Congress of the United States
Washington, DC 20515

October 29, 2024

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:

As members of Congress committed to improving the health and safety of our pregnant, birthing, and postpartum constituents, we write to commend the Centers for Medicare & Medicaid Services (CMS) for promulgating a thoughtfully considered proposed rule that establishes obstetric care Medicare Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs). As part of our efforts to advance the health and safety of all patients, we encourage CMS to incorporate guidance into the final rule that reduces roadblocks for pregnant patients with substance use disorder (SUD) seeking prenatal care.

SUD is a leading cause of maternal death and can also have severe health consequences for infants.[1] [2] However, research has shown that increasing prenatal care for pregnant people with SUD can improve both maternal health outcomes and birth outcomes.[3] Therefore, we encourage CMS to incorporate the following recommendations into the proposed obstetric care Medicare CoPs relative to organization, delivery of services, and staff training to improve maternal and fetal health outcomes:

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[1] U.S. Centers for Disease Control and Prevention. (2024). *Circumstances Contributing to Pregnancy-Related Deaths: Data From Maternal Mortality Review Committees in 38 U.S. States, 2020*.
https://www.cdc.gov/maternal-mortality/php/report/index.html

[2] National Institute on Drug Abuse. (2024). Substance Use While Pregnant and Breastfeeding.
https://nida.nih.gov/publications/research-reports/substance-use-in-women/substance-use-while-pregnant-breastfeeding

[3] Nidey, N, Kair, L.R., Wilder, C, Froelich, T.E., Weber, S, Folger, A, Marcotte, M, Tabb, K, & Bowers, K. (2022). Substance Use and Utilization of Prenatal and Postpartum Care. *J Addict Med. 16(1)*, 84-92.
https://doi.org/10.1097/ADM.0000000000000843

1. Provide guidance for providers on how to obtain informed consent for drug testing during the prenatal period and during labor and delivery.
2. Prohibit drug testing of people during pregnancy and labor and delivery without the patient's informed consent.
3. Enhance provider training requirements regarding SUD during pregnancy.

Provide guidance for providers on how to obtain informed consent for drug testing during the prenatal period and during labor and delivery.

CMS should include guidance for medical providers in the obstetric care CoPs on obtaining informed consent for drug toxicology testing during the prenatal period and during labor and delivery. The risk of arrest, prosecution, or family separation following a positive toxicology test makes patients afraid to access health and medical services during pregnancy, putting them and their fetus at an increased risk of harm.[4]

Maternal toxicology testing often takes the form of a verbal screen or urine test to monitor for conditions such as diabetes or preeclampsia. However, many pregnant patients are not informed that the urine tests can also be used to screen for substance use.[5] Additionally, doctors have reported that because urine tests are regularly provided in prenatal care, patients are not given an option to refuse urine drug testing.[6]

The requirement for providers to obtain informed consent prior to medical intervention is both a legal and ethical requirement that is outlined in the American Medical Association's Code of Medical Ethics.[7] However, it is also important for providers to have guidance on how to obtain informed consent specifically for drug testing of pregnant and postpartum patients, as these patients may face additional consequences following a positive toxicology test. At least 24 states and the District of Columbia consider prenatal substance exposure to be child abuse or neglect, requiring the provider to file a report to the state child welfare system after a positive maternal toxicology test.[8] Some states allow these reports to be used for cases of criminal prosecution or for involuntary commitment related to prenatal substance use.[9]

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[4] American College of Obstetricians & Gynecologists. (2020, December). *Opposition to criminalization of individuals during pregnancy and the postpartum period.* https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period

[5] Branigin, A. (2022, July 2). A false positive on a drug test upended these mothers' lives. *The Washington Post.* https://www.washingtonpost.com/lifestyle/2022/07/02/false-positive-drug-test-mothers/

[6] Martin, N, (2015). How Some Alabama Hospitals Quietly Drug Test New Mothers — Without Their Consent. *ProPublica.* https://www.propublica.org/article/how-some-alabama-hospitals-drug-test-new-mothers-without-their-consent

[7] AMA Code of Medical Ethics. *Opinion 2.1.1 Informed Consent.* *https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent*

[8] Legislative Analysis and Public Policy Association. (2024, June). *Substance Use During Pregnancy and Child Abuse or Neglect: Summary of State Laws.* https://legislativeanalysis.org/wp-content/uploads/2024/06/Substance-Use-During-Pregnancy-and-Child-Abuse-50-State-Summary.pdf

[9] Jarlenski, M, Hogan, C, Bogen, D.L., Chang, J.C, Bodnar, L.M., Van Nostrand, E. (2017). Characterization of U.S. state laws requiring health care provider reporting of perinatal substance use. *Womens Health Issues 27(3)* **https://doi.org/10.1016/j.whi.2016.12.008**

Ensuring providers have guidance on how to obtain informed consent for drug testing during pregnancy is also a matter of health equity. There are significant racial disparities in those who are subjected to maternal toxicology testing without consent. Research shows that Black patients are much more likely to be drug tested during pregnancy, despite not having a higher probability of a positive test result than other racial groups.[10]

CMS might consider incorporating guidance from the American College of Obstetricians and Gynecologists (ACOG) on how to obtain informed consent for routine testing and other potential drug testing during the prenatal period and during labor and delivery. ACOG recommends that pregnant women should be made aware of "the potential ramifications of a positive test result, including any mandatory reporting requirements."[11] Patients should also understand that they are able to refuse drug testing and still receive all routine prenatal tests.

Prohibit drug testing of people during pregnancy and labor and delivery without their informed consent.

CMS should also include policies that specifically prohibit drug testing of people during pregnancy and labor and delivery without their informed consent. While the Supreme Court determined in 2001 that diagnostic tests on pregnant patients without the patient's consent constitutes an unreasonable search, drug testing of pregnant patients without their consent is still a relatively common practice.[12] [13] In fact, a 2022 study of 5 Massachusetts hospitals found that verbal consent was obtained for less than a third of maternal toxicology tests.[14]

This high occurrence of drug testing of people during pregnancy and labor and delivery without informed consent is concerning, as experts warn that nonconsensual drug testing can undermine trust between patients and providers.[15] In fact, research found that the most common strategy that pregnant patients with SUD employ to avoid their provider detecting their substance use is to skip medical visits or avoid prenatal care altogether.[16]

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[10] Jarlensky M, Schroff, J., Terplan, M, Roberts, S.C.M., Brown-Podgorski, B., & Krans, E.E. (2023). Association of race with urine toxicology testing among pregnant patients during labor and delivery. *JAMA Health Forum*. *4(4).* https://jamanetwork.com/journals/jama-health-forum/fullarticle/2803729.

[11] 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-andopioid-use-disorder-in-pregnancy

[12] Ferguson v. City of Charleston, 532 U.S. 67 (2001). www.oyez.org/cases/2000/99-936

[13] Branigin, A. (2022, July 2). A false positive on a drug test upended these mothers' lives. *The Washington Post.* https://www.washingtonpost.com/lifestyle/2022/07/02/false-positive-drug-test-mothers/

[14] Koenigs, K.J., Chou, J.H., Cohen, S., Nolan, M., Liu, G., Terplan, M., Cummings, B.M., Nielsen, T., Smith, N.A., Distrefano, J., Bernstein, S.N., & Schiff, D.M., (2022). Informed consent is poorly documented when obtaining toxicology testing at delivery in a Massachusetts cohort. *Am J Obstet Gynecol MFM. 4(4)*. **https://doi.org/10.1016/j.ajogmf.2022.100621**

[15] Branigin, A. (2022, July 2). A false positive on a drug test upended these mothers' lives. *The Washington Post.* https://www.washingtonpost.com/lifestyle/2022/07/02/false-positive-drug-test-mothers/

[16] Stone, R. (2015). Pregnant women and substance use: fear, stigma, and barriers to care. *Health Justice 3(2).* **https://doi.org/10.1186/s40352-015-0015-5**

Additionally, patients' fear of their provider reporting their substance use to law enforcement or other government agencies deters pregnant people from seeking prenatal care, which ends up increasing risks to maternal, child, and fetal health.[17] Providers may be required to report results of non-consensual drug testing to child welfare services or law enforcement depending on state law. These reports can lead to criminal charges against the patient. A report documenting over 1,800 cases of pregnancy related criminalization between 2006 and 2022 found that, in 92% of cases, law enforcement officials used alleged illegal substance use as a basis for charging pregnant people with criminal child neglect or endangerment.[18] Pregnant people were also charged with criminal child neglect or endangerment for allegations of using legal substances, including alcohol and nicotine.[19]

Ensuring that pregnant patients are aware of all potential ramifications that could result from any medical test in advance of a patient consenting to that test will assuage fears and encourage patients to seek essential prenatal care. Therefore, CMS should incorporate guidance into the obstetric care CoPs that specifically prohibits drug testing of pregnant, birthing, and postpartum patients without their informed consent. CMS should ensure that any updated guidance related to informed consent and drug testing of pregnant patients is not redundant with or in conflict with current requirements mandated by existing state or federal policy.

Enhance provider training requirements regarding SUD during pregnancy.

In the proposed rule, CMS proposes a core set of training requirements for providers offering obstetrics services. CMS should consider expanding this core set of training requirements to include instruction for providers related to the drug testing of pregnant, birthing, and postpartum patients. These training requirements should include:

- How and when to obtain informed consent for drug testing of pregnant, birthing, and postpartum patients, in accordance with the guidance that CMS may incorporate into the obstetric care Medicare CoPs.
- The federal, state, and local laws in which providers practice. Providers should know if the state in which they practice has mandatory reporting laws following a positive toxicology test during pregnancy, which will allow them to convey this information to the patient. This knowledge will in turn allow that patient to give informed consent.
- Relevant clinical considerations for treating pregnant patients with SUD, including applicable hospital guidance and clinical guidance from relevant medical agencies, such as ACOG.

[17] American College of Obstetricians & Gynecologists. (2020, December). *Opposition to criminalization of individuals during pregnancy and the postpartum period.* https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period

[18] Kavattur P.S., Frazer, S., El-Shafei, A., Tiskus, K., Laderman, L., Hull, L., Walter-Johnson, F., Sussman, D., & Paltrow, L.M. (2023, September). *The Rise of Pregnancy Criminalization: A Pregnancy Justice report.* Pregnancy Justice. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/9-2023-Criminalization-report.pdf.

[19] Kavattur P.S., Frazer, S., El-Shafei, A., Tiskus, K., Laderman, L., Hull, L., Walter-Johnson, F., Sussman, D., & Paltrow, L.M. (2023, September). *The Rise of Pregnancy Criminalization: A Pregnancy Justice report.* Pregnancy Justice. https://www.pregnancyjusticeus.org/wp-content/uploads/2023/09/9-2023-Criminalization-report.pdf.

- The effect of social determinants of health in treating patients with SUD, including the racial disparities of who is most subjected to negative outcomes due to substance use during pregnancy. CMS might consider co-developing trainings with people who have experienced criminalization due to pregnancy and SUD. Research has shown that trainings that are co-developed with people with lived experience may prevent overreporting of the co-occurrence of pregnancy and substance use.[20]

CMS should ensure that these training requirements are not overly burdensome or impossible for facilities to meet. CMS should also provide support to providers to implement these requirements.

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In closing, we commend CMS for taking these important steps to improve maternal health care. We encourage CMS to consider these proposals in an effort to improve maternal health care for all patients, including those pregnant, birthing, and postpartum patients with SUD.

Sincerely,

Jerrold Nadler
Member of Congress

Joyce Beatty
Member of Congress

Nikema Williams
Member of Congress

Bonnie Watson Coleman
Member of Congress

[20] Roberts, S.C., Taylor, K.J., Alexander, K., Goodman, D., Martinez, N., & Terplan, M. (2024). Training health professionals to reduce overreporting of birthing people who use drugs to child welfare. *Addiction Science & Clinical Practice*. *19(32).* **https://doi.org/10.1186%2Fs13722-024-00466-6**

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