December 22, 2023

U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 509F
Attn: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking NPRM
200 Independence Avenue SW
Washington, DC 20201

Re: 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)

The Center for Reproductive Rights (the "Center") respectfully submits the following comment on the Notice of Proposed Rulemaking ("Proposed Rule" or "NPRM") on the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking, published on November 1, 2023.

Since 1992, the Center 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 commend the Department of Health and Human Services ("Department" or "HHS") for its commitment to ensuring patients and their health care providers have access to their vital health information in a safe and secure manner. We appreciate the Department's effort to implement and enforce the 21st Century Cures Act and believe that, with some modifications, the disincentives in this Proposed Rule to enforce the information blocking prohibitions at 45 CFR Part 171 (the "Information Blocking Rule") will help to ensure that patient information is shared effectively and efficiently without criminalizing patients and providers.

We also appreciate the Office of the National Coordinator ("ONC") explaining how privacy protections may be ensured, considering the information blocking prohibitions, in the preamble of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule ("HTI-1 Final Rule"). However, that preamble language does not provide certainty, and the lack of clarity in the application of the Information Blocking Rule and this Proposed Rule still creates risks for health care providers, who provide services that are highly sensitive and increasingly criminalized, and their patients, who are at risk of criminalization when that information is shared.

We note that basic reproductive and gender-affirming health care is increasingly criminalized across the country. Given this context, the Centers for Medicare and Medicaid Services ("CMS") and ONC should take additional measures to ensure that health information, especially sensitive health information, is protected from disclosure that could lead to patient harassment and criminalization. We recommend several revisions that will help to ensure that health care providers and patients are protected under this rule: (1) clearly explain the interplay between the Proposed Rule and the Health Insurance Portability and Accountability Act and its implementing regulations (collectively, "HIPAA") as well as other privacy laws; (2) expressly implement a "good faith" exception allowing providers to withhold information under the Information Blocking Rule to prevent harassment and criminalization of the patient and exempting providers withholding information in such circumstances from enforcement under the Proposed Rule; (3) clearly define the "knowingly" standard of and the "necessary and reasonable" exceptions to the Information Blocking Rule, and related enforcement in the Proposed Rule to protect providers who knowingly withhold patient information to prevent harassment and criminalization; and (4) incorporate a separate appeals process related to the disincentives in the Proposed Rule.

I. A strong rule to protect patients and health care providers is urgently needed at a time when basic health care has an increasing risk of criminalization.

We commend the Department for its commitment to ensuring that patients receive comprehensive care that is fully reflective of their needs and not hampered by limited access to health information. However, recent changes in the health care landscape have resulted in an environment in which patients and providers risk ongoing harassment and criminalization. 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 Organization*,[1] which overturned the federal constitutional right to an abortion, law enforcement agencies and even civilians in many states actively pursue opportunities to criminalize people who seek reproductive care. As currently drafted, the Proposed Rule could result in the disclosure of sensitive health information, including reproductive health information, based on provider concerns related to financial disincentives. Furthermore, the results of such disclosures could be criminal penalties against a patient who sought that care. 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.[2] Post-*Dobbs*, abortion bans have made abortion care unavailable across entire regions.[3] As of this writing, abortion care is illegal in fourteen states.[3] As a result, thousands of individuals are unable to obtain abortions lawfully in their state of residency, and patients and providers across the country live in fear of criminal

[1] 213 L. Ed. 2d 545, 142 S. Ct. 2228 (2022).
[2] 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.
[3] *Id*.

repercussions for obtaining or providing abortion care, even when and where it remains legal, because of a complicated legal landscape across states. 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. The Information Blocking Rule requirements for sharing patient information enforced by the Proposed Rule may be used to support disclosure of health information to prosecute a patient or a health care provider. This Proposed Rule, as currently written, makes it difficult for health care providers to act in their patients' best interest without fear of enforcement by HHS.

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 between health care providers is always positive. There are circumstances in which information sharing is not in a patient's best interest. Such reporting of health information can have a detrimental effect on the patient-provider relationship and may result in fewer people seeking critical health care. Patients, especially those in states that ban or severely limit access to reproductive care, may be fearful that anyone who has access to their medical records could potentially report them to authorities for obtaining the prohibited care. Indeed, research shows that unnecessary reporting by health care providers is frequently the driver for the criminalization of pregnant people.[4] The ready availability of a patient's medical history due to current interoperability rules and policy, and intermediaries that facilitate the easy sharing of health information, compounds the risk that patients who access reproductive health care may face whenever they seek out a health care provider.

It is important to note that the Information Blocking Rule and Proposed Rule could also result in the exchange of other at-risk forms of care, including contraceptive access, in vitro fertilization ("IVF"), and gender-affirming health care. Anti-abortion politicians continue to conflate abortion and contraception and limit access to family planning services.[5] They are also actively strategizing about how and when to restrict access to IVF.[6] Similarly, gender-affirming health care is under attack across the country; an increasing number of states have banned such health care for minors, and a growing number of legislative proposals seek to ban that care for adults.[7] Each of these types of care is highly personal and sensitive and being able to openly share and discuss this information with a provider without fear of disclosure, harassment, and criminalization is vital to the patient-provider relationship and delivery of quality care. The

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

[5] *See Don't Be Fooled: Birth Control Is Already at Risk,* NAT'L WOMEN'S L. CTR (June 17, 2022), https://nwlc.org/resource/dont-be-fooled-birth-control-is-already-at-risk/; Christina Cauterucci, *Birth Control Is Next,* SLATE (Apr. 21, 2023), https://slate.com/news-and-politics/2023/04/birth-control-is-next-republicans-abortion.html.

[6] Kavitha Surana, "*We Need to Defend This Law": Inside an Anti-Abortion Meeting with Tennessee's GOP Lawmakers,* PROPUBLICA (Nov. 15, 2022, 12:00 PM), https://www.propublica.org/article/inside-anti-abortion-meeting-with-tennessee-republican-lawmakers.

[7] *Bans on Best Practice Medical Care for Transgender Youth*, MOVEMENT ADVANCEMENT PROJECT, https://www.lgbtmap.org/equality-maps/healthcare/youth_medical_care_bans (last visited May 26, 2023); *LGBTQ Policy Spotlight: Bans on Medical Care for Transgender People*, MOVEMENT ADVANCEMENT PROJECT (Apr. 15, 2023), https://www.mapresearch.org/2023-medical-care-bans-report.

Proposed Rule could have a chilling effect on the patient-provider relationship because there are no safeguards to protect sensitive information from disclosure, risking patient criminalization.[8]

Although information sharing can lead to more holistic care that results in a stronger patient-provider relationship, the current political landscape poses severe risks to patients. If implemented as written, the Proposed Rule may force providers to choose between the best interests of their patients, to whom they have certain obligations, and complying with the law to avoid financial disincentives, because providers will believe they have no avenues by which they can limit sharing of patient information that may result in criminalization. The Department should consider the context of the post-*Dobbs* landscape before finalizing the Proposed Rule. Our recommendations and proposed modifications reflect this context, and we encourage the Department to implement these recommendations into its final rule.

II. We recommend that CMS and ONC take measures to ensure adequate protections for health care providers, who must limit the disclosure of patient health information in their patients' best interests, especially given the current context of criminalization.

a. Background related to recommendations.

Under the existing definition of information blocking, a provider commits information blocking when they know that a practice is unreasonable and is likely to interfere with the access, exchange, or use of electronic health information except as required by law or covered by a regulatory exception. Currently, under the Information Blocking Rule, "[r]easonable and necessary" activities are referred to as "exceptions" to information blocking, meaning that such activities are not considered information blocking. The Information Blocking Rule includes the privacy exception and preventing harm exception, whereby providers may engage in reasonable and necessary activities to withhold information sharing to protect privacy or prevent harm.[9] However, providers must meet a high threshold to fit these exceptions and they remain at risk despite acting in their patient's best interest. The risk is particularly high where the provider primarily offers sensitive health care services.

Further, the preventing harm exception is not defined to include the harassment and criminalization of sensitive health care decisions and services among the harms legitimately prevented. While the HTI-1 Final Rule includes preamble language to suggest that a health care provider could limit information sharing to meet requests for confidential communication under the HIPAA Privacy Rule, and that withholding the data would then be "required by law" and not subject to information blocking, this will require extensive administrative activity by health care providers that provide sensitive health care services and the patients they serve. It is also only

[8] Nat'l Inst. of Health, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research* 78-81 (Nass SJ et al. eds. 2009) ("One out of eight respondents also admitted to engaging in behaviors intended to protect their privacy, even at the expense of risking dangerous health effects. These behaviors included lying to their doctors about symptoms or behaviors, refusing to provide information or providing inaccurate information, paying out of pocket for care that is covered by insurance, and avoiding care altogether . . . When adolescents perceive that health services are not confidential, they report that they are less likely to seek care, particularly for reproductive health matters or substance abuse."), https://www.ncbi.nlm.nih.gov/books/NBK9579/.
[9] 45 CFR 171.201.

explained in preamble and is not specifically defined in the regulatory text, which leads to uncertainty about whether a health care provider can truly rely on such guidance. The Center makes the following recommendations to ensure that patient health information is shared in a way that facilitates care but does not increase the risk of patient harassment and criminalization based on disclosure of sensitive health information.

b. We recommend that CMS and ONC expressly clarify that providers who are withholding information to protect patient privacy as afforded under HIPAA and to prevent potential harassment or criminalization of patients or themselves will not be deemed to have committed information blocking.

Because the Information Blocking Rule does not expressly protect providers who withhold sensitive health information to prevent harassment and criminalization of patients, health care providers may disclose information to comply with information blocking requirements, even in cases where it would be reasonable to withhold such disclosure per existing privacy laws. Moreover, under the Proposed Rule, such providers may be at risk of financial disincentives because the Proposed Rule does not expressly prevent enforcement against providers choosing to withhold information due to potential criminal action against patients.

As noted in Section I of this comment, the Proposed Rule comes at a time when reproductive health care is increasingly being regulated and criminalized, and reporting by health care providers has led to criminal action against patients.[10] Providers acting in accordance with privacy law, and in alignment with providers' professional and ethical obligations to their patients, should be protected against enforcement action, penalties, or other disincentives. Specifically, withholding of patient information for such purposes should not be deemed to be information blocking.[11] CMS and ONC should state that they will not enforce the Information Blocking Rule and provider disincentives in the Proposed Rule against providers who withhold patient information based on concerns regarding patient harassment and criminalization. We also encourage ONC to create an exception that addresses patient and provider harassment and criminalization in subsequent modifications to the Information Blocking Rule.

[10] *See* Cecilia Nowell, *The Long, Scary History of Doctors Reporting Pregnant People to the Cops*, Mother Jones, Apr. 15, 2022, https://www.motherjones.com/criminal-justice/2022/04/self-induced-abortion-herrera-texas-murder-hospital/ (reporting on instances of women who were reported to authorities by medical staff after seeking reproductive care in hospital and other health care settings). Providers are also known to secretly and non-consensually drug test pregnant patients and newborn infants and use that information to report parents for child abuse and neglect. Khaleda Rahman, *How Hospitals Are Secretly Drug Testing Pregnant Women,* NEWSWEEK (May 10, 2023, 5:00 AM), https://www.newsweek.com/how-hospitals-secretly-drug-testing-pregnant-women-1799176.

[11] *See e.g.* California Health and Human Services Agency (CalHHS) Data Exchange Framework (DxF), Amended Policy and Procedure: Permitted Required and Prohibited Purposes under California Health and Safety Code § 130290 (stating that participants subject to the are not required to exchange abortion or abortion-related services information as part of the exchange and/or access required by the DxF).

c. We recommend that CMS and ONC establish a new "good faith" exception to information blocking whereby providers acting in "good faith" to withhold sensitive health information are presumed to be acting reasonably and in the best interests of their patients.

Given the context of harassment and criminalization of personal health-related decision-making, there should be a strong presumption that providers who routinely furnish sensitive health care services are acting reasonably by withholding certain personal health information. Information sharing only facilitates care coordination and access to health care if patients can seek such health care without fear of harassment and criminalization. Therefore, CMS and ONC should create an explicit exception to information blocking under the Information Blocking Rule and its enforcement under the Proposed Rule whereby health care providers who are acting in "good faith" to protect patients from harm related to disclosure of sensitive health care decisions are deemed to be acting reasonably, and therefore not considered to be engaged in information blocking and not subject to disincentives.

Health care providers have professional and ethical obligations to their patients, and chief among them is the obligation to do no harm. Where providers have a concern that disclosure of patient health information may result in criminal action against the patient, or may restrict patients' access to the health care services they need, providers should be considered to be acting reasonably by withholding patient information. Such a "good faith" exception would allow providers to do no harm by protecting patient privacy, autonomy, and access to care, and also would uphold providers' ability to make health care related decisions in the best interests of their patients. The protections in place to empower providers to withhold patient information in an effort to prevent harassment and criminalization should also be widely publicized to prevent the chilling effect on patients seeking care and the unnecessary reporting by health care providers.

d. We recommend that CMS and ONC clarify that providers who knowingly withhold patient information to prevent harassment and criminalization are acting reasonably and shall not be subject to enforcement under the Proposed Rule due to such withholding of information.

In addition to the explicit protection against enforcement under the "good faith" exception as described above, CMS and ONC should expressly, in the regulatory text, interpret the "knowingly" standard of the Information Blocking Rule to exempt providers who are withholding patient health information to protect patients from potential harassment and criminal action. CMS and ONC should also expressly define "reasonable and necessary" practices to include withholding of sensitive health information, given that patients cross state lines to obtain care that is lawful in those states but criminalized in others.[12] Hostile states are actively seeking

[12] For example, the stark differences in availability and legality of abortion care have created a landscape that is nearly impossible for the average patient to navigate. Because the legality of abortion varies across state lines, different states may each have different interpretations of whether the same instance of care was provided lawfully. The Proposed Rule does not adequately consider the confusion of the post-*Dobbs* landscape and puts providers at risk of financial disincentive if they do not disclose such information despite knowing the risks to their patients.

such information to prosecute people for seeking care.[13] Such reasonable and necessary withholding should be expressly exempt from enforcement under the Proposed Rule.

In revising the Proposed Rule, CMS and ONC should remember that the underlying and paramount purpose behind information sharing is to facilitate access to patient care. Without clear protections for providers who are acting in their patients' best interests by withholding patient information in the current environment, patient care will suffer. Providers will feel compelled to share patient health information, and patients' trust in providers will diminish, resulting in hampered access to care, including for the most vulnerable individuals. Indeed, research shows that unnecessary reporting by health care providers is frequently the driver for the criminalization of pregnant people.[14]

Providers should be empowered to act in the best interests of their patients to knowingly withhold health information when, in their professional judgment, it is reasonable and necessary to do so. These terms should be expressly defined to include circumstances in which the health information in question may be used to target, harass, and criminalize the patient or the health care provider. Also, as noted above, CMS and ONC should ensure that provider and patient populations understand the protections in place to prevent unnecessary and potentially harmful disclosure of patient information.

e. We recommend that CMS and ONC provide for an appeals process related to the disincentives described in the Proposed Rule; failure to do so may implicate due process concerns.

Considering the severity of consequences faced by providers deemed to have committed information blocking, and the possibility of facing numerous processes for appeals, there must be a separate appeals process related to the disincentives described in the Proposed Rule. Solely relying on the existing program appeal processes leaves providers with inconsistent and potentially duplicative appeals processes to challenge the financial disincentives. Without a sufficient appeals process, providers are at great risk from a future Administration that does not support the provision of certain health care services, leading to an untenable situation for a health care provider who is acting in the best interest of their patients.

[13] *See* Cora Neas, *Seattle Hospital Sues After Texas Attorney General Asks for Handover of Patient Records*, KXAN Austin (Dec. 20, 2023), https://www.kxan.com/news/texas/seattle-hospital-sues-after-texas-attorney-general-asks-for-handover-of-patient-records/amp/.

[14] *See, e.g.*, Khaleda Rahman, *How Hospitals Are Secretly Drug Testing Pregnant Women,* NEWSWEEK (May 10, 2023, 5:00 AM), https://www.newsweek.com/how-hospitals-secretly-drug-testing-pregnant-women-1799176; Lynn 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, & LAW 299, 311 (2013), https://doi.org/10.1215/03616878-1966324; Sandhya Dirks, *Criminalization of Pregnancy Has Already Been Happening to the Poor and Women of Color*, NPR (Aug. 3, 2022, 10:30 AM), https://www.npr.org/2022/08/03/1114181472/criminalization-of-pregnancy-has-already-been-happening-to-the-poor-and-women-of.

III. Conclusion

While information sharing is important for care coordination and access, and we commend CMS and ONC for taking steps to ensure appropriate information is shared, implementing the Proposed Rule and the Information Blocking Rule in the current political environment risks the criminalization of reproductive and gender-affirming health care and disproportionately impacts low-income communities of color. CMS and ONC, in collaboration with OCR, must explicitly protect providers and patients from disclosures of sensitive health information that can lead to harassment or criminalization. We urge CMS and ONC to revise the Proposed Rule as described above.

CMS and ONC should also provide technical assistance to health care providers to ensure their understanding of the Information Blocking Rule and the final rule implementing disincentives, particularly its interplay with privacy law, exceptions related to the protection of sensitive health information, and the appeals processes related to provider disincentives. Providers' ability to make health care related decisions in the best interests of patients is central to the access to and provision of quality health care. Providers should be encouraged to use their expertise and good faith to do no harm by choosing not to disclose private and sensitive health information that may result in harassment and criminalization of their patients, without risking enforcement from HHS. Relatedly, patients should be able to trust that their providers will not disclose private health information in a manner that will jeopardize patients' health, well-being, and safety.

We appreciate the opportunity to comment on the Proposed Rule. We urge CMS and ONC to consider additional protections in the final rule based on our comments. If CMS and ONC require any additional information about the issues raised in this letter, please contact Vidhi Bamzai, Federal Policy Counsel, at vbamzai@reprorights.org.