September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs: Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1809-P) Maternal Health Proposals

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) CY25 Medicare Outpatient Prospective Payment System proposed rule (CMS-1809-P). The 32 undersigned organizations support CMS's proposals to revise the Conditions of Participation for hospitals and critical access hospitals (CAHs) to improve maternal health outcomes. We commend the Biden-Harris Administration for recognizing and taking concrete action to address both the escalating maternal health crisis and overdose crisis in the U.S.,[1] and we urge CMS to take this opportunity to expand these proposals to include substance use-related maternal health needs, recognizing that overdose is now a leading cause of maternal mortality.[2]

Overdose mortality more than tripled among pregnant and postpartum individuals from 2018 to 2021,[3] and birthing individuals with opioid use disorder are 4.6 times more likely to die during hospitalization.[4] SAMHSA has acknowledged that pregnant people with substance use disorders (SUD) face stigma from the health care community and other significant barriers in seeking and receiving treatment for their SUD during pregnancy, and even more so for people of color.[5] Targeted drug testing disproportionately impacts low-income individuals of racial or ethnic minorities, and many states have adopted punitive measures to prosecute pregnant individuals who use substances that have no clinical benefit for the parent, child, or family, and dozens of national organizations have opposed such measures.[6] As the National Institutes of Health (NIH)

[1] Somer Brown, "Without Maternal Mental Health and Substance Use Interventions, We Can't Address the Maternal Mortality Crisis," SAMHSA, https://www.samhsa.gov/blog/without-maternal-mental-health-substance-use-interventions-we-cant-address-maternal-mortality.
[2] American Medical Association, "AMA Report on Overdose Crisis in Pregnant and Postpartum People" (Feb. 29, 2024), https://www.ama-assn.org/press-center/press-releases/ama-report-overdose-crisis-pregnant-and-postpartum-people.
[3] Beth Han et al., "Pregnancy and Postpartum Drug Overdose Deaths in the US Before and During the COVID-19 Pandemic," JAMA Psychiatry, 81(3), 270-283 (Nov. 22, 2023), https://doi.org/10.1001/jamapsychiatry.2023.4523.
[4] SAMHSA, "Evidence-Based, Whole-Person Care for Pregnant People Who Have Opioid Use Disorder" (Mar. 2024), https://store.samhsa.gov/sites/default/files/whole-person-care-pregnant-people-oud-pep23-02-01-002.pdf.
[5] *Id.*
[6] Stephen W. Patrick, David M. Schiff, Committee on Substance Use and Prevention, "Policy Statement: A Public Health Response to Opioid Use in Pregnancy," American Academy of Pediatrics, 139(3), (Mar. 2017), https://doi.org/10.1542/peds.2016-4070.

noted, pregnant individuals are "less likely to receive an appointment to an addiction treatment center" and often "face punitive policies for their substance use, including fines, loss of custody of their children, involuntary commitment, and incarceration," which in turn has adverse outcomes for families and children as well, particularly for Black and American Indian/Alaska Native children.[7] The historical and ongoing impacts of racism, colonialism, sexism, classism, punitive drug policies, and discrimination against people with SUD all compound to exacerbate health outcomes for pregnant and postpartum Black, Indigenous, and other people of color (BIPOC) who use substances.[8]

Devastatingly, hospitals often fail to identify, treat, and provide appropriate follow-up care for SUD for pregnant and postpartum individuals. Even though substance use during pregnancy is common, many individuals do not disclose information about their substance use or seek SUD treatment out of fear of losing their child or other punitive consequences.[9] The American Medical Association (AMA), the American College of Obstetricians and Gynecologists (ACOG), the American Society of Addiction Medicine (ASAM), the American Academy of Pediatrics, SAMHSA, the Office of National Drug Control Policy (ONDCP), and other experts in the field agree that universal screening for substance use is necessary to improve access to care and both maternal and child health outcomes, and also that medications for opioid use disorder (MOUD) are the standard of care for treatment of opioid use disorder in pregnancy.[10] It is vital that this screening and treatment be available to individuals when they are in the hospital (e.g., inpatient, emergency department, and ambulatory settings), and that hospitals help individuals obtain appropriate follow-up care and support services to manage their SUD. Facilitated referrals for follow-up care are a necessary component of improving maternal health outcomes, because pregnant and postpartum individuals are less likely to get an appointment for the addiction treatment they need.[11] In order to implement these best practices, there must be (1) conditions of participation requiring hospitals to adopt nationally recognized and evidence-based policies; (2) required trainings to educate providers on best practices and to challenge stigma; (3) strong patient privacy and informed consent protections to encourage treatment access, rather

---

[7] National Institutes of Health, "Overdose Deaths Increased in Pregnant and Postpartum Women from Early 2018 to Late 2021" (Nov. 22, 2023), https://www.nih.gov/news-events/news-releases/overdose-deaths-increased-pregnant-postpartum-women-early-2018-late-2021; Office of National Drug Control Policy, "Substance Use Disorder in Pregnancy: Improving Outcomes for Families" 2 (Oct. 2021), https://www.whitehouse.gov/wp-content/uploads/2021/10/ONDCP_Report-Substance-Use-Disorder-and-Pregnancy.pdf.

[8] Caroline Le & Sarah Coombs, "Substance Use Disorder Hurts Moms & Babies," National Partnership for Women & Families (2021), https://nationalpartnership.org/wp-content/uploads/2023/02/substance-use-disorder-hurts-moms.pdf; Stephen W. Patrick et al., *supra* note 6.

[9] American Society of Addiction Medicine, "The ASAM Criteria," Chapter 21: Supporting Patients who are Pregnant and Parenting (4th Ed. 2023).

[10] American Medical Association, *supra* note 2; The American College of Obstetricians and Gynecologists, "Opioid Use and Opioid Use Disorder in Pregnancy" (Aug. 2017), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy; American Society of Addiction Medicine, *supra* note 9; Stephen W. Patrick et al., *supra* note 6; SAMHSA, *supra* note 4; Office of National Drug Control Policy, *supra* note 7. These approaches were also identified as "best practices" in CMS's Maternal Opioid Misuse (MOM) Model. Meg Tucker et al., "Evaluation of the Maternal Opioid Misuse (MOM) Model: Third Annual Report (Implementation Year 2)," CMS 31-33 (May 2024), https://www.cms.gov/priorities/innovation/data-and-reports/2024/mom-third-ann-eval-rpt.

[11] American Society of Addiction Medicine, *supra* note 9; Office of National Drug Control Policy, *supra* note 7.

than criminalization or punishment; and (4) the inclusion of SUD and MH quality metrics and data transparency.

While these recommendations focus primarily on SUD, we note that mental health (MH) conditions are another significant challenge for pregnant and postpartum individuals, and people with SUD often have co-occurring MH conditions. The CDC data collected from Maternal Mortality Review Committees indicates that "mental health conditions," which broadly include MH, SUD, and suicide, are the leading cause of pregnancy-related deaths.[12] Similar to SUD, the nationally recognized and evidence-based standard of care for perinatal MH conditions includes screening for mood and anxiety disorders and referring to, or providing, follow-up treatment. The Alliance for Innovation on Maternal Health at ACOG has drafted a patient safety bundle outlining best practices that hospitals can implement to improve the quality of care for individuals with perinatal MH conditions.[13] ACOG and the American Psychiatric Association have developed toolkits, and Postpartum Support International has developed a certification in perinatal mental health, that can serve as a basis for training programs.[14] Given the impact of both MH and SUD on the maternal health crisis, both conditions need to be prioritized in policies that address the maternal health crisis.

We applaud CMS for its effort to address the maternal health crisis, and for identifying that hospital and CAH obstetrical services must be provided in accordance with nationally recognized acceptable standards for physical and behavioral health. §§ 482.59, 485.649. However, to meaningfully address these compounding crises, we urge CMS to incorporate stronger standards to address the intersection with substance use and maternal health to help change the culture and practices in hospital settings. Accordingly, we offer the following recommendations.

First, CMS should require hospitals and CAHs, as a condition of participation, to develop evidence-based policies for the identification, treatment, and follow-up care of patients who present with an SUD-related condition, and ensure that such policies meet patient needs and advance health equity. These requirements should be incorporated into the proposed conditions of participation for emergency services at §§ 482.55(c), 485.618(e)(1) and for discharge planning at § 482.43,[15] as well as in other relevant sections of the conditions of participation for other ambulatory settings and pharmaceutical services. The evidence-based and nationally recognized standards include (1) universal SUD screening and diagnosis, including brief interventions; (2)

---

[12] Centers for Disease Control and Prevention. "Pregnancy-Related Deaths: Data From Maternal Mortality Review Committees in 36 U.S. States, 2017–2019," (May 28, 2024), https://www.cdc.gov/maternal-mortality/php/data-research/mmrc-2017-2019.html?CDC_AAref_Val=https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html.

[13] Alliance For Innovation On Maternal Health. "Perinatal Mental Health Conditions," https://saferbirth.org/psbs/perinatal-mental-health-conditions/.

[14] The American College of Obstetricians and Gynecologists. "Perinatal Mental Health," https://www.acog.org/programs/perinatal-mental-health; American Psychiatric Association. "Perinatal Mental Health Toolkit," https://www.psychiatry.org/psychiatrists/practice/professional-interests/women-s-mental-health/maternal-mental-health-toolkit; Postpartum Support International. "Certification in Perinatal Mental Health," (August 2018), https://www.postpartum.net/professionals/certification/.

[15] Sika Yeboah-Sampong, Ellen Weber, & Sally Friedman, "Emergency: Hospitals Can Violate Federal Law by Denying Necessary Care for Substance Use Disorders in Emergency Departments," Legal Action Center (July 20, 2021), https://www.lac.org/resource/emergency-hospitals-can-violate-federal-law-by-denying-necessary-care-for-substance-use-disorders-in-emergency-departments.

medications for opioid use disorder (buprenorphine or methadone), and (3) facilitated referrals for individuals with SUDs to treatment and support services.[16] Hospitals and CAHs should also be encouraged to develop and implement protocols and standards that encourage the use of peers, harm reduction, and cultural humility to provide the most effective and affirming care and to help address racial and ethnic disparities.[17] Consistent with SAMHSA guidance, they should also ensure that care is person-centered and trauma-informed.[18]

Second, CMS should require hospitals and CAHs to have annual trainings for staff on substance use disorders, including best practices for working with pregnant and postpartum individuals who use substances, the provision of culturally humble and linguistically effective care, and the provision of MOUD. We encourage CMS to incorporate SUD into the proposed staff training requirement for obstetrical services at § 482.59, and to develop standalone trainings for other hospital staff – such as emergency department, pharmacy, and outpatient department staff – who are likely to interact with patients with SUD. ONDCP and others have recommended training as one critical way to improve access to evidence-based SUD treatment among pregnant and postpartum individuals.[19] Furthermore, research has shown that patients who initiate MOUD within 7 days of an opioid use disorder-related hospital visit had lower odds of a fatal or nonfatal overdose at 6 months.[20] However, among Medicare beneficiaries who presented to the hospital after a nonfatal overdose in 2020, only 4% of patients received any MOUD and only 6% filled a naloxone prescription, and the average number of days until the MOUD initiation was 72 (over 10 weeks).[21] The removal of the X-waiver has been insufficient to meaningfully expand access to this evidence-based care.[22] One systematic review

---

[16] *See supra* notes 10-11 and accompanying text.

[17] *See, e.g.*, The American College of Obstetricians and Gynecologists, "Recommendations to the Indian Health Service on American Indian/Alaska Native Pregnant Women and Women of Childbearing Age with Opioid Use Disorder," Indian Health Service (2018), https://www.ihs.gov/sites/opioids/themes/responsive2017/display_objects/documents/acogguidelines2018.pdf; National Harm Reduction Coalition, "Pregnancy and Substance Use: A Harm Reduction Toolkit" (Sept. 21, 2023), https://harmreduction.org/issues/pregnancy-and-substance-use-a-harm-reduction-toolkit/.

[18] SAMHSA, *supra* note 4; Stephen W. Patrick et al., *supra* note 6.

[19] Office of National Drug Control Policy, *supra* note 7; Meg Tucker et al., *supra* note 10; *see also* Public Health on Call, "Treating Substance Use Disorder in Pregnancy," Johns Hopkins Bloomberg School of Public Health (Nov. 30, 2022), https://johnshopkinssph.libsyn.com/549-treating-substance-use-disorder-in-pregnancy; Alliance for Innovation on Maternal Health, "Care for Pregnant and Postpartum People with Substance Use Disorder Patient Safety Bundle" (2022), https://saferbirth.org/wp-content/uploads/U2-FINAL_AIM_Bundle_CPPPSUD.pdf; RTI International, "State Policy Levers for Expanding Family-Centered Medication-Assisted Treatment," U.S. Department of Health & Human Services, Assistant Secretary for Planning and Evaluation 27-29 (Feb. 2019), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//187076/ExpandFCMAT.pdf; Becky Normile, Carrie Hanlon, & Hannah Eichner, "State Options for Promoting Recovery Among Pregnant and Parenting Women with Opioid or Substance Use Disorder," National Academy for State Health Policy 13 (Oct. 2018), https://nashp.org/wp-content/uploads/2018/10/NOSLO-Opioids-and-Women-Final.pdf.

[20] Scott G. Weiner, et al., "Opioid Overdose After Medication for Opioid Use Disorder Initiation Following Hospitalization or ED Visit," JAMA Network Open, 7(7), (July 22, 2024), https://doi.org/10.1001/jamanetworkopen.2024.23954.

[21] Christopher M. Jones et al., "Overdose, Behavioral Health Services, and Medications for Opioid Use Disorder After a Nonfatal Overdose," JAMA Internal Medicine, 184(8), 954-962 (June 17, 2024), https://doi.org/10.1001/jamainternmed.2024.1733.

[22] Paul J. Christine, et al., "Buprenorphine Prescribing Characteristics Following Relaxation of X-Waiver Training Requirements," JAMA Network Open, 7(8), (Aug. 5, 2024), https://doi.org/10.1001/jamanetworkopen.2024.25999.

found that the institutional environment was the most common reason (81.2% of articles) for physician reluctance to address substance use in their practice, suggesting that "effort should be directed at creating institutional environments that facilitate delivery of evidence-based addiction care while improving access to both education and training opportunities for physicians to practice necessary skills."[23] Thus, annual trainings and continuing education opportunities, coupled with standards on access to SUD care, are an important way CMS can help to increase access to culturally humble and linguistically effective high quality care, particularly for pregnant and postpartum individuals.

Third, CMS should require hospitals and CAHs, as a condition of participation, to implement informed consent policies and protect patient privacy with respect to substance use by pregnant and postpartum individuals, especially as it relates to drug testing and reporting to agencies. People should not be punished, criminalized, or reported to family regulation (child welfare) entities for their health conditions; they should be able to access the treatment they need.[24] With respect to informed consent, any drug testing of the patient or newborn should be preceded by an appropriately documented informed consent conversation in the person's primary language and at their health literacy level to build trust between providers and patients and acknowledge potential consequences.[25] Hospitals should be required to collect race and ethnicity data on whom they drug test and report to any agencies, including family regulation entities, and they should be prohibited from reporting patients who are being treated with medications for opioid use disorder.[26] With respect to patient privacy, hospitals and CAHs must adhere to and provide more guidance to providers on state and federal confidentiality requirements, including the recent changes to the HIPAA privacy rule and 42 C.F.R. Part 2, as unnecessary reporting patient-identifiable information not only deters individuals from accessing SUD treatment, but it also deters them from accessing other prenatal and perinatal health care.[27] Additionally, federally- and state-required notifications of neonatal substance-related conditions (i.e., NAS or NOWS) should not include patient identity, unless required by law.

Fourth, CMS should require that the Quality Assessment and Performance Improvement (QAPI) program include MH and SUD quality metrics, and that data be made publicly available. These requirements should be incorporated into the proposed conditions of participation for the quality assessment and performance improvement program at §§ 482.21, 485.641, as well as other relevant sections. We applaud CMS for requiring that hospitals and

---

[23] Melinda Campopiano von Klimo et al., "Physician Reluctance to Intervene in Addiction," JAMA Network Open, 7(7), (July 17, 2024), https://doi.org/10.1001/jamanetworkopen.2024.20837.

[24] National Institutes of Health, *supra* note 7; Office of National Drug Control Policy, *supra* note 7.

[25] *See, e.g.,* CMS, QSO-24-10-Hospitals, "Revisions and Clarifications to Hospital Interpretive Guidelines for Informed Consent" 2 (Apr. 1, 2024), https://www.cms.gov/files/document/qso-24-10-hospitals.pdf; New York State Department of Health AIDS Institute, "Clinical Guidelines Program: Substance Use Screening, Risk Assessment, and Use Disorder Diagnosis in Adults" (May 30, 2024), https://www.ncbi.nlm.nih.gov/books/NBK565474/pdf/Bookshelf_NBK565474.pdf; SAMHSA, *supra* note 4; The American College of Obstetricians and Gynecologists, *supra* note 10; Stephen W. Patrick et al., *supra* note 6.

[26] *See Costin v. Glen Falls Hospital*, No. 23-379 (2d Cir. 2024); Elizabeth Brico, "A Cop at My Bedside: The Nightmare of Disclosing MAT Before Giving Birth," Filter (Apr. 5, 2019), https://filtermag.org/a-cop-at-my-bedside-the-nightmare-of-disclosing-methadone-use-before-giving-birth/.

[27] National Institutes of Health, *supra* note 7; The American College of Obstetricians and Gynecologists, *supra* note 10.

CAHs use QAPI to reduce maternal health disparities, and we urge CMS to further address the root causes of the maternal health crisis by requiring facilities to include MH and SUD quality metrics at § 482.21(b)(4). To fulfill this requirement, facilities can collect data on maternal MH- and SUD-specific metrics for the QAPI program on evidence-based practices, such as postpartum depression screening and follow-up and initiation and engagement of substance use disorder treatment,[28] the latter of which is consistent with CMS's proposed metrics for APP in this proposed rule. Furthermore, facilities can prioritize identifying social needs that can worsen mental health outcomes by including metrics in their QAPI program, such as social need screening and intervention.[29] Given the racial/ethnic disparities among maternal health outcomes, facilities should be required to stratify these data by race and ethnicity.[30] We support CMS's requirement that facilities have a process for incorporating data and recommendations from the Maternal Mortality Review Committees into the QAPI program and encourage facilities to further engage with local stakeholders and individuals with lived experience in MH and SUD when determining which data and quality indicators will be collected. Lastly, we appreciate CMS soliciting comments on how to best share data collected by QAPI efforts and recommend that CMS, or other relevant federal entities, collect and make these data publicly available so that the information can be centrally located.

* * *

Thank you for considering our views. We look forward to continuing to work with you to improve maternal health outcomes and reduce the devastating consequences of the overdose epidemic. Please contact Deborah Steinberg at the Legal Action Center, dsteinberg@lac.org, with any questions or for further discussion.

Sincerely,

Addiction Policy Forum
American Academy of Addiction Psychiatry
American Association of Psychiatric Pharmacists
American Psychiatric Association
American Society of Addiction Medicine
Anxiety and Depression Association of America

---

[28] The National Committee for Quality Assurance. "Postpartum Depression Screening and Follow-up (PDS-E)," https://www.ncqa.org/hedis/measures/postpartum-depression-screening-and-follow-up/; The National Committee for Quality Assurance. "Initiation and Engagement of Substance Use Disorder Treatment (IET)," https://www.ncqa.org/hedis/measures/initiation-and-engagement-of-substance-use-disorder-treatment/. *See also* The American College of Obstetricians and Gynecologists. "Screening and Diagnosis of Mental Health Conditions During Pregnancy and Postpartum," https://www.acog.org/clinical/clinical-guidance/clinical-practice-guideline/articles/2023/06/screening-and-diagnosis-of-mental-health-conditions-during-pregnancy-and-postpartum; Policy Center for Maternal Mental Health. "Universal Screening for Maternal Mental Health Disorders," https://www.issuelab.org/resources/40013/40013.pdf.

[29] The National Committee for Quality Assurance. "Proposed New Measure for HEDIS®1 Measurement Year (MY) 2023: Social Need Screening and Intervention (SNS-E)," https://www.ncqa.org/wp-content/uploads/2022/02/04.-SNS-E.pdf.

[30] *See* Alliance for Innovation on Maternal Health, *supra* note 19.

Colorado Consumer Health Initiative
Community Catalyst
Drug Policy Alliance
Edwin C Chapman MD PC
Faces & Voices of Recovery
IC&RC
Imperishable Ministries of Western New York
International Society of Psychiatric-Mental Health Nurses
Legal Action Center
NAADAC, the Association for Addiction Professionals
National Alliance on Mental Illness
National Association of State Mental Health Program Directors
National Behavioral Health Association of Providers
National Council on Alcoholism and Drug Dependence-Maryland Chapter
National Disability Rights Network (NDRN)
National Health Law Program
New Jersey Association of Mental Health and Addiction Agencies, Inc.
Partnership to End Addiction
Shriver Center on Poverty Law
Technical Assistance Collaborative, Inc.
The Kennedy Forum
Treatment Communities of America
Triple Track Treatment
United States of Care
Women on the Rise GA
Yakima Valley College