VIA ELECTRONIC TRANSMISSION June 16, 2023

Melanie Fontes Rainer
Director, Office for Civil Rights
Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201

Re: RIN 0945-AA20
HIPAA Privacy Rule to Support Reproductive Health Care Policy

Dear Director Rainer,

Thank you for the opportunity to comment in response to the Notice of Proposed Rulemaking (Proposed Rule), "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," released by the Department of Health and Human Services Office for Civil Rights (OCR or the Department) on April 12, 2023 and published in the Federal Register on April 17, 2023.[1] Pregnancy Justice commends OCR for taking a critical step towards increasing reproductive health care privacy. We nonetheless urge the Department to strengthen the Proposed Rule to ensure that the most marginalized perinatal patients—including those who use substances and those who self-manage their abortions—are not left at risk of criminalization and other punitive state action.

Pregnancy Justice, formerly known as National Advocates for Pregnant Women, is a non-partisan legal advocacy organization dedicated to the welfare of pregnant people and their families. Our comment draws on over twenty years of work on cases in which state actors intervened in a pregnant person's medical decision-making or punished them and their family based on the assumption that their acts or omissions while pregnant put their fetus at risk. Since 1973, we have documented over 1,700 cases in which birthing people were arrested, prosecuted, convicted, detained, or forced to undergo medical interventions because state actors believed their rights could be denied in the interest of fetal protection.[2]

[1] 88 Fed. Reg. 23506-23553 (Apr. 17, 2023).
[2] Pregnancy Justice, *Arrests and Deprivations of Liberty of Pregnant Women, 1973-2020* (Sept. 2021), https://www.pregnancyjusticeus.org/arrests-and-prosecutions-of-pregnant-women-1973-2020/; Lynn M. Paltrow & Jeanne Flavin, *Arrests of and Forced Interventions on Pregnant Women in the United States, 1973–2005: Implications for Women's Legal Status and Public Health*, 38 J. Health Pol., Pol'y, & L. 299 (Apr. 2013),

Pregnancy Justice, in coalition with over 100 other reproductive justice organizations and allies, wrote and submitted a comment urging the Department to improve the Proposed Rule by: (1) making explicit that testing and treatment for substance use in the perinatal period are forms of "reproductive health care" and are thus covered by the Proposed Rule; (2) extending the protections of the Proposed Rule to self-managed abortion; (3) extending the protections of the Proposed Rule to other forms of stigmatized, highly sensitive health care, such as gender-affirming care; (4) strengthening the attestation provision and ensuring robust enforcement; and (5) further clarifying the scope of the Proposed Rule.[3] Pregnancy Justice contends that each of the suggested modifications in the coalition comment would dramatically strengthen the Proposed Rule, and thus incorporates them by reference herein.

I. The Proposed Rule Must Include Explicit Protections Against Disclosures Related to Pregnancy and Substance Use

Of particular importance is the first suggestion to amend the Proposed Rule to clarify in explicit terms that the definition of "Reproductive Health Care" includes drug testing, drug screening, and treatment for substance use disorders throughout the perinatal period. The practice of drug testing pregnant people and reporting the results of those tests to state authorities is the leading reason why pregnant people face criminalization and other punitive state actions due to their pregnancy status or outcomes.[4] In fact, over eighty-four percent of the arrests and prosecutions identified in Pregnancy Justice's research involved allegations of the use of controlled substances, even though the vast majority of state criminal laws do not make using drugs—as opposed to possessing drugs—illegal. Accordingly, these prosecutions transform drug use or dependency by one group of people—pregnant women—into criminal "child abuse," "chemical endangerment" or even "murder."[5] Moreover, at least forty-one percent of these cases originated from reports from health care providers or hospital social workers, indicating that the prosecutions would never have been brought were it not for the common practice of nonconsensual drug testing and reporting.[6]

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https://read.dukeupress.edu/jhppl/article/38/2/299/13533/Arrests-of-and-Forced-Interventions-on-Pregnant.

[3] Letter from Over 100 Reproductive Justice and Allied Organizations to Director Fontes Rainer (June 16, 2023), *available at* https://www.pregnancyjusticeus.org/wp-content/uploads/2023/06/HIPAA-Coalition-Letter-6.16.23-Final.pdf.

[4] Paltrow & Flavin, *supra* note 1 at 299.

[5] *Id.* at 323.

[6] *Id.* at 311.

Drug testing perinatal patients without a specific medical concern and without their informed consent is widely opposed by leading medical organizations.[7] For instance, the American College of Obstetricians and Gynecologists (ACOG) provides, "testing and reporting puts the therapeutic relationship between the obstetrician–gynecologist and the patient at risk, potentially placing the physician in an adversarial relationship with the patient."[8] In addition to eroding patient-provider trust, ACOG recognizes that testing and "reporting during pregnancy may dissuade women from seeking prenatal care and may unjustly single out the most vulnerable, particularly women with low incomes and women of color."[9] ACOG concludes that "[d]rug enforcement policies that deter women from seeking prenatal care are contrary to the welfare of the mother and fetus."[10]

Indeed, the consequences of drug testing, reporting, and criminalizing pregnant people for substance use extend far beyond the individual women investigated. When pregnancy and substance use are subject to prosecution and candid communications with health care providers are used as the basis for child welfare and law enforcement actions, women are deterred from seeking medical care and supportive services that would improve pregnancy outcomes.[11] For example, research revealed that the prosecution of women for pregnancy and substance use under Tennessee's fetal assault law (which

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

[8] American College of Obstetricians and Gynecologists, *ACOG Committee Opinion: Substance Abuse Reporting and Pregnancy: The Role of the Obstetrician–Gynecologist* (reaffirmed June, 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2011/01/substance-abuse-reporting-and-pregnancy-the-role-of-the-obstetrician-gynecologist.

[9] *Id.*

[10] *Id.*; *see also* American College of Obstetricians and Gynecologists, *Opposition to Criminalization of Individuals During Pregnancy and the Postpartum Period* (Dec. 2020) ("Criminalization of pregnant people for actions allegedly aimed at harming their fetus poses serious threats to people's health and the health system itself. Threatening patients with criminal punishment erodes trust in the medical system, making people less likely to seek help when they need it."), https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period.

[11] See Rebecca L. Haffajee et al., *Pregnant Women with Substance Use Disorders—The Harm Associated with Punitive Approaches*, 384 N. ENGL. J. MED. 2364 (2021); Laura J. Faherty et. al., *Association of Punitive and Reporting State Policies Related to Substance Use in Pregnancy with Rates of Neonatal Abstinence Syndrome*, JAMA (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2755304.

was in effect for only two years) resulted in twenty fetal deaths and sixty infant deaths in 2015 alone.[12]

The Department must clarify that its definition of "Reproductive Health Care" encompasses testing for and treatment of substance use in pregnancy to guard against this common pathway to pregnancy criminalization. The omission of drug testing and treatment during the perinatal period from the current definition of "Reproductive Health Care" risks the further erosion of patient-provider trust and will deter the most vulnerable pregnant people from seeking necessary medical care.

II. The Proposed Rule Must Narrow the Exception for Child Abuse Reports to Ensure Perinatal Patients Are Not Criminalized for Acts or Omissions During Pregnancy

By maintaining the Privacy Rule's expansive exception for child abuse reports under 45 CFR 164.512(b)(1)(ii), the Proposed Rule overlooks the most common pathway through which people face criminalization on the basis of their pregnancy status or pregnancy outcomes: when a medical provider files a report to the local child protective services agency, which in turn informs criminal law enforcement. The Proposed Rule's broad exception will effectively swallow the rule by failing to guard against the mechanism by which the majority of investigations and subsequent criminal prosecutions against pregnant people begin.

The Proposed Rule attempts to correct for this troublesome loophole by pointing to the fact that under federal law, a fetus is not considered a child.[13] We commend the Department's efforts to ensure that the exception for child abuse reporting will not permit investigations against pregnant people for so-called "abuse" against their fetuses under a state's expansive interpretation of its child abuse statute to embrace the notion of fetal personhood. That said, the Proposed Rule does not go remotely far enough, and does not make adequately clear when federal law will preempt a state's interpretation of its own child abuse statutes to include so-called abuse against fertilized eggs, embryos, and fetuses.

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[12] Meghan Boone & Benjamin J. McMichael, *State-Created Fetal Harm*, 109 Georgetown L. J. 475, 514 (2021).

[13] *See* 88 Fed. Reg. 23,526 (April 17, 2023) ("[T]he Department understands the term 'person' as it is used in the SSA, HIPAA, and the HIPAA Rules to be consistent with 1 U.S.C. 8. Congress also defined the term 'child' in 1 U.S.C. 8, and the Department similarly understands the term "child" in the Privacy Rule to be consistent with that definition.").

In reality, medical providers frequently file child abuse reports with child protective services once an infant is born, but on the basis of a pregnant person's acts or omissions that occurred while the neonate was still in utero. For example, a medical provider may file a report the day an infant is born on the basis of a drug test performed on a urine sample taken from a pregnant person while she was at the hospital for labor and delivery. A medical provider may also file a report on the basis of a drug test performed on an infant's meconium or first urine sample. Even if such a report is based on a test taken after the infant was born—and thus after the infant is considered a "child" under the terms of the Proposed Rule and 1 U.S.C. 8—it would reflect drugs that were consumed and metabolized while the infant was still in utero. Accordingly, it leads to the exact same form of pregnancy criminalization as a case that begins with the report of a drug test performed on a pregnant person's urine sample provided during a prenatal care appointment.

For instance, Pregnancy Justice has provided legal support to dozens of women criminally prosecuted for "chemical endangerment of a minor" in Alabama due to their alleged substance use during pregnancy. A significant percentage of these cases began when hospital staff filed reports to the Department of Human Resources (DHR), Alabama's so-called "child welfare" agency, based on a mother's drug test immediately before or after labor and delivery and/or an infant's drug test using a meconium or first urine sample. Notably, DHR cannot open a child abuse case against a pregnant person while the fetus is still in utero, and thus waits until immediately after birth to launch an investigation against a postpartum person. Moreover, in some counties, DHR shares any information it receives from medical providers about alleged substance use during pregnancy with criminal law enforcement as a matter of course, leading to parallel DHR and criminal proceedings.

The chemical endangerment statute, passed in 2006 to prevent parents from exposing their children to toxic fumes from home-based methamphetamine labs, was never intended to apply to pregnancy and substance use.[14] Yet in 2013, the Alabama Supreme Court concluded that the word "child" as written in the chemical endangerment statute includes unborn children, thereby judicially expanding the law to permit prosecution of women, at any stage of pregnancy, for use of any controlled substance, including those prescribed to her.[15] Since then, district attorneys have

[14] ALA. CODE § 26-15-3.2; Nina Martin, *Take a Valium, Lose Your Kid, Go to Jail*, ProPublica (Sept. 23, 2015), https://www.propublica.org/article/when-the-womb-is-a-crime-scene; Amy Sieckmann, *State Bills Crack Down on Meth,* The Annniston Star, May 5, 2005, at 1B.
[15] *See Ex parte Ankrom*, 152 So.3d 397 (Ala. 2013); *Hicks v. State*, 153 So.3d 53 (Ala. 2013).

charged over 600 pregnant and postpartum women for chemical endangerment based on the theory that their alleged substance use during pregnancy endangered the "child"—a fertilized egg, embryo, or fetus—within her uterus.[16]

For example, Pregnancy Justice's client, H.B., of Etowah County, AL, is facing criminal "chemical endangerment" charges due to her alleged substance use during pregnancy.[17] Ms. B. was arrested from her hospital bed just days after giving birth, incarcerated pretrial in the Etowah County Jail for over two months, and forcibly separated from her toddler and newborn.[18] The Etowah County Sheriff's investigative report indicates that the hospital at which Ms. B. delivered her baby reported a positive toxicology test to Etowah County DHR the day after she gave birth, which in turn shared that information with the Sheriff's investigator.[19] The investigator proceeded to subpoena Ms. B.'s prenatal care provider for records regarding substance use tests throughout her pregnancy.[20] Relying on this combination of records, the Etowah County Sheriff arrested Ms. B. from the hospital a few days later, and the DA brought criminal chemical endangerment charges against her. Ms. B. is one of over 150 pregnant and postpartum women who have faced such charges in Etowah County alone.[21]

In its current form, the Proposed Rule does not adequately protect against the disclosure of private health care information that led to the criminal prosecution of Ms. B., as well as hundreds of other women across Alabama, on the basis of their alleged substance use during pregnancy. First, the Proposed Rule does not clearly bar medical providers from disclosing the results of toxicology tests performed on neonate's first urine after birth or meconium—even though these tests only reflect potential drug use while the neonate was in utero and was thus not considered a "child" under federal law. The Proposed Rule's provision that the term "child" in 1. U.S.C. 8 governs child

[16] Full list of case names and docket numbers on file with author. An analysis of these cases will be included in a forthcoming publication by Pregnancy Justice this fall.
[17] Amy Yurkanin, *Pregnant women held for months in one Alabama jail to protect fetuses from drugs* (Sep. 8, 2022), AL.com, https://www.al.com/news/2022/09/pregnant-women-held-for-months-in-one-alabama-jail-to-protect-fetuses-from-drugs.html.
[18] Amy Yurkanin, *After two months, new mom released from Etowah County Jail* (Sep. 16, 2022), AL.com, https://www.al.com/news/2022/09/after-two-months-new-mom-released-from-etowah-county-jail.html#:~:text=Hali%20Burns%20had%20been%20charged,prescription%20medications%20caused%20false%20positives.
[19] Investigative Report on file with author.
[20] *Id.*
[21] Full list of case names and docket numbers on file with author. An analysis of these cases will be included in a forthcoming publication by Pregnancy Justice this fall.

abuse reports does not adequately guard against this concern, given that medical providers make such a report once the child is born.

Second, once law enforcement authorities learn of a positive toxicology result from the so-called child welfare authorities who received the report from a medical provider, the Proposed Rule does not prevent law enforcement authorities from obtaining further reproductive health care information from prenatal care providers by issuing a subpoena. The Proposed Rule merely provides, "Any disclosure of PHI in response to a request from an investigator, whether in follow up to the report made by the covered entity . . . or as part of an investigation initiated based on an allegation or report made by a person other than the covered entity, would be required to meet the conditions of disclosures to law enforcement or for other investigations or legal proceedings."[22]

In order to guard against the wrongful disclosure of reproductive healthcare information, the Department must state unambiguously that the Proposed Rule prohibits the disclosure of medical information about the perinatal patient and neonate—not only during pregnancy and while the fetus was in utero, but also during labor and delivery and in the course of postpartum care and early newborn care. This expanded prohibition on disclosure, as well as the Proposed Rule's definition of "child" under 1 U.S.C. 8, must apply not only to child abuse reports under 45 CFR 164.512(b)(1)(ii), but also to disclosures to law enforcement or for other investigations or legal proceedings under 45 CFR 164.512(e) and (f).

III. Conclusion

Pregnancy Justice commends the Department for its efforts to strengthen reproductive health care privacy. We urge the Department to modify the Proposed Rule, consistent with the above recommendations, to ensure that the most marginalized perinatal patients—including those who use substances or self-manage their abortions—do not remain at outsized risk of criminalization or other punitive state actions.

Sincerely,

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[22] *See* 88 Fed. Reg. 23,526 (April 17, 2023).