

October 4, 2024

VIA ELECTRONIC SUBMISSION

Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW Floor 7
Washington, DC 20201

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

Dear Assistant Secretary Tripathi,

Physicians for Reproductive Health (PRH) is pleased to have the opportunity to submit comments to the Department of Health and Human Services (the Department) on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. PRH is a physician-led national advocacy organization that organizes, mobilizes, and amplifies the voices of medical providers across the United States to advance sexual and reproductive health, rights, and justice. Our programs combine education, advocacy, and strategic communications to ensure access to the full spectrum of equitable, comprehensive reproductive health care. We believe that this work is necessary for all people to live freely with dignity, safety, and security.

PRH greatly appreciates the Department's acknowledgement of the importance of privacy for reproductive health care, especially in the wake of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*. Even prior to this ruling, as states began to significantly limit or criminalize abortion, we have seen individuals' private health information used against them for investigations or proceedings. This has worsened in the year following the ruling as anti-choice legislators and prosecutors attempt to punish people for seeking or providing abortion care. This has had a chilling effect on access to comprehensive reproductive health care and threatens the trust that is foundational to the patient-provider relationship.

While we recognize the importance of data sharing for improving health outcomes, it must not come at the cost of people's privacy or expose them to surveillance and criminalization for seeking health care. We commend the Department for taking steps to ensure that information blocking exceptions cover providers who refuse to share private electronic health information (EHI) to protect their patients from the risk of potential criminalization due to their health care decisions or adverse health outcomes.

Protecting EHI Related to Reproductive Health Care from Being Shared.

Even before *Roe v. Wade* was overturned, people faced criminalization for their pregnancy outcomes, including abortion care. *If/When/How: Lawyering for Reproductive Justice* identified 61 cases over 20 years in 26 states of people criminally investigated or arrested for allegedly

ending their own pregnancies or helping someone to do so.¹ Cases were most often brought to law enforcement by health care providers and social workers after individuals sought care. This breach of patient-provider trust underscores the longstanding distrust in health care systems by communities who are disproportionately surveilled and criminalized. Even if charges are not filed, an investigation by law enforcement or a government agency is traumatic and has far-reaching consequences, including loss of employment, family separation and harassment. It is essential for health care providers to understand that they are not required to share a patient's EHI, and that there are protections under this Proposed Rule that will protect providers who refuse to share EHI that could put their patient at risk of being criminalized. There are very real consequences when individuals believe that they cannot rely on health care providers because of fear the provider would report them to law enforcement. Fear of criminalization can cause individuals to discontinue or refuse necessary health care, which can result in poor individual and community health outcomes. All patients, regardless of where they live, should be able to safely seek medical care throughout their pregnancy for any reason without fear their health care provider will disclose their EHI to anyone without their consent, including law enforcement.

Reproductive health care is a broad spectrum of services and needs to be understood as such. While the country has understandably focused on abortion access since the Supreme Court eliminated the constitutional right to abortion, all aspects of reproductive health care deserve protection and many people have been criminalized for seeking health care services beyond abortion care. Members of law enforcement have sought to obtain private health information in order to use the information to investigate or criminalize pregnant individuals for behaviors during their pregnancy that they otherwise would not be criminalized for. For example, the common practice of drug testing pregnant people, often without explicit informed consent, and reporting positive test results to authorities, including social workers, governmental agencies and law enforcement, can also lead to criminalization of pregnant people and punitive actions, such as arrest or family separation.² Pregnancy Justice has documented over 1,800 instances nationwide between 1973 and 2022 in which women were arrested, prosecuted, convicted, detained, or forced to undergo medical interventions that would not have occurred but for their status as pregnant persons whose rights state actors assumed could be denied in the interest of fetal protection.³ An alarming 92% of these arrests and prosecutions involved allegations of substance use even though most criminal codes do not make using drugs illegal.⁴ Eighty-six percent of the prosecutions studied by Pregnancy Justice applied existing criminal statutes intended for other purposes such as child abuse or child endangerment. A new report from Pregnancy Justice reveals the continuation of this alarming trend in the first year post-*Dobbs*,

¹ Self-Care, Criminalized: The Criminalization of Self-managed Abortion from 2000 to 2020, Laura Huss, Farah Diaz-Tello, & Goleen Samari, available at <https://ifwhenhow.org/wp-content/uploads/2023/10/Self-Care-Criminalized-2023-Report.pdf>.

² Lynn M. Paltrow & Jeanne Flavin, *Arrests of and Forced Interventions on Pregnant Women in the United States, 1973–2005: Implications for Women's Legal Status and Public Health*, 38 J. Health Pol., Pol'y, & L. 299 (Apr. 2013), <https://read.dukeupress.edu/jhpl/article/38/2/299/13533/Arrests-of-and-Forced-Interventions-on-Pregnant>.

³ Purvaja S. Kavattur, et al., *The Rise of Pregnancy Criminalization: A Pregnancy Justice Report*, Pregnancy Justice (Sept. 2023), <https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/9-2023-Criminalization-report.pdf>.

⁴ *Id.* at 40.

with at least 210 pregnant people facing criminal charges associated with pregnancy, pregnancy loss, or birth, and the majority of charges alleging substance use during pregnancy.⁵

It is essential for health care providers to understand that they are not required to share patient's health information, and the exceptions amended and reaffirmed in the HTI-2 Proposed Rule can help ensure that providers stop sharing sensitive EHI related to a person's reproductive health and help minimize the risk of surveillance and criminalization that people who are pregnant or could be pregnant face.

Protecting Care Access Exception

The proposed new Protecting Care Access Exception is an important step towards protecting patient reproductive health care information as it addresses a broad range of actions, individuals, and investigations. Specifying that health care providers, based on a good faith belief, may take action to prevent the access, exchange, or use of particular EHI the provider believes could create a risk of exposing the patient, care provider or other persons who assist in the access or delivery of health care to potential administrative, civil or criminal investigation. The Protecting Care Access Exception is critical to protecting people from surveillance and criminalization for seeking reproductive health care, including abortion care, as the exception specifically allows providers to not share EHI related to lawful reproductive health care if they believe that sharing the EHI could cause the patient to have potential exposure to legal action for seeking the care. We applaud the Department for taking an affirmative step to help protect people who seek out reproductive health care, including abortion care, from surveillance, criminalization, and incarceration.

The new proposed exception protects a provider against information blocking penalties when they decide not to disclose EHI because of a good faith belief that doing so would reduce their patient's risk of exposure to legal action. Due to the legally complex and polarized context of reproductive health care, in particular abortion care, across states, providers experience significant confusion around when it is legally permissible not to disclose pregnancy-related information. Under the proposed rule, providers may still experience confusion around whether their good faith belief of potential legal action and/or evidence to demonstrate their good faith belief meets the Protecting Care Access Exception. To address this confusion and strengthen the protections of the new proposed exception, we recommend that the Department add to § 171.206 the alternative provision for the good faith belief standard, which creates a presumption that an actor's belief meets the standard unless the Department has or finds evidence to the contrary.

We also appreciate that the Protecting Care Access allows providers to protect reproductive health information as part of an organizational policy that is based on their circumstances and technological capabilities, in addition to a case-by-case basis. We recognize that patient-provider communication and trust is crucial for determining the risk of legal action a patient may experience if their EHI is shared. In order to have meaningful impact, there must be room for

⁵ Wendy A. Bach & Madalyn K. Wasiluck, *Pregnancy as a Crime: Preliminary Report on the First Year After Dobbs*, Pregnancy Justice (Sept. 2024), <https://www.pregnancyjusticeus.org/wp-content/uploads/2024/09/Pregnancy-as-a-Crime.pdf>.

providers and patients to work together to carefully evaluate the potential risks of disclosing reproductive health information and discuss patient concerns and preferences. We urge the Department to make clear that a trusting, transparent patient-provider relationship is a key aspect of interoperable exchanges.

Furthermore, we do not support including additional conditions to the applicability of the Protecting Care Access Exception. The proposed exception must allow for the variability of providers and circumstances that involve or potentially relate to reproductive health care to benefit from exceptions to information blocking penalties, since there is already a complex compliance scenario that poses risks for potentially violating restrictive state or federal abortion laws and other limitations on reproductive health care.

This proposed exception does not eliminate the risk of criminalization for people's reproductive health care decision, as the Protected Care Access Exception only provides actors with defenses against information blocking and doesn't affirmatively require health care providers to not share EHI about highly sensitive care with law enforcement and/or other investigative third parties. However, this exception is an important tool for providers to have to protect the privacy and safety of their patients. In order to have a greater impact and to better combat criminalization, we urge the Department to provide detailed guidance, education, and training for health care systems, providers, and all entities covered by this rule. Given the intentionally confusing and constantly evolving landscape around the legality of reproductive health care, ongoing and in-depth education will be necessary for this rule to be implemented as intended. Especially with regards to the new Protecting Care Access Exception, the Department must share further guidelines to ensure that it is easily understood by providers and consistently applied.

Privacy Sub-Exception: Individuals Request Not to Share EHI

Similarly, the amendments to the Privacy Exceptions are a key step to protecting the privacy of people seeking health care. The proposal to broaden the privacy sub-exception regarding individuals request not to share EHI reaffirms and makes clear to health care providers that they do not have to disclose a patient's EHI if the patient has requested their information not be shared. This change prioritizes the patient request, even if another law would compel the health care provider to disclose patient EHI. In light of the risk of potential exposure to legal action flowing from uses and disclosures of EHI related to reproductive health care, we believe that this change offers meaningful protections against criminalization.

The proposed changes that allow providers to respect an individual's request to restrict access, exchange, or use of their EHI are crucial to maintaining and strengthening patient's ability to trust their providers without fear of criminalization for seeking reproductive health care. This proposed amendment will help mend the patient-provider relationship, as patients and providers are empowered to discuss and determine the level of risk a patient is willing to take and ensures that a provider's obligation to adhere to the patient's request regarding EHI sharing is prioritized and protected. No visit to the doctor or hospitalization should expose a person to criminal penalties or civil penalties. There must be room in our data exchange landscape for providers and patients to work together to consider the potential risks of disclosing reproductive health

information to third party actors, including law enforcement. We support the expansion of this sub-exception, and other efforts that allow health care providers the ability to refuse to share reproductive health information. We also urge the Department to take further actions in the future to ensure providers respect the wishes of the patient and not share out health information that could result in legal action and criminalization of the patient.

Infeasibility Sub-Exception: Segmentation Condition

The modifications that the Proposed Rule makes to the Infeasibility Exceptions' segmentation condition provides additional necessary protections and assurances for providers who seek to not share a patient's EHI due to the legal risks. We commend the Department for proposing to modify this exception to explicitly account for circumstances where the provider cannot unambiguously divide up EHI in order to share requested elements and withhold other sensitive information. These proposed changes reflect the reality of current data segmentation challenges providers face when dealing with a request for EHI that requires data segmentation to protect their patients from the risk of criminalization. Due to the limitations of technologies and segmentation capabilities, providers face significant difficulties in fulfilling EHI requests without sharing information related to reproductive health care that must be protected. We urge that following the publication of the final rule, the Department should publish guidance for providers about how to utilize this exception to limit the EHI they share out to third parties.

Although the proposed exceptions in HTI-2 will help ensure that providers are not punished for information blocking when they choose to not share protected EHI under one of the exceptions, these protections only go so far if health care actors are not aware that these protections exist and how they can utilize them so they can be empowered to not share information that could result in their patients facing surveillance, prosecution, and incarceration. PRH strongly recommends that prior, during, and after the publication of the final rule, HHS provides multiple education strategies to ensure that all health care actors who qualify for protection under these exceptions are aware of these protections. Further, PRH urges the Department to put forth more examples regarding how these exceptions can be utilized in instances where sharing EHI could result in harm, particularly surveillance and criminalization, to individuals due to the reproductive health care they have or have not received.

Expanding the Protections to Better Protect People from Criminalization.

As mentioned above, the HTI-2 Proposed Rule provides great steps to protecting people from the risk of harm due to sharing of EHI. However, PRH believes that these steps do not go far enough to ensure that all people are protected from criminalization due to their reproductive health care decisions and would like to propose changes the Department can make to the Proposed Rule to further expand and strengthen these protections.

Addition of Explicit Statement of the Definitions of "Reproductive Health Care" and "Patient"

We recommend that the Department adds the same explicit definition language for "reproductive health care" in the Proposed Rule that is used in the HIPAA Privacy Rule to Support Reproductive Health Care Privacy, in addition to the current reference in the Proposed Rule.

Adding this explicit language to the Proposed Rule would promote greater clarity under the rule, as well as provide stronger protections for providers and patients in case the HIPAA Privacy Rule to Support Reproductive Health Care Privacy is challenged, halted, or overruled in the courts.

We also urge the Department to strengthen the definition of “patient” in the Proposed Rule. While we appreciate the clarification that “patient” is a natural person, we recommend that the Department includes additional language explicitly stating that a natural person does *not* mean a fertilized egg, zygote, embryo, or fetus. This is a necessary clarification, as anti-abortion groups are, and have been, working to establish fetal personhood by rewriting legal definitions of “persons” to include fertilized eggs, zygotes, embryos, and fetuses. The fetal personhood movement seeks to establish personhood for pregnancies in order to further criminalize pregnant people, through weaponizing already existing criminal codes.⁶ By explicitly including in the Proposed Rule that “patient” to not include a fertilized egg, zygote, embryo, or fetus, the rule will provide further protections for pregnant people by undermining one of the major tactics utilized to criminalize pregnant people.

Removal of the “Lawful” Qualifier on “Reproductive Health Care”

The Protecting Care Access Exception provision of the Proposed Rule specifies that the exception can be utilized to prevent the sharing of EHI related to “reproductive care that was lawful.” Although we appreciate the new exceptions explicit protections to stop the sharing of EHI about a person who sought, obtained, provided, or facilitated reproductive health care, we urge the Department to remove the language of “lawful” from the rule’s reproductive health care protections.

The inclusion of the “lawful” modifier to the protections of EHI related to reproductive health care is unnecessary and confusing that will result in providers not clearly knowing when they are able to refuse to share EHI. In particular, the language of “lawful reproductive health care” will confuse providers to think they have to share information about a patient who self-managed their abortion, for example. There are currently no states that require reports to law enforcement about self-managed abortion.⁷ Only one state, Nevada, prohibits self-managed abortion and the state law does not obligate providers to report suspected self-managed abortions to authorities. Just because a person chooses to self-manage their abortion does not automatically mean that it is unlawful. In fact, many statutes banning or limiting abortion care specifically exempt the pregnant person from criminalization. Deleting the “lawful” terminology and altering the example will help clarify that providers should not feel pressured to report a self-managed abortion to law enforcement. We also urge the Department to provide explicit language and guidance to educate providers that EHI related to self-managed abortion does not need to be shared with law enforcement and other third-party actors, as the information is protected under the exceptions added and amended under this rule.

⁶ Pregnancy Justice, *Who Do Fetal Homicide Laws Protect? An Analysis for a Post-Roe America*, August 17, 2022, <https://www.pregnancyjusticeus.org/who-do-fetal-homicide-laws-protect-an-analysis-for-a-post-ro-e-america/>.

⁷ *Patient Confidentiality and Self-Managed Abortion: A Guide to Protecting Your Patients and Yourself*, If/When/How: Lawyering for Reproductive Justice (2020), available at <https://tinyurl.com/MandatoryReportingFactSheets>.

Addition of Explicit Protections for Pregnant People Who Use Substances

A major limitation of this rule is that it does not explicitly provide protections for pregnant people who are criminalized for substance use during their pregnancy. As noted above, pregnant people regularly face legal intervention and criminalization for behaviors during pregnancy that they otherwise would not be criminalized for, which results in serious harm to their health, well-being, and the well-being of their children and families. The American College of Obstetricians and Gynecologists (ACOG) notes that criminalizing pregnant people for actions that the state alleges harms a fetus, including substance use, poses serious threats to people's health.⁸ ACOG points out that "bias and racism play a role in discriminatory behavior when determining who and when to test or report."⁹ Black and Indigenous women seeking pregnancy are more likely to be screened for illicit substance use.¹⁰ Such testing – often undisclosed and performed without explicit consent – has resulted in parents losing their children or being incarcerated.¹¹ This is particularly harmful for Black and Indigenous families because their children are more likely to be removed from their custody, turned over to the state, and left in the foster care system much longer than children of White families.¹² It is important to note that a drug test cannot determine the existence of a substance use disorder¹³ and leading medical groups such as ACOG agree that a positive drug test should not be construed as child abuse or neglect.

The current Proposed Rule does not make it clear whether the screening, testing, and treatment for substance use of people seeking reproductive health care would be protected EHI that providers can refuse to share without being in violation of information blocking. We urge the Department to add explicit language that ensures providers are not forced to share information that is utilized to criminalize pregnant people, including substance use during pregnancy. Further, we urge the Department to put out guidance for providers regarding their ability to not provide EHI to law enforcement or other third-party actors that can utilize the information to take legal action against the pregnant person.

Addition of Explicit Protections for Other Forms of Stigmatized Health Care

We appreciate the work the Department has taken to protect people from surveillance and criminalization related to their reproductive health care decisions. Abortion care is health care and everyone who seeks abortion care should be able to do so without barriers and risk of

⁸ American College of Obstetrics and Gynecologists, *Opposition to Criminalization of Individuals During Pregnancy and the Postpartum Period*. (Dec. 2020), available at <https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period>.

⁹ *Id.*

¹⁰ Kunins HV, Bellin E, Chazotte C, Du E, Arnsten JH. *The effect of race on provider decisions to test for illicit drug use in the peripartum setting*. *J Womens Health (Larchmt)* 2007;16:245-255.

¹¹ Perritt, J. *#WhiteCoatsforBlackLives – Addressing Physicians' Complicity in Criminalizing Communities*, November 5, 2020. *N Engl J Med* 2020; 383:1804-1806

¹² Roberts DE. *Prison, foster care, and the systemic punishment of Black mothers*. *UCLA Law Rev* 2012;59:1474-1500.

¹³ Center for Substance Abuse Treatment. *Drug Testing in Child Welfare: Practice and Policy Considerations*. HHS Pub. No. (SMA) 10-4556 Rockville, MD: Substance Abuse and Mental Health Services Administration, 2010, available at <https://ncsacw.acf.hhs.gov/files/drugtestinginchildwelfare.pdf>.

criminalization. Reproductive health care, in particular abortion care, needs protections like those asserted in this Proposed Rule because of the criminal penalties, harassment, and even violence that is directed at providers of abortion care and their patients. However, reproductive health care is not the only form of health care that is stigmatized and can result in people being investigated, surveilled, prosecuted, and incarcerated. Sadly, we are seeing these scenarios play out with other types of essential health care such as gender-affirming care as statements impose criminal penalties and felony classifications, forcing patients to travel out of state for their care, move out of state so they can continue care, or tragically forego care all together.

Those who are HIV positive, unhoused, have unmet mental health needs, and/or use substances that are criminalized have all been targeted while seeking or obtaining health care. This occurs because this care has been stigmatized and criminalized leading to heightened surveillance and policing, threatening their safety and well-being in their own communities. The Department should explicitly expand the proposed protections and create guidance to prevent the sharing of EHI related to other forms of stigmatized health care. By explicitly recognizing that providers do not have to share EHI related to all forms of stigmatized health care, the Department can take stronger steps to making sure people do not fear punishment for seeking care and creating conditions for open conversations with their providers about their care.

Conclusion.

Overall, PRH strongly supports the important steps the Proposed Rule takes to ensure that health care actors are empowered to not share EHI that, if shared out, could result in criminalization and other legal harms for the patient. We emphasize that nobody should be criminalized or persecuted for seeking health care and that we must make every effort to safeguard EHI. Please do not hesitate to reach out to Jennifer Blasdell, Chief of Staff, jblasdell@prh.org, with any questions.

Sincerely,

Jamila Perritt, MD, MPH, FACOG
President & CEO
Physicians for Reproductive Health