DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center For Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, Maryland

Substance Abuse and Mental Health Services Administration
Rockville, Maryland

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Dear Colleague:

As overdose deaths involving opioids, particularly illicitly manufactured fentanyl, continue to remain extremely high across the country[1], we are pleased that the opportunity to treat people with safe and effective medications for opioid use disorder (OUD), such as buprenorphine, has increased with the passage of Section 1262 of the Consolidated Appropriations Act, 2023. This section of the Act removes the requirement that a health care practitioner apply for a separate waiver to dispense certain controlled medications, including buprenorphine. Medication treatment saves lives, and we encourage colleagues in the field to screen for OUD and to initiate or refer for treatment as indicated.

An often-cited barrier to prescribing buprenorphine for the treatment of OUD is the perception that patients must engage in counseling and other services in order to start or continue receiving the medication.[2,3,4] This letter serves to clarify the importance of counseling and other services as part of a comprehensive treatment plan, but to also reiterate that the provision of medication should not be made contingent upon participation in such services.[5,6]

Providing interventions in a person-centered manner is an important treatment principle. This means assessing and taking into account a person's stage of change[7] as treatment begins and progresses, incorporating the patient's goals and priorities into the treatment plan, and applying a shared decision-making approach. It also means that counseling and other services can and should be offered as individuals stabilize on buprenorphine and progress in their treatment and recovery. This is because many studies have indicated that counseling services provide patients

[1] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control (2022). Opioids - Data Overview. Available at: https://www.cdc.gov/opioids/data/index.html
[2] Mendoza, S., Rivera-Cabrero, A. S., & Hansen, H. (2016). Shifting blame: Buprenorphine prescribers, addiction treatment, and prescription monitoring in middle-class America. Transcult Psychiatry, 53(4), 465-487. doi:10.1177/1363461516660884
[3] Netherland, J., Botsko, M., Egan, J. E., Saxon, A. J., Cunningham, C. O., Finkelstein, R., . . . Collaborative, B. (2009). Factors affecting willingness to provide buprenorphine treatment. J Subst Abuse Treat, 36(3), 244-251. doi:10.1016/j.jsat.2008.06.006
[4] Quest, T. L., Merrill, J. O., Roll, J., Saxon, A. J., & Rosenblatt, R. A. (2012). Buprenorphine therapy for opioid addiction in rural Washington: the experience of the early adopters. J Opioid Manag, 8(1), 29-38. doi:10.5055/jom.2012.0093
[5] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.
[6] Substance Abuse and Mental Health Services Administration (SAMHSA): Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings. SAMHSA Publication No. PEP21-06-01-002. Rockville, MD: National Mental Health and Substance Use Policy Laboratory. Substance Abuse and Mental Health Services Administration, 2021.
[7] Prochaska, J. O., DiClemente, C. C., & Norcross, J. C. (1992). In search of how people change. Applications to addictive behaviors. Am Psychol, 47(9), 1102–1114. https://doi.org/10.1037//0003-066x.47.9.1102

with the tools to manage their condition, achieve and sustain better health, and improve their quality of life.[8,9,10] Many individuals with substance use disorders (SUDs) have complex psychosocial issues that may impact treatment and for which medication alone may be insufficient for optimal outcomes. In addition, several studies of patients undergoing treatment with buprenorphine for OUD have demonstrated greater treatment adherence and lower health care utilization when the medication is combined with counseling.[11,12,13,14]

The decision as to when counseling and other services, such as case-management and peer support, are to be provided should be made in collaboration with the individual patient. Additionally, the evidence-base does not provide direction on the type of counseling or services that might be optimal for different patients and at different stages of treatment and recovery progression. This reflects the person-centered nature of treatment interventions, as well as the need for practitioners to work with patients and to meet them where they are to support sustained recovery.

Given the elevated risk of fatal overdose without medication therapy, any difficulty in connecting patients with counseling and/or other behavioral health resources should not prevent practitioners from prescribing buprenorphine for the treatment of OUD.[15] Evidence reveals that when counseling or other resources are not immediately available, patients can still benefit from buprenorphine treatment.[16,17] While counseling should always be offered to patients, this reflects the understanding that engaging people with OUD in treatment is complex and can begin with stabilization on medication. As with any chronic condition, treatment planning should meet people where they are, be supportive, person-centered, and shared.

The Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Food and Drug Administration (FDA) are committed to addressing the overdose epidemic through the provision of person-centered care and reducing barriers to accessing evidence-based treatments for SUDs.

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[9] Ray, L. A., Meredith, L. R., Kiluk, B. D., Walthers, J., Carroll, K. M., & Magill, M. (2020). Combined Pharmacotherapy and Cognitive Behavioral Therapy for Adults with Alcohol or Substance Use Disorders: A Systematic Review and Meta-analysis. JAMA Netw Open, 3(6), e208279. doi:10.1001/jamanetworkopen.2020.8279

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[14] Mutter, R., Spencer, D., & McPheeters, J. (2022). Factors Associated With Initial Treatment Choice, Engagement, and Discontinuation for Patients With Opioid Use Disorder. Psychiatr Serv, 73(6), 604-612. doi:10.1176/appi.ps.202100239

[15] Practitioners should be aware of applicable state laws or regulations that may still be in effect regarding the prescribing and dispensing of buprenorphine for the treatment of OUD, and will need to seek further guidance from their state officials considering the impact of Section 1262 of the Consolidated Appropriations Act, 2023, in their state.

[16] Oleskowicz, T. N., Ochalek, T. A., Peck, K. R., Badger, G. J., & Sigmon, S. C. (2021). Within-subject evaluation of interim buprenorphine treatment during waitlist delays. Drug Alcohol Depend, 220, 108532. doi:10.1016/j.drugalcdep.2021.108532

[17] Samso Jofra, L., Puig, T., Sola, I., & Trujols, J. (2022). Interim opioid agonist treatment for opioid addiction: a systematic review. Harm Reduct J, 19(1), 7. doi:10.1186/s12954-022-00592-x

Please visit the SAMHSA store and FDA website for further resources to assist in treating opioid use disorders. We thank you for your efforts in helping to save and improve lives.

Sincerely,

/Miriam E. Delphin-Rittmon/

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health
and Substance Use

/Patrizia Cavazzoni/

Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research