

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder**

**AGENCY:** Department of Health and Human Services, Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) issues the Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (Practice Guidelines). Pursuant to 21 U.S.C. § 823(g)(2)(H)(i)(II), the Department of Health and Human Services (HHS) may issue practice guidelines regarding physician eligibility for a waiver under 21 U.S.C. §823(g)(2), in order to increase the availability of buprenorphine. The Practice Guidelines eliminate the requirement that physicians with a Drug Enforcement Administration (DEA) registration number apply for a separate waiver to prescribe buprenorphine for opioid use disorder treatment.

**DATES:** Notice is effective upon [FEDERAL REGISTER WILL INSERT DATE UPON PUBLICATION]

**FOR FURTHER INFORMATION CONTACT:** Meriam Mikre, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Immediate Office, 200

Independence Avenue SW, Washington, DC 20201, Telephone: 202-690-7694. Email:

[ASH@hhs.gov](mailto:ASH@hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### *A. Background*

The United States faces an opioid epidemic that has engendered a public health crisis and has forever altered and, in too many instances, prematurely ended American lives. The facts are stark. For the 12 months ended in May 2020, provisional overdose death counts from the Centers for Disease Control and Prevention show that overdose deaths have increased 18% since the previous 12 months, with a total of more than 81,000 overdose deaths. While every effort should be made to prevent opioid use in the first instance, the best public-health and medical evidence is clear: access to medication-assisted treatment (MAT), including buprenorphine that can be prescribed in office-based settings, is the gold standard for opioid use disorder (OUD).

The Drug Addiction Treatment Act of 2000 (DATA 2000) was passed to in order to improve access to treatment for OUD by allowing practitioners to prescribe approved Schedule III through V medications for OUD treatment in an outpatient setting. To dispense buprenorphine, a medical practitioner must satisfy the requirements of 21 U.S.C. §§ 823(g)(1) or 823(g)(2). Under § 823(g)(1), “practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate [DEA] registration for that purpose.” The “Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both).” See 21 U.S.C. § 823(g)(1). A practitioner may also seek

a waiver from the Drug Enforcement Administration (DEA) registration requirement by submitting a notice of intent (NOI), with specific statutorily required certifications, to the Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS. *Id.* at § 823(g)(2)(B). Once SAMHSA approves the waiver request and notifies the Department of Justice (DOJ) of that approval, DOJ will make a determination whether the practitioner meets statutory requirements, and then issue a waiver-identification number that authorizes a practitioner to treat patients with buprenorphine. The Secretary of HHS may create exemptions from the certification requirements under 21 U.S.C. § 823(g)(2) by issuing practice guidelines pursuant to 21 U.S.C. § 823(g)(2)(H)(i)(II).

*B. Purpose of Practice Guidelines*

The Office of the Assistant Secretary for Health in HHS has determined that the need for physicians to make all of the certifications under 21 U.S.C. 823(g)(2)(b) represents a significant perceived barrier to prescribing buprenorphine in the United States and removing the certification requirements would dramatically improve access to buprenorphine and save lives.

*C. Authority*

The Secretary of HHS may create exemptions from the certification requirements under 21 U.S.C. § 823(g)(2) by issuing practice guidelines pursuant to 21 U.S.C. § 823(g)(2)(H)(i)(II). HHS hereby issues the following practice guidelines exemption:

1. With respect to the prescription of medications that are covered under 21 U.S.C. 823(g)(2)(C), such as buprenorphine, a physician licensed under State law, and who possesses a DEA registration under 21 U.S.C. § 823(f), is hereby exempt from the

certification requirements under 21 U.S.C. § 823(g)(2)(B)(i)-(ii).

2. This exemption applies only to physicians, not all “qualifying practitioners” as defined under 823(g)(2)(G)(iii).
3. This exemption applies only to the prescription of drugs or formulations covered under 21 U.S.C. § 823(g)(2)(C), such as buprenorphine. It does not apply to the prescription, dispensation, or use of methadone for the treatment of opioid use disorders.
4. Physicians utilizing this exemption shall place an “X” on the prescription and clearly identify that the prescription is being written for opioid use disorders. Charts for patients being treated for opioid use disorder shall be maintained separately from charts for patient who are not being treated for opioid use disorder to ensure their confidentiality pursuant to Title 42, Part 2.
5. Physicians utilizing this exemption will be limited to treating no more than 30 patients at any one time, and must maintain and retain records of the prescriptions issued.
  - a. The limitation on treating no more than 30 patients at one time does not apply to hospital based physicians, such as Emergency Department physicians, who may initiate treatment in the Emergency Department but do not engage in a long term treatment relationship with the patient.
6. Physicians utilizing this exemption may only treat patients who are located in states where those physicians are authorized to practice medicine.
7. Prescribers, including physicians and other practitioners, may continue to seek a DATA-waiver per current protocols. These prescribers will not be subject to the specific prescribing limitations of physicians using this exclusion.
8. An interagency working group will be established to monitor the implementation and

results of these practice guidelines, as well as the impact on diversion.

- a. The working group will be chaired by a representative from the Immediate Office of the Secretary in HHS, and include representatives from the Office of National Drug Control Policy, the Drug Enforcement Administration, the Department of Justice, the National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, and the Centers for Disease Control and Prevention.
  - b. The working group will meet at least twice yearly, and make formal recommendations to the Secretary of Health and Human Services on whether the guideline should be continued, discontinued, or modified.
9. Colleges of Medicine are strongly encouraged to continue implementing comprehensive training in substance use disorder diagnosis and management as a component of their core, required curriculum.

**DATED:** JAN 12 2021

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Alex M. Azar II

Secretary of Health and Human Services