June 16, 2023

U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 509F
Attn: HIPAA and Reproductive Health Care Privacy NPRM
200 Independence Avenue SW
Washington, DC 20201

**Re: Comments on Notice of Proposed Rulemaking on HIPAA Privacy Rule To Support Reproductive Health Care Privacy (RIN 0945-AA20)**

The Center for Reproductive Rights ("the Center") respectfully submits the following comment on the Notice of Proposed Rulemaking ("the proposed rule" or "NPRM") on the HIPAA Privacy Rule To Support Reproductive Health Care Privacy, published on April 17, 2023.

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

We commend the Department of Health and Human Services ("the Department" or "HHS") for taking vital steps towards expanding and enhancing the privacy protections of the HIPAA Privacy Rule ("Privacy Rule"). As we describe in more detail below, a strong rule is urgently needed, as basic health care is increasingly criminalized across the country.

While the rule takes critical steps to protect patients in this dangerous time, we recommend that the Department take additional measures to ensure that protected health information ("PHI") is protected from disclosure. The Department can do so by, at minimum, clarifying that the rule's protections apply to *all* reproductive health care, not just care "lawful in the state in which it is provided." This is particularly urgent because one of the largest drivers of pregnancy criminalization is unnecessary reporting by health care providers. Furthermore, while the rule promotes the patient-provider relationship, the Department can include more meaningful protections, especially for other patients who also experience discrimination in the health care system. These protections should include: (a) expanding protections for PHI related to gender-affirming care and care for substance use disorders; (b) strengthening the final rule to safeguard patients from malicious and unnecessary reporting; (c) safeguarding the data that is disclosed under the public health exception; and (d) strengthening the attestation requirement to deter bad faith requests for disclosure. Lastly, we note that the proposed rule would bring the United States one step closer to alignment with international human rights law and global public health guidance.

## I. A strong rule to protect patients and health care providers is urgently needed at a time when basic health care is increasingly criminalized.

We commend the Department for recognizing the urgent need for a strong rule to protect patients and providers in the face of ongoing harassment and the criminalization of basic health care. Reproductive health care, including abortion, is essential health care and a human right. We appreciate the Department's recognition that it is vital to protect access to this care and that the increasing criminalization and stigmatization of this care does and will continue to result in adverse public health outcomes, which this rule seeks to ameliorate. We also appreciate that the proposed rule recognizes the need to protect not just patients, but also providers and those who facilitate access to care, from criminal, administrative and civil investigations as the political climate continues to escalate hostility against all of these groups. The proposed rule comes at a critical time, when abortion care is increasingly criminalized across the country and patients must, now more than ever, be able to trust that their providers will keep their medical information private.

The Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*,[1] which overturned the federal constitutional right to an abortion, has had a devastating impact on abortion access in an already challenging landscape. Prior to *Dobbs*, patients were already traveling 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 thirteen states.[4] 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 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 criminalization of essential health care services has already created a substantial rift in the trust relationship between patients and providers. Patients 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.[5] The ready availability of a patient's medical history due to current interoperability rules compounds the risk that patients who access reproductive health care may face whenever they seek out a health care provider.

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[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] *See After* Roe *Fell: Abortion Laws by State*, CTR FOR REPROD. RIGHTS, https://reproductiverights.org/maps/abortion-laws-by-state/ (last visited Feb. 16, 2023).
[4] *Id.*
[5] Laura Huss, Farah Diaz-Tello, & Goleen Samari, *Self-Care, Criminalized: August 2022 Preliminary Findings*, If/When/How (2022), https://www.ifwhenhow.org/resources/self-care-criminalized-preliminary-findings/ (finding that thirty-nine percent of adult cases came to the attention of law enforcement through health care providers).

In states where abortion has been made illegal, health care providers must also fear arrest and prosecution for providing medically appropriate care. Even in states with abortion bans that provide exceptions for emergency care, providers face a confusing legal situation that can prevent them from communicating openly with their patients about their options and that may threaten their patients' timely access to care. In the year since *Dobbs*, a shocking number of reports have surfaced of patients whose lives and health were put at risk because they were turned away by providers when they presented with emergent pregnancy complications.[6] A recent study examining dozens of hospitals in Oklahoma, a state which imposes severe penalties on health care professionals who violate its abortion ban, found that not a single institution appeared able to articulate clear, consistent policies for providing emergency obstetric care to pregnant patients.[7] The report's findings raise grave concerns about the ability of a pregnant person in Oklahoma – and in the other twelve U.S. states with similar abortion bans – to receive clear, sufficient, and necessary information to make informed decisions about their medical care and treatment in the wake of the U.S. Supreme Court's overturning of *Roe v. Wade*.[8] Additionally, even where abortion is legal, abortion providers may now face harassment and intimidation from anti-abortion politicians and an anti-abortion movement emboldened by the overturning of *Roe*.[9] For example, in Indiana, the state Attorney General asked the state medical board to discipline a doctor who had provided abortion services to a ten-year-old.[10]

Other forms of reproductive health care are under increasing attack as well. Attacks on contraceptive access and in vitro fertilization ("IVF") continue to proliferate.[11] Anti-abortion politicians also continue to conflate abortion and contraception and limit access to family planning services.[12] Already, they are strategizing about how and when to restrict access to IVF.[13]

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[6] Jacqueline Howard & Tierney Sneed, *Texas Woman Denied an Abortion Tells Senators She "Nearly Died on Their Watch"*, CNN (Apr. 26, 2023), https://www.cnn.com/2023/04/26/health/abortion-hearing-texas-senators-amanda-zurawski/index.html#:~:text=Eighteen%20weeks%20into%20her%20pregnancy,unable%20to%20terminate%20the%20pregnancy.

[7] *No One Could Say: Accessing Emergency Obstetrics Information as a Prospective Prenatal Patient in Post*-Roe *Oklahoma,* CTR FOR REPROD. RIGHTS (2023), https://reproductiverights.org/hospitals-study-oklahoma-2023/.

[8] *Id.*

[9] *See, e.g.,* Kiely Westhoff, *Indiana's Attorney General Wants a State Board to Discipline a Doctor Who Provided Abortion Services to a 10-Year-Old. Her Attorney Says It's to 'Intimidate' Providers,* CNN (Dec. 8, 2022, 8:34 PM), https://www.cnn.com/2022/12/01/us/indiana-abortion-doctor-attorney-general/index.html; Jason Hanna & Sarah Boxer, *The Indiana Doctor Who Provided Abortion Services to a 10-Year-Old Ohio Rape Victim Is Suing the State's Attorney General Over His Investigation,* CNN (Nov. 3, 2022, 4:53 PM), https://www.cnn.com/2022/11/03/us/doctor-caitlin-bernard-suing-indiana-ag/index.html.

[10] Kiely Westhoff, *Indiana's Attorney General Wants a State Board to Discipline a Doctor Who Provided Abortion Services to a 10-year-old. Her Attorney Says It's to 'Intimidate' Providers,* CNN (Dec. 8, 2022, 8:34 PM), https://www.cnn.com/2022/12/01/us/indiana-abortion-doctor-attorney-general/index.html.

[11] *See* Arwa Mahdawi, *US Anti-Abortion Extremists Are Already Waging War on IVF,* GUARDIAN (Sept. 24, 2022, 9:00 AM), https://www.theguardian.com/commentisfree/2022/sep/24/republicans-ivf-abortion-week-in-patriarchy.

[12] *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.

[13] 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.

Although the proposed rule only addresses investigations related to reproductive health care, patients increasingly face criminalization for obtaining other forms of care. For example, gender-affirming health care is under attack across the country, as 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.[14] Additionally, some states' proposed restrictions have started linking abortion care and gender-affirming health care. Conversely, some states seeking to protect access to both abortion and gender-affirming care have begun addressing these stigmatized services together in their "shield laws," which protect individuals in their state from the reach of hostile laws in other states.[15]

Like reproductive health care, gender-affirming care is highly personal and especially sensitive given that it is also highly stigmatized. Even before states began criminalizing this type of care, LGBTQI+ patients have struggled to find compassionate providers they can trust.[16] Transgender, intersex, and genderqueer patients must be able to trust that their health care choices will not be weaponized against them by health care providers, and the parents of LGBTQI+ children who elect to provide appropriate care to their children must be able to trust that their health care providers will not attempt to criminalize them or file a malicious child abuse report against them.

## II. The proposed rule advances critical protections, but the Department can do more to alleviate confusion and promote the patient-provider relationship.

We agree with the Department that safeguarding the patient-provider relationship is vital. Importantly, the Department emphasizes that the "Federal Government seeks to ensure that individuals have access to high-quality health care."[17] Further, the Department notes that the primary reasons for this rulemaking are "the risks to privacy, patient trust, and health care quality that occur when it is the very act of obtaining health care that subjects an individual to an investigation or proceeding, potentially disincentivizing the individual from obtaining medically necessary health care."[18] This aligns with the purpose of the Privacy Rule, as adopted in 2003: to promote the patient-provider relationship in an effort to promote better health outcomes for

[14] *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.

[15] *See, e.g.,* Margery A. Beck, *Nebraska Legislature Votes to Fold Abortion Ban Into Bill Banning Trans Health Care for Minors*, AP NEWS (May 16, 2023), https://apnews.com/article/abortion-transgender-ban-nebraska-filibuster-94f1e637e2d9034f608c793bf929e888; H.B. 1469, 68th Leg., Reg. Sess. (Wash. 2023); S.B. 23-188, 74th Gen. Assemb., Reg. Sess. (Colo. 2023).

[16] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR FOR AMER. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/ (finding that, over the course of one year, 8% of LGBTQ people and 22% of transgender people studied avoided or postponed needed medical care because of mistreatment by health care staff).

[17] HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23521 (proposed Apr. 17, 2023) (to be codified at 45 C.F.R. pt. 160).

[18] *Id.*

patients.[19] The Department rightly recognizes the changes to the health care landscape post-*Dobbs* and that the patient-provider relationship is at serious risk due to the criminalization of care.

We also agree with the Department that some forms of health care, like reproductive health care, are particularly sensitive. The rule is not unique in its effort to protect a specific type of health care information; the Department has previously implemented special protections for other types of care.[20] We agree with the Department that limiting disclosure of reproductive health information will increase the likelihood that patients will seek health care because they have confidence that their providers will protect their privacy. This will only improve the quality of care provided to, and received by, patients.

Sustaining the patient-provider relationship is at the heart of the HIPAA Privacy Rule and reflected in this NPRM; however, the final rule should do more to provide meaningful protections for the patient-provider relationship.

*a. Limiting the protections of the proposed rule to where "health care is lawful in the state in which it is provided" adds confusion to an already complicated legal landscape on abortion access.*

While the proposed rule is a significant step forward in protecting the patient-provider relationship and protecting patients from undue harassment and investigation, we urge the Department to issue a final rule that protects all patients' reproductive health care information, regardless of how or where they obtained care or whether the care provided was aftercare for abortion services. This is necessary not only because all patients are entitled to access their basic human right of health care without fear of a violation of privacy, but also because the implementation of the rule is impracticable in light of an unclear and shifting legal landscape on abortion rights. Although only two states prohibit self-managed abortion,[21] which is the termination of pregnancy without the involvement of a health care provider, there were numerous prosecutions for pregnancy outcomes in an array of states while *Roe* was in effect.[22] Simultaneously, ongoing attacks on abortion rights in state legislatures and the courts, as well as

[19] *See* Health Insurance Portability and Accountability Act, 45 C.F.R. § 264(a)–(b) (2006) (requiring the Department to submit recommendations to protect the confidential health information of patients), https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf.; U.S. DEP'T OF HEALTH & HUM. SERVS., RECOMMENDATIONS OF THE SECRETARY OF HEALTH AND HUMAN SERVICES, PURSUANT TO SECTION 264 OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (1997), https://aspe.hhs.gov/reports/confidentiality-individually-identifiable-health-information ("Will we strengthen, not strain, the very lifeblood of our health care system -- the bond of trust between a patient and a doctor; In short, will we be able to harness these revolutions in biology, communications, and health care delivery to breath *[sic]* new life into the trust between our patients and their doctors . . . .").

[20] The Department had implemented specific protections for psychotherapy notes. HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23522.

[21] NEV. REV. STAT. § 200.220; S.C. CODE ANN. § 44-41-80(b). Though currently enjoined, South Carolina's recent six-week ban would repeal this statute. S.C. CODE ANN. § 44-41-730, preliminary injunction granted by Planned Parenthood South Atlantic et al. v. South Carolina et al., Court of Common Pleas for the 5th Judicial Circuit, C/A No.: 2023-CP-40-002745 (May 26, 2023).

[22] *Arrests and Other Deprivations of Liberty of Pregnant Women, 1973-2020*, NAT'L ADVOCS. FOR PREGNANT WOMEN, https://www.pregnancyjusticeus.org/wp-content/uploads/2021/09/FINAL_1600cases-Factsheet.docx.pdf.

lawsuits challenging abortion restrictions, contribute to a legal landscape that may make it virtually impossible for covered entities to determine whether care was provided lawfully under the proposed rule.

Under the current circumstances, it is more important than ever for the proposed rule to be as clear as possible, both for providers and patients. The final rule must protect PHI regardless of the circumstances under which and when care was obtained. Otherwise, it fails to achieve its goal of protecting the patient-provider relationship in entire swaths of the country, and exposes patients and providers to potential legal and criminal repercussions for obtaining or providing this essential health care.

i. The proposed rule must clarify that the personal health information of patients who self-manage their abortion, regardless of where they choose to do so, is protected by this rule.

We urge the Department to specifically clarify that patients who self-manage their abortions are protected by the rule. In the wake of the *Dobbs* decision, an increasing number of individuals are turning to self-managed abortion as an alternative to institutional health care.[23] When individuals have access to safe, effective methods and accurate information, they can self-manage an abortion on their own, with low risk of adverse effects.[24] This approach is also supported by the World Health Organization.[25] Nonetheless, self-managed abortion can subject patients in some states to legal risk.

Only two states explicitly prohibit self-managed abortion, [26] but pregnant people are frequently arrested and prosecuted for self-managing their abortions.[27] Too often, politically-motivated prosecutors stretch other areas of the law – for example, feticide laws, child neglect laws, or laws that govern practicing medicine on oneself – to punish individuals who seek to end their own

[23] In the immediate aftermath of the *Dobbs* decision, online searches for medication abortions increased by 162% - most of these occurring in states with extremely restrictive abortion laws. Aid Access, an international organization providing resources and support to people and providers on SMA, saw a significant increase in requests for medication in that time period as well. *See* Nisha Verma & Daniel Grossman, *Self-Managed Abortions in the United States*, 12 CURRENT OBSTETRICS AND GYNECOLOGY REP. 70, 71 (2023).

[24] *Self-Managed Abortions*, WHOLE WOMAN'S HEALTH, https://www.wholewomanshealth.com/abortion-care/self-managed-abortion/; Abigail R.A. Aiken, *Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United States: A Population Based Study*, 10 THE LANCET 1, 1 (2022); *Abortion Care Guideline*, WORLD HEALTH ORG. (Mar. 8, 2022), https://www.who.int/publications/i/item/9789240039483.

[25] *Abortion Care Guideline*, WORLD HEALTH ORG. (Mar. 8, 2022), https://www.who.int/publications/i/item/9789240039483.

[26] NEV. REV. STAT. § 200.220; S.C. CODE ANN. § 44-41-80(b). Though currently enjoined, South Carolina's recent six-week ban would repeal this statute. S.C. CODE ANN. § 44-41-730, preliminary injunction granted by Planned Parenthood South Atlantic et al. v. South Carolina et al., Court of Common Pleas for the 5th Judicial Circuit, C/A No.: 2023-CP-40-002745 (May 26, 2023). Additionally, some states that ban abortion have not expressly exempted the pregnant person from liability, which may create more confusion as to whether self-managed abortion is lawful in that state.

[27] *See* Nisha Verma & Daniel Grossman, *Self-Managed Abortion in the United States,* 12 CURRENT OBSTETRICS & GYNECOLOGY REP. 70, 72 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9989574/.

pregnancies.[28] These practices frequently also punish individuals who have experienced miscarriages and stillbirths.[29] As attacks on abortion access continue to proliferate, we can also expect such prosecutions to become increasingly commonplace.

Many state laws do not directly prohibit self-managed abortion, but the current landscape could sow confusion for HIPAA-covered entities. We are concerned that a HIPAA-covered entity may not be clear on whether self-managed abortion is considered "lawful" health care under the proposed rule and may inadvertently disclose protected information as a result. Health care providers should never be in a position of policing and reporting on their patients. Nonetheless, provider reporting plays an outsized role in the criminalization of pregnancy. We urge the Department to clarify that health information related to a self-managed abortion is protected health information under these circumstances. At minimum, the final rule should include a presumption that a self-managed abortion is lawful under the meaning of the rule unless directly prohibited by the state. The Department should also clarify that pregnancy outcomes resulting from an individual's actions during their own pregnancy are encompassed by the rule's definition of "reproductive health care."

ii. The restriction of the proposed rule that health care must have been lawful in the state in which it was provided will be difficult to implement because of the continuous attacks on reproductive health care in state legislatures and the courts.

The rapidly evolving legal landscape of reproductive health care issues further complicates implementation of the rule. Emboldened by the *Dobbs* decision in June of 2022, many states have since raced to ban abortion. Thirteen states already outright ban abortion.[30] Many more states are expected to follow suit. These developments follow the decades-long attack on abortion access by the anti-abortion movement. Between 2011 and 2022, states passed more than 500 laws restricting access to reproductive health care, resulting in the closure of clinics and a

[28] *See* Audrey Gibbs, *Repro Legal Helpline Relaunches to Better Respond to Increased Calls on Self-Managed Abortions,* MS. MAGAZINE (May 6, 2020), https://msmagazine.com/2020/05/06/repro-legal-helpline-relaunches-to-better-respond-to-increased-calls-on-self-managed-abortions/; Nisha Verma & Daniel Grossman, *Self-Managed Abortion in the United States,* 12 CURRENT OBSTETRICS & GYNECOLOGY REP. 70, 72 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9989574/; *Decriminalization of and Support for Self-Managed Abortion,* AM. PUB. HEALTH ASS'N (Oct. 26, 2021), https://www.apha.org/Policies-and-Advocacy/Public-Health-Policy-Statements/Policy-Database/2022/01/07/Decriminalization-of-and-Support-for-Self-Managed-Abortion#:~:text=This%20policy%20statement%20recommends%20that,full%20range%20of%20safe%20abortion.

[29] *See* Amy Yurkanin, *She Lost Her Baby, Then Her Freedom,* THE MARSHALL PROJECT (Sept. 1, 2022, 6:00 AM), https://www.themarshallproject.org/2022/09/01/she-lost-her-baby-then-her-freedom#:~:text=She%20is%20now%20serving%2018,years%20in%20an%20Alabama%20prison; Sam Levin, *She Was Jailed for Losing a Pregnancy. Her Nightmare Could Become More Common,* THE GUARDIAN (June 4, 2022, 1:00 PM), https://www.theguardian.com/us-news/2022/jun/03/california-stillborn-prosecution-roe-v-wade; Cary Aspinwall et al., *They Lost Pregnancies for Unclear Reasons. Then They Were Prosecuted,* WASH. POST (Sept. 12, 2022, 6:00 AM), https://www.washingtonpost.com/national-security/2022/09/01/prosecutions-drugs-miscarriages-meth-stillbirths/.

[30] *After Roe Fell: Abortion Laws by State*, CTR. FOR REPROD. RTS., https://reproductiverights.org/maps/abortion-laws-by-state/ (last visited Jun. 16, 2023).

shortage of abortion providers across the country.[31] Over 400 bills attempting to limit abortion access have been introduced in state legislatures across the country since the beginning of 2023 alone.[32] Many of the new and previously existing restrictions are subject to ongoing litigation, and the landscape of which laws are enforceable is constantly changing as courts temporarily or permanently enjoin or approve parts or all of these restrictions. Targeted attacks on medication abortion further complicate the legal and political landscape. Due to the constantly changing legal status of abortion access in states across the country, it will be a significant burden for covered entities to monitor these changes in real time to comply with the rule. This is particularly true for providers with independent practices who have fewer resources and staff to allocate towards this administrative task.

Already, 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, contributing to the confusion. For example, a Massachusetts provider is permitted under Massachusetts state law to provide medication abortion via telemedicine regardless of the patient's location.[33] Under Massachusetts law, the care was lawful. However, if the patient is located in a state that is enforcing a total criminal abortion ban, covered entities in that state may believe that the care was not lawful. This would put the patient at significant risk despite a reasonable belief by the patient that they obtained care lawfully.

The ongoing attack on medication abortion is yet another example of how this landscape may become even less clear. In *Alliance for Hippocratic Medicine v. FDA* ("*Alliance*"), Plaintiffs argue that mifepristone, one of the medications used for medication abortion, should not have been approved by the FDA.[34] A district court judge in Texas entered preliminary injunctive relief in favor of Plaintiffs in April 2023, purporting to remove the FDA's 2000 approval of the medication, but that order has been stayed by the Supreme Court as the government's appeal of the district court's order is litigated.[35] Meanwhile, some states have filed suit to protect and expand access to mifepristone.[36] In *State of Washington v. FDA ("Washington")*, the Attorney General of Washington, alongside sixteen other states and the District of Columbia, sued the

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[31] Elizabeth Nash & Sophia Naide, *State Policy Trends at Midyear 2021: Already the Worst Legislative Year Ever for U.S. Abortion Rights*, GUTTMACHER INST. (July 1, 2021), https://www.guttmacher.org/article/2021/07/state-policy-trends-midyear-2021-already-worst-legislative-year-ever-us-abortion (as of July 1, 2021, states had enacted 1,320 restrictions on abortion since *Roe* was decided in 1973, including 573 between 2011 and 2021 alone).

[32] *State Legislation Tracker: Major Developments in Sexual & Reproductive Health,* GUTTMACHER INST., https://www.guttmacher.org/state-legislation-tracker (last visited June 16, 2023).

[33] *See* Act of Jul. 29, 2022, ch. 127, 2022 Mass. Acts (expanding protections for reproductive and gender-affirming care).

[34] *Alliance for Hippocratic Medicine v. FDA*, CTR. FOR REPROD. RTS., https://reproductiverights.org/case/alliance-for-hippocratic-medicine-v-fda/ (last visited June 16, 2023).

[35] *Id.*

[36] Steve LeBlanc, *Concerned US States Start Stockpiling Abortion Drugs After Court Ruling,* AP NEWS (Apr. 10, 2023), https://apnews.com/article/democrats-states-stockpiling-abortion-pills-mifepristone-bab172f4037eb73fe90142ba28c23cc0; Letter from Rob Bonta, California Attorney General, to Danielle Gray, Executive Vice President of Walgreens Boots Alliance & Sam Khichi, Executive Vice President of CVS Health. (Feb. 16, 2023), https://ag.ny.gov/sites/default/files/2-16-23_multistate_pharmacy_letter.pdf.

FDA for improperly restricting the drug.[37] In *Washington*, the district court ordered the FDA to maintain the status quo with regard to mifepristone in all seventeen states and the District of Columbia, but declined to issue an injunction protecting access to mifepristone nationwide.[38] Providers in Virginia, Montana, and Kansas also filed a lawsuit seeking relief equivalent to that obtained by Plaintiffs in *Washington*.[39] Virginia, Montana, and Kansas are not states protected by the *Washington* order, and they are hostile toward reproductive health care.[40] The legal uncertainty caused by the decisions in *Alliance* has brought about chaos and confusion for these providers, challenging their ability to provide medication abortion services.[41]
Carving out care that was not provided "lawfully" undermines the purpose of the rule, which is to protect the patient-provider relationship. In a large and growing area of the United States where access to care has already been criminalized, the rule would clearly be unable to protect patients and providers. But with more and more patients traveling to obtain care, no state will remain untouched by the effects of such medical care bans. To protect their patients from hostile state actions, providers in states where care is lawful will likely also be discouraged from recording certain types of health care in their patients' medical records in case they travel to or live in a hostile state. The proposed rule's limited application would therefore fail to convey meaningful protection of the patient-provider relationship and allow abortion and transgender health bans to undercut public health, even in states where such care is lawful. Meaningful protection requires extending the prohibition on disclosure to all reproductive health care, regardless of the circumstances under which it was obtained or provided. At minimum, we recommend that the Department include in the final rule a presumption that reproductive health care was lawfully obtained under circumstances where a patient travels for care, in order to continue to further the Privacy Rule's goal of protecting the patient-provider relationship.

*b. Communities that frequently experience discrimination in health care already have a deficit of trust in the health care system and are also more likely to be targeted for surveillance and investigations.*

The patient-provider relationship is vital but is often a fragile relationship due to underlying issues in health care. Many individuals and communities already distrust health care providers and systems because of systemic discrimination in health care, including on the basis of race, socio-economic status, and sexual orientation and gender identity. There is an entrenched

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[37] Michael Martin & Gurjit Kaur, *Washington State Attorney General Says FDA Rules on Abortion Drug Are Unreasonable,* NPR (Feb. 25, 2023), https://www.npr.org/2023/02/25/1159565357/washington-state-attorney-general-says-fda-rules-on-abortion-drug-are-unreasonab.
[38] Perry Stein, Robert Barnes & Ann E. Marimow, *In a Divided Nation, Dueling Decisions on Abortion Pill*, WASH. POST (Apr. 9, 2023, 6:36 PM), https://www.washingtonpost.com/politics/2023/04/09/abortion-ruling-texas-washington-clash/. The states subject to the preliminary injunction are: Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, Nevada, New Mexico, Rhode Island, Vermont, Hawaii, Maine, Maryland, Minnesota, Oregon, Pennsylvania, Washington, and Washington, D.C. *AG Ferguson: Full Protections for Mifepristone Access Remains Intact in 18 States*, WASH. STATE OFF. OF THE ATT'Y GEN. (Apr. 13, 2023), https://www.atg.wa.gov/news/news-releases/ag-ferguson-full-protections-mifepristone-access-remain-intact-18-states.
[39] *Center Files Lawsuit to Ensure Access to Abortion Drug in Three States*, CTR. FOR REPROD. RTS. (May 8, 2023), https://reproductiverights.org/virginia-montana-kansas-mifepristone-lawsuit-filed/.
[40] *Id.*
[41] "Over the last few months, access to mifepristone has been repeatedly disrupted by one legal development after another, creating chaos and confusion for abortion providers and people seeking care," said Rabia Muqaddam, senior staff attorney at the Center. *Id.*

mistrust between Black and brown patients and the health care system stemming from the history of reproductive health care experiments, such as forced sterilization, in addition to ongoing discrimination, mistreatment, and coercion. Health policies and health care systems have resulted in the forced and/or involuntary sterilization of countless people, including Indigenous, Black, Latinx, incarcerated, and immigrant women.[42] Health care inequities in the United States persist. Black women have the highest maternal mortality rate of any group in the United States and their pain is frequently ignored or trivialized.[43] Black patients experience significantly poorer health outcomes and are more likely to be denied adequate care than their white counterparts.[44] These biases result in deadly outcomes and continue to impact patients today.[45]

Unfortunately, members of these communities still experience serious discrimination and are more likely to be subjects of criminal legal investigations and proceedings related to reproductive health care. Alarmingly, but unsurprisingly, low-income, Black, and brown women comprise the majority of people subjected to criminal proceedings arising from their pregnancies – a significant disparity when compared to their white counterparts.[46] Providers are 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.[47] Because these tests are done without consent, patients are unable to provide context for any irregularity that may show up. For example, a pregnant woman in New Jersey who consumed a bagel with poppy seeds prior to a doctor's appointment was secretly drug tested by her doctor and tested positive for opiates after giving birth. Because of this, she had to endure a Child Protective Services investigation which caused long-lasting trauma and "'completely ruined any trust [she] would ever have with any medical professional.'"[48] This is not a unique experience; women in Illinois and Pennsylvania have also experienced surreptitious drug testing and reporting to enforcement agencies.[49] In states or provider settings where providers have some discretion in conducting drug testing,

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[42] Sanjana Manjeshwar, *America's Forgotten History of Forced Sterilization,* BERKELEY POL. REV. (Nov. 4, 2020), https://bpr.berkeley.edu/2020/11/04/americas-forgotten-history-of-forced-sterilization/; *1978: Madrigal v. Quilligan,* LIBR. OF CONG.: A LATINX RES. GUIDE: CIV. RTS. CASES AND EVENTS IN THE U.S., https://guides.loc.gov/latinx-civil-rights/madrigal-v-quilligan (last visited June 12, 2023); Caitlin Dickerson, et al., *Immigrants Say They Were Pressured Into Unneeded Surgeries,* N.Y. TIMES (Sept. 29, 2020), https://www.nytimes.com/2020/09/29/us/ice-hysterectomies-surgeries-georgia.html; Kat Stafford, *Why Do So Many Black Women Die in Pregnancy? One Reason: Doctor's Don't Take Them Seriously,* AP NEWS: FROM BIRTH TO DEATH (May 23, 2023), https://apnews.com/article/black-women-maternal-mortality-rate-df872e86c4bb56ef222b19141dc377f8.

[43] *Id*.

[44] Kat Stafford, *Why Do So Many Black Women Die in Pregnancy? One Reason: Doctor's Don't Take Them Seriously,* AP NEWS: FROM BIRTH TO DEATH (May 23, 2023), https://apnews.com/article/black-women-maternal-mortality-rate-df872e86c4bb56ef222b19141dc377f8.

[45] *Id*.

[46] 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.

[47] 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.

[48] *Id*.

[49] *Id*.

Black women are tested at a much higher rate.[50] These examples are enormous, but not uncommon, betrayals of the patient-provider relationship, and the rule should do more to prevent the reporting of patients when they are seeking care.

Rebuilding that trust with the medical community requires systemic change. Ensuring that health information is adequately protected from disclosure is an important step to rebuilding that trust between patients and providers, especially because patients in these communities are much more likely to be subject to abortion bans and, therefore, policed. The patient-provider relationship is essential to providing quality health care and maintaining public health. We support the Department's efforts to continue to protect that relationship by enhancing protections for reproductive health information and encourage the Department to consider some additional, enhanced protections to safeguard the patient-provider relationship in light of the disproportionate impact on marginalized communities.

*c. The rule should reach beyond reproductive health care to other types of care and health conditions that also impact the patient-provider relationship, including gender affirming care and substance use disorders.*

We appreciate that the proposed rule goes beyond abortion care to include a broader range of reproductive health care. This is important, as the Department acknowledges, because of the sensitivity of reproductive health care as a whole and the importance of preserving trust in the patient-provider relationship. However, there are other types of health care that are similarly sensitive and stigmatized. Importantly, as the Department recognizes, many conditions connected to reproductive health care and, in particular, pregnancy, can manifest in conditions treated in other health care specialties.[51] It is essential to ensure that the rule is broad enough to protect any health information that may be related to reproductive health care, even if the connection may not be obvious at first glance.

The Department should urgently consider other types of care where health care information may be similarly sensitive, such as gender affirming care. Like abortion care, health care for transgender and genderqueer individuals is a highly stigmatized form of health care that is increasingly criminalized. As a result of escalating political attacks and existing social stigma and bias against nonbinary, genderqueer and transgender individuals, in addition to a recent wave of legislation targeting transgender people, gender affirming care is exceedingly personal and sensitive and requires high levels of trust between patients and providers.

Transgender and genderqueer patients already frequently experience discrimination in accessing care. In a 2017 study, one in five LGBTQ people, including nearly one third of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away.[52] That rate was substantially higher for LGBTQ

[50] *Id*.
[51] HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23530 (proposed Apr. 17, 2023) (to be codified at 45 C.F.R. pt. 160).
[52] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR FOR AMER. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/.

people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[53] Eight percent of lesbian, gay, bisexual, and queer people and 29% of transgender people reported that a doctor or other health care provider had refused to see them because of their actual or perceived sexual orientation in the year before the survey.[54] When transgender people were able to access care, 21% reported being verbally harassed and 29% being physically assaulted by health care professionals.[55] Additionally, LGBTQ individuals have reported "that health care professionals have used harsh language towards them, refused to touch them or used excessive precaution, or blamed the individuals for their health status."[56] When transgender patients are able to find a trusted provider, it is essential to ensure that the patient-provider relationship is supported and protected by this rule, and that when transgender patients encounter biased providers, they can trust that they will not be exposed to harassing investigations based on the provider's animus toward transgender people.

In an unnerving parallel that mirrors the criminalization of abortion, 2023 has brought a tsunami of legislation that criminalizes transgender health care, putting providers and patients, including the parents of young patients, in danger for accessing, providing, or facilitating care.[57] Eighteen states currently ban best practice medical care – surgical care and medication – for transgender youth, with a nineteenth banning surgical care only.[58] Five of those states have enacted felony penalties against those providing this medically necessary care to minors.[59] An increasing number of proposed bans do not only apply to minors: nearly a third of bills (29%) introduced in 2023 would ban or restrict care for both transgender children and transgender adults.[60] In these states, health care providers, and in some states, the parents of transgender youth, face a very real and urgent risk of being subject to investigation, arrest, and prosecution for facilitating or providing needed health care without the protection of the HIPAA Privacy Rule. This will further deter patients from seeking, and providers from providing, this urgently needed form of

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[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] In fact, legislators have started linking bans on both types of care. For example, Nebraska legislators recently proposed a bill that would both ban abortion after twelve weeks of pregnancy and ban gender affirming care for minors. *See* Margery Beck, *Nebraska Legislature Votes to Fold Abortion Ban into Bill Banning Trans Health Care for Minors,* AP NEWS (May 16, 2023), https://apnews.com/article/abortion-transgender-ban-nebraska-filibuster-94f1e637e2d9034f608c793bf929e888.
[58] *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).
[59] S.B. 254, 2023 Leg., Reg. Sess. (Fla. 2023), https://www.flsenate.gov/Session/Bill/2023/254/BillText/er/HTML (providing felony penalties in the third degree for practitioners who provide medical care to minors); S.B. 184, 2022 Leg., Reg. Sess. (Ala. 2022), http://alisondb.legislature.state.al.us/ALISON/SearchableInstruments/2022RS/PrintFiles/SB184-enr.pdf (enacting Class C felony penalties for practitioners who provide medical care to anyone under nineteen years of age); H.B. 71, 67th Leg., Reg. Sess. (Idaho 2023), https://legislature.idaho.gov/sessioninfo/2023/legislation/H0071 (creating felony penalties for practitioners who provide medical care to minors, effective January 2024); H.B. 1254, 68th Leg., Reg Sess. (N.D. 2023), https://www.ndlegis.gov/assembly/68-2023/regular/bill-overview/bo1254.html (making surgical care for minors a felony crime and providing medication a misdemeanor crime); S.B. 613, 59th Leg., Reg. Sess. (Okla. 2023), http://www.oklegislature.gov/BillInfo.aspx?Bill=sb613&Session=2300 (creating a felony penalty for providing medical care to minors but the penalty is currently unenforceable pursuant to an agreement made by the state's Attorney General).
[60] *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.

care.[61] For transgender and genderqueer patients whose care plan includes reproductive health care, the risk is compounded, and may result in patients avoiding the health care setting altogether. We urge the Department to ensure that the final rule also protects patients, providers, and those who facilitate access to care against investigations related to gender affirming care, regardless of where the care was provided.

The final rule should also protect health information related to substance use disorders, particularly if the information is discovered during the course of providing or obtaining reproductive health care or gender affirming care. The fear of criminalization and/or reporting to government agencies is an enormous deterrent from seeking health care and causes significant harm. Substance use disorders are highly stigmatized even among health care providers, and as a result, many individuals with substance use disorders are deterred from seeking care because they fear judgment or that their provider will report them to authorities. The stigma against substance use is compounded for pregnant patients with substance use disorders, who are routinely mistreated, reported, investigated and criminalized for using substances during pregnancy.[62] In fact, even some treatments for substance use disorders – for example, methadone or buprenorphine treatment – face stigma due to ignorance about how they actually work, and some buprenorphine providers even refuse to care for pregnant patients despite the documented benefits to a pregnancy.[63]

Health care providers should never be in the role of policing and reporting the patients who entrust them with their care. Nonetheless, mandatory reporting laws in some states may put them in a position where they feel forced to report their patients. For example, twenty-six states and the District of Columbia require health care professionals to report suspected prenatal drug use to some degree.[64] As a result, a health care visit for prenatal care or delivery can become an entry point into the criminal legal system for parents and into state custody for children – even though

[61] Transgender and gender-diverse individuals who do not receive gender-affirming care, including puberty blockers and hormones, are at significantly higher risk of experiencing moderate to severe depression and suicidality than those who receive care. Diana Tordoff, et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care,* 5 JAMA NETWORK Open no. 2, 2022 at 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423; Anthony Almazan &Alex Keuroghlian, *Association Between Gender-Affirming Surgeries and Mental Health Outcomes,* 156 JAMA Surgery 611 (2021), https://jamanetwork.com/journals/jamasurgery/article-abstract/2779429.

[62] Caroline Le & Sarah Combs, *Substance Use Disorder Hurts Moms & Babies*, NAT'L P'SHIP FOR WOMEN & FAMILIES: MOMS & BABIES (2021), https://nationalpartnership.org/wp-content/uploads/2023/02/substance-use-disorder-hurts-moms.pdf.

[63] Stephen Patrick et al., *Association of Pregnancy and Insurance Status with Treatment Access for Opioid Use Disorder,* 3 JAMA NETWORK OPEN no. 1, 2020 at 1, 6, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769427 (finding that pregnant people were 17% less likely to get an appointment with a buprenorphine provider than non-pregnant people); Julia Philippi et al., *Reproductive-Age Women's Experiences of Accessing Treatment for Opioid Use Disorder: "We Don't Do That Here,"* 31 WOMEN'S HEALTH ISSUES 455, 459 (2021), https://www.whijournal.com/article/S1049-3867(21)00033-5/fulltext (finding that "[p]roviders did not feel always comfortable treating pregnant patients" and that they were "'too much of a high risk . . . .'").

[64] *Substance Use During Pregnancy*, GUTTMACHER INST. (June 1, 2023), https://www.guttmacher.org/state-policy/explore/substance-use-during-pregnancy.

research has not demonstrated a causal link between substance use and child abuse or neglect.[65] In fact, research has found that treating substance use disorder as a form of child abuse or neglect has been more harmful to children and their families than the alleged effects of substance use on pregnancy and parenting.[66] It is critical that the final rule include investigations on the basis of health care related to substance use in its prohibition on use and disclosures. At minimum, the final rule should clarify that protected health information related to drug testing, drug screening, and treatment for substance use disorders throughout the perinatal period is protected information because it is part of reproductive health care.

*d. The NPRM's rule of construction includes critical safeguards against malicious and unnecessary reporting on reproductive health but should be strengthened in the final rule.*

The proposed rule of construction in §164.512 (c)(3) is vital to protecting individuals from being reported for the mere fact that they obtained, provided, or facilitated reproductive health care. This provision will be a critical tool to prevent providers from maliciously reporting patients for obtaining an abortion, or reporting parents for child abuse when they assist their pregnant child in exercising their right to obtain an abortion. It balances this prohibition against allowing providers to still report genuine concerns of abuse, so long as that concern is not primarily because a patient accessed reproductive health care.

However, the proposed rule of construction still leaves open certain avenues for improper reporting. The proposed rule states that providers are permitted to proactively report on their patients, but may not disclose information on request by law enforcement for the purpose of investigations related to reproductive health care.[67] Unfortunately, the proposed rule fails to recognize that one of the largest driving forces for criminalization related to pregnancy status or outcomes is health care providers who unnecessarily report their patients to law enforcement.[68] Recent research investigating the criminalization of self-managed abortion examined over sixty such cases and found that in 45% of cases of adult individuals managing their abortions, the self-management of their abortion was brought to the attention of law enforcement by care workers (39% health care providers, 6% social workers.).[69] Once law enforcement became involved, the vast majority of these cases led to an arrest and prosecution.[70] Importantly, this occurred not only in the two states that criminalize self-managed abortion, but also where prosecutors used a multitude of criminal laws intended for other purposes, including mishandling of human remains, concealment of a birth, child abuse, and assault. However, because the proposed rule of

[65] *Confronting Pregnancy Criminalization: A Practical Guide for Healthcare Providers, Lawyers, Medical Examiners, Child Welfare Workers, and Policymakers,* PREGNANCY JUST. (2022), https://www.pregnancyjusticeus.org/wp-content/uploads/2022/12/202211-PJ-Toolkit-Update-2.pdf.
[66] *Id.*
[67] HIPAA Privacy Rule To Support Reproductive Health Care Privacy 88 Fed. Reg. 23506, 23526 (proposed Apr. 17, 2023) (to be codified a 45 C.F.R. pts. 160, 164).
[68] 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 39% of adult cases came to the attention of law enforcement through health care providers).
[69] *Id.*
[70] *Id.*

construction focuses on the *provision* of reproductive health care, the proposed rule is unclear on whether it protects patients who have self-managed their abortion.

Additionally, some providers, including mental health practitioners and social workers, may be subject to mandatory reporting laws, and the rule fails to clarify how it interacts with reporting requirements which may expose patients and providers to investigations based on reproductive health care. For example, more than half of all states require some reporting of suspected prenatal substance use,[71] and such reporting frequently triggers agency or criminal investigations against the pregnant person. The rule should clarify how it interacts with such mandatory reporting laws, which stand in clear conflict with the proposed rule and its purpose.

We appreciate the proposed definition of the term "person" to clarify that a person must be someone who is born alive. In conjunction with the rule of construction, this clarification is very important to help curtail malicious reporting of pregnant patients who seek access to abortion care. However, it is important to note that it may fail to provide the broad protection it intends. For example, a provider may wait until a pregnant person gives birth before reporting them for using substances during pregnancy.

The rule of construction should also protect circumstances in which a pregnant patient isn't obtaining *reproductive* health care, but the health information is discovered during the course of reproductive health events. For example, a provider might attempt to report a pregnant patient for substance use during pregnancy, if that patient discloses substance use or their medical record indicates substance use during a health care visit unrelated to reproductive health care. A pregnant person retains their full bodily autonomy throughout pregnancy and cannot and should not be punished for actions they take during their pregnancy, regardless of their pregnancy outcomes, and almost any care they seek during pregnancy is inherently related to reproductive health care. This remains true regardless of where and how they obtain the care. For these reasons, we recommend that the rule of construction clarify that a pregnant person cannot be reported for any actions taken during their pregnancy on the basis that these actions could impact or have impacted their pregnancy outcome.

Earlier, we recommended that the Department expand the purpose-based prohibition to be broader than just reproductive health care to include other types of care such as substance use and transgender health care. Extending that reasoning to the rule of construction, we recommend that the rule of construction also be broadened to include that care. For example, a parent should never be reported for having consented or facilitated access to transgender health care for their child.

We also recommend that the rule of construction prohibit providers from reporting patients for the sole reason of having received care in a state where it was not lawful. The role of health care providers is not to police the actions of their patients, but to provide compassionate, nonjudgmental health care. Limiting this rule to lawfully obtained health care could encourage some providers to report on their patients. Current interoperability rules make this a particularly urgent concern because they give providers near-instantaneous access to their patients' full

[71] *Substance Use During Pregnancy*, GUTTMACHER INST. (Apr. 30, 2023), https://www.guttmacher.org/state-policy/explore/substance-use-during-pregnancy.

medical record. While interoperability is a crucial tool to improve care coordination, in the current legal landscape surrounding reproductive health care and transgender health care it also poses a real risk to patients and providers. Some providers are willing to report on their patients based on their personal biases, and uncertainty over the legal status of care provided elsewhere may lead to inappropriate reporting and disclosures. Combined with the previously discussed lack of clarity as to when and where certain instances of care were unlawful, the free-flowing exchange of electronic medical records poses a grave danger to many patients and providers. In fact, the information blocking rule has already facilitated some of the harms this rule is trying to prevent. The Department should expand the scope of the rule of construction to protect all covered care, whether obtained lawfully or not, and take steps to mitigate the risk that interoperability poses to patients' privacy and freedom.

*e. The public health exception to the proposed rule should be limited to statistically significant parameters to reduce the risk of re-identification of patient data.*

The proposed rule maintains the existing public health exception allowing providers to report reproductive health care for public health purposes. However, this assumes incorrectly that public health data will not be tied back to an individual. Where data sets are not large enough to be statistically significant, the risk of de-anonymization is high. Research has shown that there are legitimate privacy concerns even with larger sets of de-identified and sampled datasets, and that today's technology, in combination with publicly available data online, makes it possible to re-identify "anonymized data.[72] In fact, there are recorded incidents where individuals have been identified *despite* anonymized data.[73] Given the highly stigmatized nature of reproductive health care, it is essential that the final rule ensure public health data is adequately protected. We recommend that the Department should only allow disclosure for public health purposes where a data set is large enough to be statistically significant, and consider additional measures to restrict the types of markers used or publicly disclosed in public health disclosures.

Smaller, rural communities are at particular risk for improper disclosure because seemingly standardized identity markers may be traced back to individuals quite easily. Consider a data set that includes race, gender, and municipality or zip code. In some areas, a Black woman of reproductive age who lives in a small, overwhelmingly white community could be very easily re-identified. We hope to avoid situations where individual data will be exposed despite anonymization, especially in the context of reproductive health care, which is subject to not only greater scrutiny but increased stigma, harassment, and even violence in the post-*Dobbs* world. We recommend that the Department ensure that this information can only be disclosed and used for public health purposes where there is a statistically significant population that will allow the

[72] See, e.g., Luc Rocher, Julien M. Henrickx & Yves-Alexandre de Montjoye, *Estimating the Success of Re-Identifications in Incomplete Datasets Using Generative Models*, NATURE COMMC'NS (2019), https://www.nature.com/articles/s41467-019-10933-3.pdf; Boris Lubarsky, *Re-Identification of "Anonymized" Data*, 1 GEO. L. TECH. REV. 202, 208 (2017).

[73] *See* Lucy Chikwetu, Yu Miao, Melat K. Woldetensae, Diarra Bell, Daniel M. Goldenholz & Jessilyn Dunn, *Does Deidentification of Data From Wearable Devices Give Us A False Sense of Security? A Systematic Review*, 5 The Lancet 1, 7 (2023); Latanya Sweeney, *Only You, Your Doctor, and Many Others May Know*, TECH. SCIENCE (Sept. 28, 2015), https://techscience.org/a/2015092903/; Ji Su Yoo, Alexandra Thaler, Latanya Sweeney & Jinyan Zang, *Risk to Patient Privacy: A Re-identification of Patients in Maine and Vermont Statewide Hospital Data*, TECH. SCIENCE (Oct. 8, 2018), https://techscience.org/a/2018100901/.

information to be safely anonymized. Where it is unavoidable to disclose a small data set for public health reasons, HHS should consider additional measures to protect the PHI from future re-identification and de-anonymization.

*f. The Department should revise the attestation requirement in order to avoid bad faith attestations and reduce administrative burdens on providers.*

To use or disclose protected health information under one of the proposed exceptions, the Department proposes the provision of an attestation by the requesting party. A valid attestation "verifies that the use or disclosure is not otherwise prohibited."[74] It must include a description identifying the information sought, including the purpose of the disclosure and a "clear statement that the use or disclosure is not for a purpose prohibited" under the rule, among other requirements.[75] While we commend the Department's effort to ensure that PHI is only disclosed for legitimate reasons under the Privacy Rule, we do not believe the attestation requirement is strong enough to prevent impermissible disclosures. Although a step in the right direction, attestations are unlikely to prevent bad faith requests for PHI, are burdensome on providers, and will be difficult to enforce.

Attestations generally require a signature in the presence of a witness, who also signs the document, attesting to the contents of the document and the authenticity of its signer.[76] Attestations are not notarized, nor do they require any form of judicial review or approval. Attestations are the simplest and least enforceable means of stating information. Comparatively, declarations are similar statements, but a declarant may be found guilty of perjury if the declaration is found to be false.[77] Search warrants have even higher standards and must articulate probable cause, describe the area to be searched, and be signed by a neutral magistrate judge prior to executing a search.[78] There are many documented instances indicating that the practice of falsifying information for warrants is pervasive amongst law enforcement.[79] Because the attestation requirements are so weak in comparison to alternatives like declarations or warrants, law enforcement may be even more likely to act in bad faith when completing attestations to obtain protected reproductive health information.

We suggest that the Department heighten the standard for requests for disclosure to, at minimum, a declaration. This will have a deterrent effect on bad faith requestors who misrepresent or falsify the purpose of their request. In most circumstances, it is unlikely that a false attestation will be discovered until the PHI has been disclosed and used for prohibited purposes. At this point, it

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[74] HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23553 (proposed Apr. 17, 2023) (to be codified at 45 C.F.R. pt. 160).
[75] *Id*.
[76] *Attestation*, CORNELL L. SCH.: LEGAL INFO. INST. (Feb. 2022), https://www.law.cornell.edu/wex/attestation.
[77] Declaration, BLACK'S LAW DICTIONARY (11th ed. 2019).
[78] Groh v. Ramirez, 540 U.S. 551 (2004); United States v. Grubbs, 547 U.S. 90 (2006); Coolidge v. New Hampshire, 403 U.S. 443 (1971).
[79] Blanche B. Cook, *Something Rots in Law Enforcement and it's the Search Warrant: The Breonna Taylor Case*, 102 B.U. L. REV. 1, 54 (2022) (addressing that the search warrant used to enter Breonna Taylor's home was based on a lie from LMPD Detective Joshua Jaynes); Melanie D. Wilson, *An Exclusionary Rule for Police Lies*, 47 AM. CRIM. L. REV. 1, 5 (2010) (discussing how technology has been used to gather evidence of police lies and how that evidence has been mounting in recent years).

will be too late to protect a patient, their information, and their identity. The rule aims to prevent this information from being used for investigative purposes, but where false attestations lead to PHI disclosure, the NPRM's purpose is easily circumvented. To avoid these complications, we recommend that the Department revise the attestation requirement to, at minimum, include a signed declaration made under penalty of perjury that the requester is not making the request for a prohibited purpose. In the event that PHI is disclosed under false pretenses, the requesting party should be subject to a significant financial penalty.

Importantly, the burden of determining the validity of an attestation, and consequently whether PHI should be disclosed, would fall on the parties holding the PHI and may disproportionately impact small providers. Large health care systems with sophisticated legal departments will likely have the resources to address these requests, although increasingly they may be using automated systems to essentially rubber stamp these requests. However, small, independent providers will not have the same resources or ability to properly determine the veracity of attestations. This task would be overly burdensome on small and rural hospitals and provider offices, which primarily serve older, sicker, and poorer patient populations, and would add yet another administrative task for health care providers, who are already navigating a myriad of health care regulations.[80] Regardless of whether a provider is large or small, responding to law enforcement and other disclosure requests will be a significant burden. Irrespective of the final iteration of the attestation requirement, the Department should provide health care providers with education and grants to ensure that providers are fully trained on the attestation/declaration requirement, how to determine the veracity of requests for disclosure, and potential enforcement options. In the event that providers experience harassment by parties seeking disclosure, the Department should be available to provide guidance and assistance supporting providers and their right to choose not to disclose the information.

## III. International human rights law and global public health guidance support the proposed changes to the privacy rule.

The government is obligated under international human rights law to ensure that reproductive health services, including abortion, are provided in a manner that respects women, pregnant people, and girls' privacy and guarantees confidentiality. [81] United Nations human rights experts are clear that "states must respect and protect key principles of non-discrimination, equality and privacy . . . especially in relation to sexual and reproductive health rights."[82]

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80 Jacqueline LaPointe, *Low Reimbursement, Staffing Shortages Lead to Rural Hospital Closures*, REVCYCLE INTELLIGENCE (Sept. 13, 2022), https://revcycleintelligence.com/news/low-reimbursement-staffing-shortages-lead-to-rural-hospital-closures..

[81] General Comment No. 36: Article 6 of the International Covenant on Civil and Political Rights, on the right to life. Geneva: United Nations Human Rights Committee (124th session); 2018 (CCPR/C/GC/36); Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Report to the United Nations General Assembly. New York (NY): United Nations; 2016 (A/HRC/32/32).

[82] The CEDAW Committee has recommended States "[r]equire all health services to be consistent with the human rights of women, including the rights to autonomy, privacy, confidentiality, informed consent and choice[.]" CEDAW Committee General Recommendation No. 24, ¶ 31€; U.N. Office of the High Commissioner for Human Rights, World Contraception Day, 26 September 2021 (23 September 2021), https://www.ohchr.org/en/statements/2021/09/world-contraception-day-26-september-2021.

Additionally, the World Health Organization's most recent Abortion Care Guideline emphasizes that "everyone has a right to privacy and confidentiality in sexual and reproductive health (SRH) care."[83] The Guideline reiterates the human rights principles that reproductive health care "must be provided in a way that respects fully the woman's, girl's or other pregnant person's privacy and guarantees confidentiality" and "medical and health-care professionals must not be required or mandated to report cases of women who have undergone abortions."[84]

While challenges still exist in safeguarding the privacy of patients and protecting patients and providers who obtain or provide health care, the proposed rule would bring the United States one step closer to alignment with international human rights and global public health guidance.

## IV. Conclusion

We appreciate the opportunity to comment on this NPRM, and we commend the Department for taking these vital steps to strengthen privacy protections under the HIPAA Privacy Rule. We urge the Department to consider additional protections in the final rule based on our comments. If the Department requires any additional information about the issues raised in this letter, please contact Freya Riedlin, Federal Policy Counsel, at friedlin@reprorights.org.

Signed,

The Center for Reproductive Rights

[83] *Abortion Care Guideline*, WORLD HEALTH ORG. (2022), https://www.who.int/publications/i/item/9789240039483.
[84] *Id.*