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September 6, 2024

File Code CMS-1809-P (VIA ELECTRONIC DELIVERY)

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

Pregnancy Justice welcomes the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) as the agency considers proposed changes included in the Calendar Year (CY) 2025 Medicare hospital Outpatient Prospective Payment System (OPPS) and Medicare Ambulatory Surgical Center (ASC) proposed rule to the Medicare Conditions of Participation (CoPs) for hospitals.

Pregnancy Justice protects and advances pregnant peoples' bodily autonomy and rights by defending those who have been criminalized, advocating for proactive policy and legal change, and shifting the public narrative on this important topic. We focus on those most vulnerable to investigation, arrest, detention, or family separation related to pregnancy. This includes pregnant people who are poor, of color, with disabilities, do not conform to gender binary stereotypes, and/or use drugs. The criminalization of pregnancy is rooted in sexism, as it seeks to impose traditional gender norms through its attempt to undermine pregnant peoples' rights and personhood. Our efforts to defend against pregnancy criminalization and punitive treatment are guided by the principles of reproductive justice, which is defined by SisterSong Women of Color Reproductive Justice Collective as the human right to maintain personal bodily autonomy, have children, not have children, and parent the children we have in safe and sustainable communities.

Since its founding over 20 years ago (as National Advocates for Pregnant Women), Pregnancy Justice has worked across disciplines, including reproductive rights and justice, public health, drug policy, criminal justice reform, racial justice, and prosecutorial accountability, among others, to achieve its mission. This includes co-authoring a letter to UN Special Procedures on US Abortion Rights,[1] releasing our second landmark study, Rise of Pregnancy Criminalization,[2] 2024 testimony to the Senate Committee on the Judiciary,[3] and representing dozens of pregnant people who face criminal charges because of pregnancy, from murder to child neglect.

Below, we provide background information on the problem of pregnancy criminalization in America. Most importantly, we then offer recommendations about how CMS could strengthen the newly proposed obstetric care CoPs to help reduce the negative health impacts of pregnancy criminalization.

Background

Pregnancy criminalization is charging pregnant people for conduct that would not be illegal, except for the fact that they are pregnant. This includes being charged with murder for experiencing a stillbirth, or for having a miscarriage and not knowing what to do with the fetal remains. It also includes charging a pregnant person with a crime following a toxicology screening that they were given without informed consent. Far too often, criminal investigations are based on a single positive toxicology test result.

Pregnant people who use substances also face punishment through the family policing system, more commonly known as the child welfare system,[4] with at least 27 states and the District of Columbia mandating reports of substance use during pregnancy to the family policing system from a mere positive toxicology test.[5] Following a report to the family policing system, infants are often separated from their parents moments after birth and can result in permanent removal or the termination of parental rights.[6] The harms of child removal are well-documented and this

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[1] Global Justice Center. Letter to UN Special Procedures on U.S. abortion rights. March 2, 2023. https://www.globaljusticecenter.net/letter-to-un-special-procedures-on-us-abortion-rights/.

[2] Kavattur PS, Frazer S, El-Shafei A, et al. The Rise of Pregnancy Criminalization: A Pregnancy Justice report. Pregnancy Justice; September 2023. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/9-2023-Criminalization-report.pdf.

[3] Rivera L. Testimony of Lourdes A. Rivera, President of Pregnancy Justice before the United States Senate Judiciary Committee, March 20, 2024. https://www.pregnancyjusticeus.org/wp-content/uploads/2024/03/Lourdes-Rivera-Senate-Judiciary-Testimony.pdf.

[4] A note on language: The term "family policing system," first used by Victoria Copeland and Brianna Harvey, and later popularized by Professor Dorothy Roberts, represent the realities of the group of state-level agencies that constitute what is often called the "child protective" or "child welfare" system. While the stated goal of this system is to protect children and promote their welfare, the reality is that states regulate and surveil children's families in a fashion that harms rather than helps. Instead of offering substantive material aid which families frequently need, the family regulation system prioritizes punishment, only exacerbating familial instability, poverty, and stress.

[5] Edwards F, Roberts SCM, Kenny KS, Raz M, Lichtenstein M, Terplan M. Medical professional reports and child welfare system infant investigations: An analysis of National Child Abuse and Neglect Data System data. Health Equity. 2023 Sep 29;7(1):653-662. doi: 10.1089/heq.2023.0136. PMID: 37786528; PMCID: PMC10541941; National Institute on Alcohol Abuse and Alcoholism. Alcohol policy information system: Pregnancy and alcohol reporting requirements. Washington, DC: National Institute on Alcohol Abuse and Alcoholism.

[6] Reddy J, Schiff D, Terplan M, Jones H, Putnam-Hornstein E. Child protection system removal and short-interval births among individuals with prenatal substance use. Obstet Gynecol. 2024;143:10.1097/AOG.0000000000005552.

trauma can result in adverse cognitive, emotional, and social outcomes for children with lifelong implications.[7]

The fact of pregnancy itself is not a medical justification for drug testing.

Medical professionals and family policing workers have a key part to play in disentangling carceral systems from healthcare and in the over-reporting of substance use during pregnancy. Substance use disorder is a leading cause of maternal death, and too many pregnant people face the specter of family policing investigations or criminal charges for being pregnant and having a substance use disorder. These individuals will avoid prenatal care out of fear of losing custody of their current and future children. The structures that punish pregnant people who use substances make it impossible to engage them in interventions that they need to have healthy pregnancy outcomes. We encourage CMS to use its CoP proposals as a critical policy lever to reduce pregnancy criminalization.

Pregnancy Justice has documented over 1,800 cases of pregnancy criminalization in the years 1973 to 2022.[8] In 92 percent of cases, law enforcement officials used alleged substance use as a basis for charging pregnant people with criminal child neglect or endangerment. The three most common substances associated with pregnancy criminalization cases were methamphetamine (39 percent of arrests), cannabis (34 percent of arrests), and cocaine (24 percent of arrests). Pregnant people were also criminalized for allegations of using legal substances. For example, nearly 21 percent of cases involved alleged use of prescription opiates (prescription status known and unknown), 16 percent of cases involved non-opiate prescription or over-the-counter medication or medication-assisted treatment, 2.5 percent of cases involved alcohol and 1.6 percent of cases involved nicotine.

Though purportedly rooted in the desire to preserve fetal life and health, criminalizing substance use disorder in pregnancy deters pregnant people from seeking healthcare and actually increases risks to maternal, child, and fetal health.[9] The states with the highest rates of pregnancy criminalization also have some of the worst maternal mortality rates in the country. All five of the states with the most pregnancy criminalization cases—Alabama, South Carolina, Tennessee, Oklahoma, and Mississippi—rank among the top 11 states in maternal mortality.[10]

According to the case information available, poor Black pregnant people and poor white pregnant people bear the brunt of the consequences of pregnancy criminalization. Research also shows that Black people are much more likely to be drug tested during pregnancy (despite not

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[7] Trivedi S. The harm of child removal. New York University Review of Law & Social Change. 2019;43:523. https://scholarworks.law.ubalt.edu/all_fac/1085/

[8] Kavattur PS, Frazer S, El-Shafei A, et al. The Rise of Pregnancy Criminalization: A Pregnancy Justice report. Pregnancy Justice; September 2023. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/9-2023-Criminalization-report.pdf.

[9] American College of Obstetricians & Gynecologists. Opposition to criminalization of individuals during pregnancy and the postpartum period. December 2020. https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period/; ("Clear evidence exists that criminalization and incarceration for substance use disorder during pregnancy are ineffective as behavioral deterrents and harmful to the health of the pregnant person and their infant."); Rivera L. Testimony of Lourdes A. Rivera, President of Pregnancy Justice before the United States Senate Judiciary Committee *supra* note 3; Boone M, McMichael BJ. State-created fetal harm. Georgetown Law Journal. 2021;109:475.

[10] *Supra* note 6 at 47; Alabama and Mississippi also rank among the top 5 states in fetal mortality. Taft I. Mississippi moms suffer another grim statistic: The nation's highest rate of stillbirths. *Mississippi Today*. August 5, 2022. https://mississippitoday.org/2022/08/05/mississippi-stillbirth-rates/.

having a higher probability of a positive test result than other racial groups), subjected to family policing, and separated from their children, despite generally similar drug use rates across racial groups.[11] Black women made up 18 percent of arrests due to pregnancy criminalization from January 2006 to June 2022, despite Black women making up only 13 percent of the U.S. population.[12] White people are also disproportionately represented, accounting for nearly 80 percent of the total reported arrests of pregnant people, despite white women only representing 58.8% of the population.[13]

Further, the rate of arrests varies by type of substance allegedly involved and by race. About half of arrests of Indigenous and Black pregnant people involved allegations of cannabis use compared to about 30 percent of arrests of white people, indicating that these two populations have been penalized more harshly for minor drug offenses and the enforcement of marijuana laws.[14]

Additionally, case information available suggests pregnancy criminalization has overwhelmingly affected poor people. Roughly 85 percent of pregnancy criminalization arrests involved a pregnant person who qualified for court-appointed representation, generally indicating the person could not afford a private attorney.[15] This suggests that most of the pregnant people arrested faced substantial financial hardship and makes it that much more critical that the government-funded healthcare programs serving this population have strong safeguards against pregnancy criminalization. Pregnant people who can afford private physicians and avoid public services are likely better able to avoid testing, reporting, and criminalization.

Medical professionals play a significant role in pregnancy criminalization, either by directly reporting to law enforcement or by contributing to investigations against pregnant people. Roughly 34 percent of pregnancy-related arrests were first instigated by a medical professional either directly or indirectly reporting to law enforcement.[16] The fear of law enforcement involvement discourages open and honest conversations between pregnant people and their healthcare providers about substance use.[17] This can interfere with providers' ability to detect substance use disorders and determine appropriate treatment options. For example, the standard of care for treating pregnant people with substance use disorder is medication-assisted treatment,[18] which cannot be implemented by healthcare providers if their patients are too afraid to speak openly about their substance use, including use of prescription medications.

Instead of receiving treatment and support, pregnant people face family separation, punishment, and substandard perinatal care. In most cases of pregnancy criminalization, newborns are

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[11] Jarlensky M, et al. Association of race with urine toxicology testing among pregnant patients during labor and delivery. *JAMA Health Forum*. 2023;4(4).https://jamanetwork.com/journals/jama-health-forum/fullarticle/2803729.
[12] Kavattur PS, Frazer S, El-Shafei A, et al. The Rise of Pregnancy Criminalization: A Pregnancy Justice report. Pregnancy Justice; September 2023. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/9-2023-Criminalization-report.pdf..
[13] *Id*. at 22
[14] *Id* at 41.
[15] *Id* at 23.
[16] *Id* at 25.
[17] American College of Obstetricians & Gynecologists. Opposition to criminalization of individuals during pregnancy and the postpartum period. December 2020. https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period/.
[18] Ramsey KS, Stancliff S, Stevens LC, et al. Substance use disorder treatment in pregnant adults. *Johns Hopkins University*; July 2021. https://www.ncbi.nlm.nih.gov/books/NBK572854/.

immediately separated from their parents often as a result of a mere positive toxicology test, thereby jeopardizing the crucial bond between a birthing parent and newborn. A recent article in the Journal of Pediatrics notes that "dyadic care is potentially compromised by punitive policies such as defining substance use in pregnancy as child abuse. Even though maternal well-being is critical to neonatal health and development, pregnant and parenting people with [opioid use disorder] experience discrimination, barriers to care, and criminalization."[19]

These practices further the distrust in our healthcare system and ultimately contribute to our country's unique, but preventable, maternal health crisis. Plainly stated, punishing pregnancy and substance use through the criminal or family policing system for the purported purpose of "preserving fetal life" ultimately worsens maternal, fetal, and child health outcomes. Every major medical and public health organization opposes punitive approaches to addressing the issue of pregnancy and substance use, which ultimately endanger maternal, fetal, and child health, disrupts the patient-provider relationship and makes it harder for people who need care to access it.[20] The threat of arrest, prosecution, or family separation makes pregnant people afraid to

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[19] Jilani SM, et al. Standardizing the clinical definition of opioid withdrawal in the neonate. *The Journal of Pediatrics*. 2023;243:33-39.e1.

[20] American College of Obstetricians & Gynecologists. Opposition to criminalization of individuals during pregnancy and the postpartum period. December 2020. https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period/. ("Clear evidence exists that criminalization and incarceration for substance use disorder during pregnancy are ineffective as behavioral deterrents and harmful to the health of the pregnant person and their infant."); American Psychological Association. Pregnant and postpartum adolescent girls and women with substance-related disorders. March 2020. https://www.apa.org/pi/women/resources/pregnancy-substance-disorders.pdf. ("Legislatures should decriminalize substance use during pregnancy and support more funding and programs that offer specialized substance use treatment to pregnant women and girls."); American Academy of Family Physicians. Substance use disorders. 2019. https://www.aafp.org/about/policies/all/substance-use-disorders.html. ("The AAFP opposes imprisonment or other criminal sanctions of pregnant women solely for substance use during pregnancy. . ."); American Psychiatric Association. Position statement on assuring the appropriate care of pregnant and newly-delivered women with substance use disorders. 2019. https://www.psychiatry.org/getattachment/d0fe00fd-8b78-47e2-9098-63dc6917e1d4/Position-Assuring-Appropriate-Care-of-Pregnant-and-Newly-Delivered-Women-with-SUDs.pdf.
("The use of the legal system to address perinatal alcohol, tobacco, and other substance use disorders is inappropriate."); American College of Nurse-Midwives. Position statement: Substance use disorders in pregnancy. November 20, 2018. https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000052/PS-Substance-Use-Disorders-in-Pregnancy-FINAL-20-Nov-18.pdf. ("ACNM supports a health care system in which individuals with substance use disorder in pregnancy are treated with compassion, not punishment."); National Perinatal Association. Position statement: Perinatal substance use. 2017. https://www.nationalperinatal.org/_files/ugd/209d80_6c125977cd764f67933962492fd13b97.pdf. ("The National Perinatal Association opposes any legal measures that involve the criminal justice system for drug use during pregnancy."); American Society of Addiction Medicine. Public policy statement on substance use and substance use disorder among pregnant and postpartum people. October 2, 2022. https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2022/10/12/substance-use-and-substance-use-disorder-among-pregnant-and-postpartum-people. ("ASAM Strongly supports reforms to reverse the punitive approach taken to substance use and SUD during and after pregnancy and respond to the shared interests of the parent-newborn dyad by providing ethical, equitable, and accessible, evidence-based care."); American Nurses Association. Position statement: Nonpunitive treatment for pregnant and breastfeeding women with substance use disorders. March 2017. https://www.nursingworld.org/~4af078/globalassets/docs/ana/ethics/nonpunitivetreatment-pregnantbreastfeedingwomen-sud.pdf. ("ANA opposes laws that may result in punitive legal actions and result in incarceration of pregnant women because of substance use disorder."); American Academy of Pediatrics. A public health response to opioid use in pregnancy. Pediatrics. March 1, 2017;139(3). *https://publications.aap.org/pediatrics/article/139/3/e20164070/53768/A-Public-Health-Response-to-Opioid-Use-in*. ("The AAP reaffirms its position that punitive measures taken toward pregnant women are not in the best interest of the health of the mother-infant dyad."); Association of Women's Health, Obstetric and Neonatal Nurses. Criminalization of pregnant women with substance use disorders. *J Obstet Gynecol Neonatal Nurs*. 2015;44:155. https://www.jognn.org/article/S0884-2175(15)31770-6/fulltext.; FASD United. Position statement: FASD United opposes criminalizing alcohol use by pregnant women. 2014. ("FASD United opposes any law or policy that would impose a criminal penalty on a pregnant woman suffering with an addiction to alcohol or drugs.").

access health and medical services, putting them and their babies at increased risk of harm.[21] In fact, "[f]or pregnant substance users, the receipt of adequate prenatal care is especially critical. Several studies have reported that increasing the adequacy of prenatal care utilization in pregnant substance users reduces risks for prematurity, low birth weight, and perinatal mortality."[22]

Obstetric Care Conditions of Participation

Pregnancy Justice appreciates CMS's efforts to improve maternal healthcare by establishing obstetric care CoPs, but we encourage CMS to go further and recognize the establishment of these CoPs as a critical policy lever to reduce pregnancy criminalization and family separation by way of the family policing system, thereby improving maternal health outcomes for the most vulnerable pregnant people.

Standards for the organization, staffing, and delivery of care within obstetrical units

In this proposal, CMS takes the approach that, rather than specify its own national standard, it will allow hospitals to adhere to existing baseline standards for the organization, staffing, and delivery of care within obstetrical units established by accrediting bodies and professional medical specialty societies. CMS is not proposing to require adherence to any specific organization's guidelines or recommendations. Rather, under this proposal, a hospital would seem to be able to stitch together elements of various organizations' standards, so long as the hospital is "able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources."

Pregnancy Justice encourages CMS to establish national standards to reduce criminalization in the provision of obstetrics services and not create a further siloed system

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[21] American College of Obstetricians & Gynecologists. Opposition to criminalization of individuals during pregnancy and the postpartum period. December 2020. https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period/; Haffajee RL, et al. Pregnant women with substance use disorders—The harm associated with punitive approaches. N Engl J Med. 2021;384:2364.; Faherty LJ, 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.; Jessup MA. Extrinsic barriers to substance abuse treatment among pregnant drug dependent women. J Drug Issues. 2003;33:285.; American Medical Association, Board of Trustees. Legal interventions during pregnancy: Court-ordered medical treatments and legal penalties for potentially harmful behavior by pregnant women. JAMA. 1990;264:2667.; Kropp F, et al. Increasing prenatal care and healthy behaviors in pregnant substance users. J Psychoactive Drugs. 2010;42:73.; Boone M, *supra* note 9.

[22] American College of Obstetricians & Gynecologists. Opposition to criminalization of individuals during pregnancy and the postpartum period. December 2020. https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period/; National Perinatal Association. Position statement: Perinatal substance use. 2017. https://www.nationalperinatal.org/_files/ugd/209d80_6c125977cd764f67933962492fd13b97.pdf.; Haffajee R, et al. Pregnant Women with Substance Use Disorders - The Harm Associated with Punitive Approaches. *N Engl J Med*. 2021;384(25):2364-2367. doi:10.1056/NEJMp2101051; Boone M, *supra* note 9; Faherty L, et al. Association of punitive and reporting state policies related to substance use in pregnancy with rates of neonatal abstinence syndrome. *JAMA Netw Open*. 2019;2(11). doi:10.1001/jamanetworkopen.2019.14078.; Jessup MA, Humphreys JC, Brindis CD, Lee KA. Extrinsic barriers to substance abuse treatment among pregnant drug dependent women. *J Drug Issues*. 2003;33(2):285-304. doi:10.1177/002204260303300202. (finding that women identified fear of punitive actions from helping institutions and individuals as a major barrier to prenatal care); American Medical Association, Board of Trustees. Legal interventions during pregnancy: Court-ordered medical treatments and legal penalties for potentially harmful behavior by pregnant women. JAMA. 1990;264:2667.; Kropp F, et al. Increasing prenatal care and healthy behaviors in pregnant substance users. *J Psychoactive Drugs*. 2010;42:73.

in which providers operate under differing standards. It is well-recognized that without the inclusion of certain standards, experiences and outcomes vary widely, generally being most harmful to people of color and people with low incomes. CMS acknowledges this in the second priority within the CMS Framework for Health Equity 2022–2032, which is to assess causes of disparities within CMS programs and address inequities in policies and operations to close gaps.[23] Within its explanation of this priority, CMS states that it *"has monitoring and oversight responsibilities related to Conditions for Coverage (CfCs) & Conditions of Participation (CoPs) that health care organizations must meet in order to participate in our programs.* ***These standards are the foundation for improving quality and protecting the health and safety of individuals receiving services from a health care organization. Reviewing these standards and considering ways to strengthen health care organizations to advance equity as they provide care is a critical policy lever.*** *This helps CMS identify and eliminate potential barriers that underserved communities and individuals may face to enrollment in, and access to, CMS benefits and services. Further, CMS plays a pivotal role in ensuring health care professionals and health insurance issuers who receive funding through any CMS programs uphold civil rights laws and protections which prohibit discrimination based on race, color, national origin, sex, age, or disability. CMS has a responsibility to monitor and oversee health care organizations' adherence to these laws. CMS also has a responsibility to embed equity solutions and policies that safeguard these rights for all those we serve, particularly members of underserved or disadvantaged communities"* (emphasis added).[24]

As CMS clearly understands, strengthening these standards, not loosening or neglecting to define them, is critical to advancing equity, which is particularly needed in maternal healthcare given the severe maternal health crisis in the United States that disproportionately affects Black, Indigenous, and other people of color, as well as people in rural communities.[25] Having strict minimum requirements will help us measure processes, outcomes, patient perceptions, and organizational systems that are necessary for high-quality healthcare.

Specifically, in its proposed changes, CMS proposes to require that if a hospital or a critical access hospital offers obstetrics services, the services must be "well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral (inclusive of both mental health and substance use disorders) health care of pregnant, birthing, and postpartum patients." **Pregnancy Justice strongly encourages CMS to include practices to avoid criminalization or family separation within any baseline requirements for Medicare providers of obstetrics services. CMS should include, in its obstetric care CoPs, specific policies designed to end routine drug testing of pregnant people, outline how informed consent is achieved, and narrow reporting to prevent criminalization or family separation that is detrimental to the pregnant person's health during and after pregnancy.**

We expand on each of these concepts below:

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[23] Centers for Medicare & Medicaid Services. *CMS Framework for Health Equity 2022–2032*. 2022. https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.
[24] *Id*. at 18.
[25] The White House. *Blueprint for addressing the maternal health crisis*. June 2022. https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.

Require Informed Consent for Drug Testing to Prevent Routine Testing of Pregnant Individuals.

Pregnant people should be empowered to know their rights throughout the entire timeline in which they could face criminalization or family policing system involvement, and patient protections must be further expanded. Depending on state law, non-consensual drug testing can result in pregnancy criminalization or family policing involvement or both. Because of this potential outcome, non-consensual drug testing can also have a chilling effect on healthcare uptake.

Regarding informed consent and shared decision making, the American College of Obstetricians and Gynecologists (ACOG) notes that the goal of the informed consent process is to provide patients with information that is necessary and relevant to their decision making (including the risks and benefits of accepting or declining recommended treatment) and to assist patients in identifying the best course of action for their medical care.[26] Just as in the case of medical treatment, informed consent for any patient testing (e.g., laboratory testing of serum or salivary samples, imaging, or pathology evaluations) requires explanation of risks and benefits, including those associated with declining the test.

Within the context of drug testing during pregnancy, ACOG affirms this by stating that drug testing "should be performed only with the patient's consent" and that "pregnant women should be informed of the potential ramifications of a positive test result, including any mandatory reporting requirements."[27] They also state that, "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."[28]

Further, testing that is not appropriately consented to is an invasion of patient privacy protections. A significant number of Members of Congress support this proposition. Earlier this year, Representative Nikema Williams (GA-05) spearheaded an effort in which more than 100 House colleagues urged the Biden-Harris Administration to protect Americans from the criminalization of their pregnancies and pregnancy outcomes.[29] Among other things, the letter calls on the Administration to make clear hospital and medical staff obligations to maintain patient privacy. We urge CMS to do so in the context of its obstetric care CoP proposals.

End Mandated Reporting of the Co-occurrence of Substance Use and Pregnancy Alone.

Mandated reporting laws require providers to report concerns of suspected child abuse and neglect to civil authorities. While that is clearly an important goal, in practice these policies are

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[26]American College of Obstetricians and Gynecologists. Informed consent and shared decision making in obstetrics and gynecology. Committee opinion No. 819. February 2021. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/informed-consent-and-shared-decision-making-in-obstetrics-and-gynecology.

[27] American College of Obstetricians and Gynecologists. Opioid use and opioid use disorder in pregnancy. Committee opinion No. 711. August 2017. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy.

[28] Id.

[29] Williams, N. Congresswoman Nikema Williams and Dem Women's Caucus lead Democrats in urging Biden administration to protect against criminalization of pregnancy and pregnancy outcomes. February 2024. https://nikemawilliams.house.gov/posts/congresswoman-nikema-williams-and-dem-womens-caucus-lead-democrats-in-urging-biden-administration-to-protect-against-criminalization-of-pregnancy-and-pregnancy-outcomes.

being used to disproportionately report pregnant people to the family policing system. States vary in their requirements for the evidence of drug exposure to the fetus or newborn in order to report a case to the child welfare system. For example, South Carolina relies on a single positive drug test result, Florida mandates reporting newborns that are "demonstrably adversely affected" by prenatal drug exposure, and Texas requires that an infant must be "addicted" to an illegal substance at birth.[30]

The proposition of curtailing mandated reporting is supported by leading medical specialty societies. For example, ACOG's position is that in states that mandate reporting, policy makers, legislators, and physicians should work together to retract punitive legislation and identify and implement evidence-based strategies outside the legal system to address the needs of women with substance use disorders.[31] Pregnancy Justice agrees with this position. Stakeholders should collaborate to remove drug enforcement policies disguised as mandatory reporting laws that deter people from seeking prenatal care and endanger the welfare of the mother, fetus, and family. **As a key stakeholder in regulating healthcare providers' policies and practices through CoPs, CMS should use this rulemaking opportunity to incorporate into its obstetric services CoP protections for pregnant people from over reporting of substance use during pregnancy that exceeds state law.**

Training Obstetrical Staff

CMS proposes a core set of training requirements for providers offering obstetrics services on select topics for improving the delivery of maternal care including, but not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. Here, too, CMS is not prescriptive on the source or content of the training.

Pregnancy Justice encourages CMS to prescribe required trainings that explicitly include instruction on avoiding practices that criminalize pregnant people. For example, healthcare professionals should be familiar with their state's mandatory reporting laws, both to law enforcement and family policing agencies, and applicable hospital guidance on drug testing. They should also understand the potentially grave consequences of reporting drug test results to state authorities and should therefore avoid reporting beyond state requirements. Care professionals should be aware that the federal Child Abuse Prevention and Treatment Act (CAPTA) and the Comprehensive Addiction and Recovery Act (CARA) alone do not require the reporting of substance-exposed newborns to family regulation agencies.[32] Rather, these laws require only de-identified, aggregate data about the number of children born who fall under the relevant categories. This data should be collected in a way that does not make families vulnerable to unnecessary family policing involvement.

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[30] American College of Obstetricians and Gynecologists. Substance abuse reporting and pregnancy: The role of the obstetrician–gynecologist. Committee opinion No. 473. January 2011. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2011/01/substance-abuse-reporting-and-pregnancy-the-role-of-the-obstetrician-gynecologist.

[31] American College of Obstetricians and Gynecologists. Informed consent and shared decision making in obstetrics and gynecology. Committee opinion No. 819. February 2021. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/informed-consent-and-shared-decision-making-in-obstetrics-and-gynecology.

[32] Pregnancy Justice. Understanding CAPTA and state obligations. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/Understanding-CAPTA-and-State-Obligations-3.pdf.

Here, too, medical specialty society positions are instructive. For example, ACOG states that physicians must be aware of relevant laws and regulations related to mandatory reporting of test results to local or state agencies, and patients must be informed about this necessity when applicable.[33] Just as we recommend that requirements are standardized for the organization, staffing, and delivery of care, so too do we recommend that trainings related to that care delivery be standardized and mandatory.

Follow the Scientific Evidence.

Law enforcement, healthcare providers, and family policing system workers should be trained to view substance use disorder not as a crime or as child neglect but as a public health issue, as the medical community has understood for decades. Substance use disorder is a treatable mental health disorder with genetic components that can and should be managed by healthcare providers, not a criminal or child welfare issue warranting punishment. Medical and public health experts widely acknowledge that punishment is ineffective both in deterring substance use and in treating people who are dependent on substances. Substance use disorder in pregnant and postpartum people should not be understood or treated any differently.

Training Recommendations.

Research has shown that trainings on the legal, scientific, and ethical aspects of reporting that are co-developed with people with lived experience may be a path to reducing health professional overreporting to family policing related to birthing people's substance use.[34] Trainings should address the nuances of CAPTA requirements as well as state obligations.[35]

In collaboration with social work students, advocates, people with lived-experience, and other experts, the organization Just Making A Change for Families created a curriculum to transform mandated reporting to "mandated supporting."[36] This curriculum offers alternative approaches to ensuring child welfare, including providing families with resources and community support. The "mandated supporting" framework seeks to center families through equitable, harm reductionist, and anti-racist practices, while divesting from systems of surveillance and punishment.

QAPI Programs

CMS proposes to revise the existing quality assessment and performance improvement (QAPI) standards for providers that offer obstetrical services to use their programs to assess and improve health outcomes and disparities among patients on an ongoing basis.

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[33] American College of Obstetricians and Gynecologists. Informed consent and shared decision making in obstetrics and gynecology. Committee opinion No. 819. February 2021. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/informed-consent-and-shared-decision-making-in-obstetrics-and-gynecology.

[34] Roberts S, et al. Training health professionals to reduce overreporting of birthing people who use drugs to child welfare. *Addiction Science & Clinical Practice*. 2024;19(1). https://www.researchgate.net/publication/380139356_Training_health_professionals_to_reduce_overreporting_of_birthing_people_who_use_drugs_to_child_welfare#full-text; Doing Right By Birth. *Doing Right By Birth*. 2024. https://doingrightbybirth.org/.

[35] Pregnancy Justice. Understanding CAPTA and state obligations. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/Understanding-CAPTA-and-State-Obligations-3.pdf

[36] Just Making a Change for Families. Mandated supporting. https://jmacforfamilies.org/mandated-supporting.

Pregnancy Justice supports the proposal for hospitals to have a process for incorporating data and recommendations from local Maternal Mortality Review Committees into the facility's QAPI program. We encourage CMS to require hospitals to collect, report and incorporate data on rates of drug testing pregnant people (including the medical justification), the demographic makeup of those tested, and the health outcomes of both the mother and fetus into QAPI programs. We agree with CMS that the findings from QAPI programs should be used to inform obstetric staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

Closing

In closing, we commend CMS for taking these important steps designed to improve maternal health care. We offer these recommendations on behalf of those people who have faced pregnancy criminalization and family separation recognizing that if these key changes were adopted, they would further the impact of CMS's proposed CoPs to better and more equitable maternal care in America.

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