 and to take such limitations in account when evaluating whether the withholding of reproductive health information was properly tailored.⁶²

⁵⁸ 89 Fed. Reg. 63498, 63633 (Aug. 5, 2024).

⁵⁹ 45 C.F.R. § 164.502(a)(5)(iii)(A)(1)–(2).

⁶⁰ 45 C.F.R. § 164.502(a)(5)(iii)(A)(3).

⁶¹ 89 Fed. Reg. 63498, 63634 (Aug. 5, 2024).

⁶² *Id.*



III. The Patient Protection and Care Access Conditions Are Appropriately Structured

In addition to the threshold condition, the proposed Protecting Care Access Exception also includes additional patient protection and care access conditions. To withhold information under the proposed exception, the threshold condition and *either* the patient protection *or* care access condition must be satisfied. The patient protection condition permits the actor to withhold electronic health information if it shows the patient obtained or inquired about reproductive healthcare or has a health condition “for which reproductive health care is often sought, obtained, or medically indicated.”⁶³ In contrast, the care access condition permits withholding of electronic health information if doing so “reduc[es] the risk of potential exposure to legal action for one or more licensed health care professionals, other health care providers, or other persons involved in providing or facilitating reproductive health care that is lawful under the circumstances.”⁶⁴

The proposed patient protection and care access conditions are appropriately broad. In particular, at least four aspects of those conditions will help ensure they properly protect patients, healthcare providers, and other facilitators of healthcare.

A. The Proposed Definition of “Lawful Under the Circumstances” Covers Key Threats to Reproductive Privacy, but Should Be Expanded to Be Coterminous with the HIPAA Privacy Rule

First, the definition of “lawful under the circumstances” recognizes that although some jurisdictions have attacked reproductive healthcare, others are maintaining (and bolstering) its lawfulness, including under federal law. This approach generally parallels the approach under the HIPAA Privacy Rule, which will help ensure consistent application,⁶⁵ except as described immediately below with respect to care provided by a third party.

However, ONC should clarify, potentially in conjunction with the Office for Civil Rights, that “lawfulness” for purposes of the proposed exception should be assessed where the provider is located.

⁶³ 89 Fed. Reg. 63498, 63804 (Aug. 5, 2024) (to be codified at 45 C.F.R. § 171.206(b)).

⁶⁴ 89 Fed. Reg. 63498, 63804 (Aug. 5, 2024) (to be codified at 45 C.F.R. § 171.206(c)).

⁶⁵ Compare 89 Fed. Reg. 63498, 63635 (Aug. 5, 2024).



B. The Presumption Regarding Third-Party Care Should be Rebuttable Only with Actual Knowledge

Second, the patient protection and care access conditions properly establish a “presumption” that care provided by a third party other than the actor is lawful, unless the actor has actual knowledge otherwise. In this instance, it is appropriate for the proposed Protecting Care Access Exception to differ from the HIPAA Privacy Rule. HIPAA establishes the presumption of lawful third-party care except where the regulated entity either (1) has “actual knowledge” or (2) is presented with “factual information” by the requestor to establish “a substantial factual basis” that the care was not lawful.⁶⁶ In contrast with the HIPAA Privacy Rule, the proposed exception is *voluntary*, and it is not necessary for it to include rebuttal by establishing a “substantial factual basis”; nothing in the NPRM would preclude actors from disclosing the information to requestors if it is not otherwise prohibited by law. Further, unlike HIPAA,⁶⁷ the information blocking rules do not preempt state law, and whether an actor must comply with legal process would be subject to a conflict of law analysis outside the scope of the proposed exception. Consequently, including a “substantial factual basis” rebuttal will unnecessarily preclude actors from protecting health information.

C. Patient Nullification Should Be Included in the Rule, But Permit Actors to Fully Inform the Patient

Third, the patient protection condition is appropriately subject to patient nullification.⁶⁸ Individual autonomy has long been the cornerstone of privacy protections,⁶⁹ and just as a patient may request

⁶⁶ 45 C.F.R. § 164.502(a)(5)(iii)(C)(1)–(2).

⁶⁷ HIPAA only preempts state laws to the extent that they are less protective than the standard provided by HIPAA. 45 C.F.R. § 160.203(b). Consequently, a state law that *mandates* disclosure where HIPAA would preclude it may be preempted. As the Department of Health and Human Services observed regarding the Privacy Rule’s protections for reproductive health information: “[C]onsistent with its HIPAA authority, the prohibition would preempt state or other laws requiring a regulated entity to use or disclose PHI in response to a court order or other type of legal process for a purpose prohibited under the proposed rule.” 89 FR 32976, 33010 (Apr. 26, 2024).

⁶⁸ 89 Fed. Reg. 63498, 63635 (Aug. 5, 2024).

⁶⁹ U.S. Department of Health, Education, and Welfare, Records, Computers, and the Rights of Citizens: Report of the Secretary’s Advisory Committee on Automated Personal Data Systems 59–64 (1973), [here](#).

that information be withheld,⁷⁰ they should be able to direct its disclosure, as suggested by the NPRM.⁷¹ Further, allowing a patient to direct disclosure of health information can help ensure that the Protecting Care Access Exception does not become a vehicle to undermine continuity of care, competition, or patient choice.

However, a patient's ability to direct disclosure should be informed, and actors should not be penalized for seeking to ensure that patients have the relevant information available in considering whether to direct disclosure. The NPRM proposes that actors should be permitted to delay disclosure to provide:

honest information that is provided in a non-discriminatory manner and that is relevant to the actor's belief that a risk of potential exposure to legal action could be created by the particular access, exchange, and use of what specific EHI, such as general information about privacy laws or other laws that the actor believes may be relevant.⁷²

Actors would also be required to provide patients with “a reasonable opportunity to consider the information and seek additional information.”⁷³ As the NPRM recognizes, this permission to provide information must be “honest,” non-discriminatory, and cause delay only as long as necessary.⁷⁴ The ACLU supports this approach.

The NPRM, however, describes this permission to share information with patients as a “non-exclusive” “alternative to include in the proposed care access condition.”⁷⁵ Instead, his permission fits more logically with the patient nullification rights under the protecting patient access condition, and should be situated in that condition.

D. The Scope of the Care Access Condition Is Appropriately Broad

Fourth, the broad applicability of the care access condition—beyond healthcare professionals—is necessary to protect all individuals who may be involved in providing or facilitating reproductive healthcare.

⁷⁰ 45 C.F.R. § 171.502(e).

⁷¹ 89 Fed. Reg. 63498, 63635 (Aug. 5, 2024).

⁷² 89 Fed. Reg. 63498, 63638 (Aug. 5, 2024).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ 89 Fed. Reg. 63498, 63637 (Aug. 5, 2024).



Recent events have demonstrated that potential liability for the provision of reproductive healthcare may reach not just the actual providers, but “friends, family, community caregivers, and others.”⁷⁶ The breadth of the care access condition is crucial to protect all individuals and entities who may be involved in funding and facilitating care.

IV. The Proposed Protecting Care Access Exception Should Extend to Gender Affirming Care, and Possibly Other Types of Health Information



ONC should extend the protections of the proposed exception to other types of healthcare information. At minimum, the protections should include information related to gender-affirming care, but ONC should also consider protections for types of sensitive information such as records under “Part 2”⁷⁷ or records for care for which decisionally capable young people are able to consent without parental involvement under state law.⁷⁸

As HHS has already recognized, gender-affirming health care is medical care. The Office of Population Affairs at HHS has defined gender-affirming care as “an array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people.”⁷⁹ Every major medical organization in the United States, including the American Academy of Pediatrics and the American Medical Association, recognizes that these treatments are medically necessary for some transgender young people and adults to treat gender dysphoria, and that they are safe and effective treatments.⁸⁰

⁷⁶ 89 Fed. Reg. 63498, 63636 (Aug. 5, 2024).

⁷⁷ 45 C.F.R. pt. 2.

⁷⁸ U.S. Department of Health and Human Services, *Does the HIPAA Privacy Rule Allow Parents the Right to See Their Children’s Medical Records?* (Dec. 19, 2002), [here](#).

⁷⁹ Office of Population Affairs, U.S. Department of Health and Human Services, *Gender Affirming Care and Young People* at 1 (2022), [here](#).

⁸⁰ *See, e.g.*, Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents*, Am. Acad. of Pediatricians (Oct. 1, 2018), [here](#); James L. Madara, *Letter to National Governors Association*, Am. Med. Assoc. (Apr. 26, 2021), available at [here](#).



Despite the medical recognition of gender affirming care, hundreds of bills attacking gender affirming care have been introduced and dozens of bans enacted across the country.⁸¹ Moreover, Attorneys General in Texas and Missouri have issued opinions attempting to restrict access to this health care, and in Texas, the Department of Child and Family Services began opening child abuse investigations to remove children from their homes simply because their parents sought best practice medical care for them, causing extraordinary harm to transgender youth and their families.⁸²

As a result of these attacks on necessary medical care, many transgender people and their families are being forced to seek care outside of their home states. Some are considering moving to less hostile states, while many others are accessing care in a different state where it remains lawful and returning to their home state.⁸³ Ensuring that electronic health information is not able to be used against families in criminal investigations or in spurious child abuse investigations, or against medical providers who are offering care that is lawful in the state in which they practice, is critically important to ensuring this care remains accessible and confidential.

V. The New “Requestor Preferences Exception” and Updated “Individual Request” Sub-Exception Will Meaningfully Advance Privacy Protections for Healthcare

Finally, the ACLU encourages ONC to finalize two other proposals included in the NPRM to provide robust privacy protections for healthcare generally and reproductive healthcare specifically.

First, ONC should finalize its proposal to include a new “requestor preferences exception.”⁸⁴ The new exception clarifies that it is not information blocking if the requestor seeks only a portion of the

⁸¹ ACLU, *Mapping Attacks on LGBTQ Rights in U.S. State Legislatures in 2024* (Sept. 5, 2024), [here](#); Movement Advancement Project, *Bans on Best Practice Medical Care for Transgender Youth*, [here](#) (last visited Oct. 1, 2024).

⁸² See, e.g., *Muth v. Voe*, 691 S.W.3d 93 (Tex. Ct. App. 2024), *petition for review filed* July 12, 2024; Madeleine Carlisle, *‘I’m Just Waiting for Someone to Knock on the Door.’ Parents of Trans Kids in Texas Fear Family Protective Services Will Target Them*, Time (May 19, 2022), [here](#).

⁸³ See, e.g., Madeleine Carlisle, *As Texas Targets Trans Youth, a Family Leaves in Search of a Better Future*, Time (July 14, 2022), [here](#).

⁸⁴ 89 Fed. Reg. 63498, 63640–41 (Aug. 5, 2024).



electronic health information available to it. This proposal adheres to fundamental data minimization principles by permitting entities to seek and receive only the information they need. Further, if ONC chooses not to expand the proposed Protecting Care Access Exception beyond reproductive healthcare, this mechanism will be useful for actors to avoid disclosures that may create unnecessary risk.

Second, the proposed change to the privacy sub-exception for individual requests to not share electronic health information provides necessary clarity for actors. As the NPRM observes, the current clause that mandates that individual requests may be implemented “[u]nless otherwise required by law”⁸⁵ may chill withholding of health information as actors seek to “account for any and all laws that might override the individual's requested restrictions.”⁸⁶ This change clarifies that actors may withhold health information under this sub-exception, despite ambiguities in other law.

Conclusion

The ACLU thanks ONC for its attention to the importance of protecting privacy and access to crucial healthcare. If ONC has any questions about these comments, please do not hesitate to contact us at cvenzke@aclu.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "C. Venzke", is written over a horizontal line.

Cody Venzke
Senior Policy Counsel
National Political Advocacy Department
ACLU

⁸⁵ 45 C.F.R. § 171.202(e).

⁸⁶ 89 Fed. Reg. 63498, 63622 (Aug. 5, 2024).

