

Elimination of the DATA-Waiver Program

This Clinical Practice Update was developed by the ACOG Committee on Clinical Consensus—Obstetrics in collaboration with Meredith L. Birsner, MD, and Mark I. Zakowski, MD, FASA, with the assistance of Mark Turrentine, MD.

This Clinical Practice Update provides revised guidance related to an update to the requirements related to the elimination of the DATA-Waiver program. This document is a focused update of related content in Committee Opinion No. 711, Opioid Use and Opioid Use Disorder in Pregnancy (Obstet Gynecol 2017;130:e81–94).

BACKGROUND

Overdose deaths involving opioids remain a leading cause of injury-related death in the United States, and deaths involving synthetic opioids (largely illicitly made fentanyl) and stimulants (such as cocaine and methamphetamine) have increased along with an acceleration of overdose deaths during the pandemic (1). Among pregnant and postpartum women aged 35–44 years, the mortality ratio more than tripled between 2018 and 2021, to 15.8 per 100,000 live births (2). Between 2010 and 2017, the number of women with opioid-related diagnoses at delivery increased by 131% (3). The first year postpartum is the highest-risk period for maternal drug-related deaths (4). Deaths involving synthetic opioids, primarily illicitly manufactured fentanyl, continued to rise, with 73,838 overdose deaths reported in 2022 (5).

All health care professionals, especially obstetrician–gynecologists, must play active roles in combating the opioid epidemic, and pregnancy provides an opportunity to identify and treat individuals with opioid use disorder. Additionally, obstetrician–gynecologists and other health care professionals can help prevent persistent opioid use after cesarean delivery by minimizing opioid prescribing (6). There is an abundant and growing body of maternal and neonatal data (7) supporting the use of buprenorphine, a form of medication for opioid use disorder, in pregnancy as monotherapy or in combination with naloxone (8). With 6.6% of pregnant people reporting opioid prescription use during pregnancy, 21% of those reporting misuse, and 27% of pregnant people wanting to stop or cut down (9), all health care professionals should remain aware of the

scope of the opioid epidemic and be prepared to initiate medical therapy (10).

UPDATED CLINICAL RECOMMENDATIONS

Based on the elimination of the DATA-Waiver, the American College of Obstetricians & Gynecologists (ACOG) recommends:

- Obstetrician–gynecologists and other health care professionals should recognize that unwillingness or inability to treat opioid use disorder in pregnancy with medications for opioid use disorder further contributes to the systemic and cultural barriers that currently make accessing care difficult (11).
- Obstetrician–gynecologists and other health care professionals should be aware of existing inequities in opioid overdose deaths and the use of medications for opioid use disorder and recognize their role in perpetuating such disparities (12, 13).
- Obstetrician–gynecologists and other health care professionals should seek training on treatment of opioid use disorder in pregnancy to help facilitate universal access to treatment and reduce overdose deaths in pregnant women (11). The American Society of Addiction Medicine and the Substance Abuse and Mental Health Services Administration offer training.
- Obstetrician–gynecologists who have completed residency training are eligible for fellowship training in addiction medicine, and subsequent training could be beneficial (14).
- Obstetrician–gynecologists and other health care professionals should educate pregnant patients



about naloxone as a life-saving medication and facilitate access as appropriate (15).

- Obstetrician–gynecologists and other health care professionals should partner in a multidisciplinary fashion with colleagues in emergency medicine, internal medicine, family medicine, toxicology, obstetric anesthesiology, and addiction medicine to tailor treatment for pregnant patients with opioid use disorder (16).
- Obstetrician–gynecologists and other health care professionals should understand federal and local requirements for Plan of Safe Care (17) and partner with patients and families, ideally by discussing this in the antepartum period.

RATIONALE

This Clinical Practice Update is provided to address the December 29, 2022, elimination of the DATA-Waiver program, a “federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medications, like buprenorphine, for the treatment of opioid use disorder (OUD)” (18). The implications of this action include:

- “A DATA-Waiver [X-waiver] registration is no longer required to treat patients with buprenorphine for opioid use disorder. Going forward, all prescriptions for buprenorphine [or buprenorphine–naloxone] only require a standard DEA [Drug Enforcement Administration] registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription” (19).
- Under federal law, “There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.” The Consolidated Appropriations Act does not affect existing state laws or regulations that may be applicable (19).
- The DEA has a new requirement that practitioners applying for a new or renewed DEA registration complete 8 hours of training on opioid or other substance use disorders. The DEA requests a self-attestation of completing this training requirement (20).

Elimination of the DATA-Waiver is a critically important step for improving access to evidence-based treatment for pregnant, postpartum, and parenting individuals with opioid use disorder. Obstetrician–gynecologists and other health care professionals can prescribe buprenorphine alone or in combination with naloxone in a medical office setting, which can increase the availability of treatment and decrease stigma (21). This is important, because social stigma and threat of criminal prosecution prevent many pregnant people from seeking prenatal care and treatment for substance use disorder (22). Overdose

deaths during pregnancy and postpartum often occurred where medical services were available but not used (2). ACOG is committed to improving access to treatment and promoting the patient–practitioner relationship rather than punitive measures through the criminal legal system (22).

In addition to the removal of the DATA-Waiver, in March 2023, the U.S. Food and Drug Administration expanded access to naloxone by approving a 4-mg naloxone hydrochloride nasal spray for over-the-counter, nonprescription use (23). Naloxone is a medication that rapidly reverses the effects of opioid overdose; it is the standard treatment for opioid overdose regardless of pregnancy status.

Opioid use disorder remains a significant public health issue of epidemic level, and there remains a crisis owing to the widespread availability of fentanyl (24) with and without xylazine (25), without a corresponding increase in access to medications for opioid use disorder. ACOG will continue to monitor the evidence as it evolves and advocate for prevention strategies that are effective and accessible to all patients for the reduction of maternal death and harm.

For More Information

ACOG has identified additional resources on topics related to this document that may be helpful for obstetrician–gynecologists, other health care professionals, and patients. You can view these resources at <https://www.acog.org/topics/opioids>.

Use of Language

The American College of Obstetricians & Gynecologists recognizes and supports the gender diversity of all patients who seek obstetric and gynecologic care. In original portions of this document, authors seek to use gender-inclusive language or gender-neutral language. When describing research findings, this document uses gender terminology reported by investigators. To review ACOG’s policy on inclusive language, see <https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language>.

REFERENCES

1. Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2003–2023. NCHS Data Brief No. 522. Accessed June 2, 2025. <https://www.cdc.gov/nchs/products/databriefs/db522.htm>
2. Han B, Compton WM, Einstein EB, Elder E, Volkow ND. Pregnancy and postpartum drug overdose deaths in the US before and during the COVID-19 pandemic. *JAMA Psychiatry* 2024;81: 270–83. doi: 10.1001/jamapsychiatry.2023.4523
3. Hirai AH, Ko JY, Owens PL, Stocks C, Patrick SW. Neonatal abstinence syndrome and maternal opioid-related diagnoses in the US, 2010–2017 [published erratum appears in *JAMA* 2021;325:2316]. *JAMA* 2021;325:146–55. doi: 10.1001/jama.2020.24991.
4. Frankeberger J, Jarlenski M, Krans EE, Coulter RW, Mair C. Opioid use disorder and overdose in the first year postpartum:



- a rapid scoping review and implications for future research. *Matern Child Health J* 2023;27:1140–55. doi: 10.1007/s10995-023-03614-7
5. National Institute on Drug Abuse. Drug overdose deaths: facts and figures. Accessed June 3, 2025. <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>
 6. Landau R, Cavanaugh PF, DiGiorgi M. Persistent opioid use after cesarean delivery in the United States of America: a systematic review. *Int J Obstet Anesth* 2023;54:103644. doi: 10.1016/j.ijoa.2023.103644
 7. Suarez EA, Huybrechts KF, Straub L, Hernandez-Diaz S, Jones HE, Connerly HS, et al. Buprenorphine versus methadone for opioid use disorder in pregnancy. *N Engl J Med* 2022;387:2033–44. doi: 10.1056/NEJMoa2203318
 8. de Lima FR, Molino GO, Gallo Ruelas M, Barbosa EC, Silva PH, Guimaraes FB, et al. Buprenorphine-naloxone versus buprenorphine for opioid use disorder during pregnancy: a systematic review and meta-analysis. *Drug Alcohol Depend* 2025;271:112632. doi: 10.1016/j.drugalcdep.2025.112632
 9. Ko JY, D'Angelo DV, Haight SC, Morrow B, Cox S, Salvesen von Essen B, et al. Vital signs: prescription opioid pain reliever use during pregnancy—34 U.S. jurisdictions, 2019. *MMWR Morb Mortal Wkly Rep* 2020;69:897–903. doi: 10.15585/mmwr.mm6928a1
 10. The Joint Commission. Quick safety issue 67: mental health conditions leading cause of pregnancy-related deaths. Accessed June 3, 2025. <https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-67/>
 11. The White House, Executive Office of the President, Office of National Drug Control Policy. Substance use disorder in pregnancy: improving outcomes for families. Accessed June 3, 2025. https://bidenwhitehouse.archives.gov/wp-content/uploads/2021/10/ONDCP_Report-Substance-Use-Disorder-and-Pregnancy.pdf
 12. Han B, Einstein EB, Jones CM, Cotto J, Compton WM, Volkow ND. Racial and ethnic disparities in drug overdose deaths in the US during the COVID-19 pandemic. *JAMA Netw Open* 2022;5:e2232314. doi: 10.1001/jamanetworkopen.2022.32314
 13. Xu KY, Schiff DM, Jones HE, Martin CE, Kelly JC, Bierut LJ, et al. Racial and ethnic inequities in buprenorphine and methadone utilization among reproductive-age women with opioid use disorder: an analysis of multi-state Medicaid claims in the USA. *J Gen Intern Med* 2023;38:3499–508. doi: 10.1007/s11606-023-08306-0
 14. American College of Academic Addiction Medicine. Addiction Medicine Fellowship Program accreditation fact sheet. Accessed June 3, 2025. <https://www.acaam.org/assets/docs/Fellowship/Addiction%20Medicine%20Fellowship%20Program%20Accreditation%20Fact%20Sheet.pdf>
 15. American Medical Association. Overdose epidemic report 2023. Accessed June 3, 2025. https://end-overdose-epidemic.org/wp-content/uploads/2023/11/23-894446-Advocacy-2023-overdose-report_FINAL.pdf
 16. American College of Obstetricians and Gynecologists. Pharmacologic stepwise multimodal approach for postpartum pain management. Clinical Consensus No. 1. *Obstet Gynecol* 2021;138:507–17. doi: 10.1097/AOG.0000000000004517
 17. Child Welfare Information Gateway. Plans of safe care for infants with prenatal substance exposure and their families. Accessed June 3, 2025. <https://www.childwelfare.gov/resources/plans-safe-care-infants-prenatal-substance-exposure-and-their-families/>
 18. Substance Abuse and Mental Health Services Administration. Waiver elimination (MAT Act). Accessed June 3, 2025. <https://www.samhsa.gov/substance-use/treatment/statutes-regulations-guidelines/mat-act>
 19. U.S. Department of Justice, Drug Enforcement Administration. DEA announces important change to registration requirement (January 12, 2023). Accessed June 3, 2025. <https://www.deadiversion.usdoj.gov/pubs/docs/A-23-0020-Dear-Registrant-Letter-Signed.pdf>
 20. Substance Abuse and Mental Health Services Administration. Training requirements (MATE Act) resources. SAMHSA. 2024. Accessed June 3, 2025. <https://www.samhsa.gov/substance-use/treatment/statutes-regulations-guidelines/mate-act>
 21. Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;130:e81–94. doi: 10.1097/AOG.0000000000002235
 22. American College of Obstetricians and Gynecologists. Opposition to criminalization of individuals during pregnancy and the postpartum period. Accessed June 3, 2025. <https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period>
 23. U.S. Food and Drug Administration. FDA approves first over-the-counter naloxone nasal spray. Accessed June 3, 2025. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>
 24. Centers for Disease Control and Prevention. Fentanyl facts. Accessed June 3, 2025. <https://www.cdc.gov/stop-overdose/caring/fentanyl-facts.html>
 25. U.S. Drug Enforcement Administration. Public safety alert. DEA reports widespread threat of fentanyl mixed with xylazine. Accessed June 3, 2025. <https://www.dea.gov/alert/dea-reports-widespread-threat-fentanyl-mixed-xylazine>

CONFLICT OF INTEREST STATEMENT

All ACOG committee members and authors have submitted a conflict of interest disclosure statement related to this published product. Any potential conflicts have been considered and managed in accordance with ACOG's Conflict of Interest Disclosure Policy. The ACOG policies can be found on acog.org. For products jointly developed with other organizations, conflict of interest disclosures by representatives of the other organizations are addressed by those organizations. The American College of Obstetricians & Gynecologists has neither solicited nor accepted any commercial involvement in the development of the content of this published product.

Published online on September 4, 2025

Copyright 2025 by the American College of Obstetricians & Gynecologists. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, posted on the internet, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from the publisher.

American College of Obstetricians & Gynecologists 409 12th Street SW, Washington, DC 20024-2188



A Clinical Practice Update is a brief statement that communicates a focused change in published ACOG guidance on a clinical topic or issue. The American College of Obstetricians & Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on www.acog.org/clinical.

This information is designed as an educational resource to aid clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard

of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology.

While ACOG makes every effort to present accurate and reliable information, this publication is provided "as is" without any warranty of accuracy, reliability, or otherwise, either express or implied. ACOG does not guarantee, warrant, or endorse the products or services of any firm, organization, or person. Neither ACOG nor its officers, directors, members, employees, or agents will be liable for any loss, damage, or claim with respect to any liabilities, including direct, special, indirect, or consequential damages, incurred in connection with this publication or reliance on the information presented.

