Drug Enforcement Administration Diversion Control Division Guidance Document

Title: Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)

Summary: This guidance document provides clarification regarding the changes set forth in the Consolidated Appropriations Act, 2023 (CAA, 2023),¹ which incorporates the MAT Act and amends the Controlled Substances Act (CSA) by eliminating the "DATA-Waiver requirement," which had been codified in <u>21 U.S.C. 823</u>. This document provides information as to when qualified practitioners can begin prescribing buprenorphine for OUD. This guidance will be sent via email to all Drug Enforcement Administration (DEA)-registered pharmacies and practitioners and will be posted on the <u>DEA guidance portal</u>.

Activity: Prescribing Buprenorphine for OUD

To Whom It Applies: All DEA-Registered Pharmacies and Practitioners

Question: When can a qualified practitioner start prescribing buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver?

Answer: Qualified practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the CAA, 2023,² which in part included provisions to expand patient access to medications for OUD. Specifically, the CAA, 2023 amended the CSA to eliminate the "DATA-Waiver requirement," which had been codified in <u>21 U.S.C. 823</u>.

Prior to the CAA, 2023, DATA-waived practitioners were allowed to administer, dispense, and prescribe any schedule III, IV, or V narcotic drug approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment to a person with an opioid use disorder (OUD) if the practitioner complied with the requirements found under 21 CFR 1301.28. This regulation detailed an exemption for practitioners from registration as a narcotic treatment program, or opioid treatment program, if the practitioner submitted notification to the Secretary of Health and Human Services (HHS) stating their intent to dispense or prescribe FDA-approved narcotic drugs, or opioid medications, for the treatment of OUD. Section 1262 of the CAA, 2023 removed the federal requirement for a practitioner to submit notification to the Secretary of HHS, and removed the other limitations previously applicable to DATA-waived practitioners.³ As of December 29, 2022, there is now no requirement that only DATA-waived practitioners can administer, dispense, or prescribe FDA-approved narcotic drugs, or opioid medications, for the treatment of OUD. DEA is in the process of amending its regulations and revising its guidance documents to reflect these statutory changes.

Section 1263(a) of the CAA, 2023 also amended the CSA by adding subsection (l) to 21 U.S.C.

¹ Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6, § 1262(a)(1), 136 Stat. 4459, 5681 (2022).

² Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6, § 1262(a)(1), 136 Stat. 4459, 5681 (2022).

³ Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6, § 1262(a)(1), 136 Stat. 4459, 5681 (2022).

<u>823</u>, which requires training for prescribers. Specifically, the new <u>21 U.S.C. 823(*l*)(1)</u> provides that, "[a]s a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner to meet" certain conditions; the specific conditions are divided into a list if the practitioner is a physician and another list if the practitioner is not a physician. Section 1263(a) of the CAA, 2023 defines the term "qualified practitioner" as a practitioner who (i) is licensed under State law to prescribe controlled substances, and (ii) is not solely a veterinarian, under <u>21 U.S.C. 823(*l*)(4)(B)</u>. The term "first applicable registration" means the first registration or renewal of registration by a qualified practitioner on or after June 27, 2023, under <u>21 U.S.C. 823(*l*)(4)(A)</u>. Please see our <u>DEA guidance portal</u> for additional information on the training requirement.

As of June 27, 2023, all practitioners are required to attest to completing the CAA, 2023 training requirement when applying for an initial registration or renewing their registration. All practitioners, who are not solely a veterinarian, must satisfy the training, credentialing, or educational requirements identified in section 1263 of the CAA, 2023 in order to obtain a DEA registration. The deadline for attesting to this training requirement is the date of a practitioner's next scheduled DEA registration submission – regardless of whether it is an initial registration or a renewal registration.

Therefore, any qualified practitioner can treat patients who screen positive for OUD with buprenorphine. This includes prescribing, administering, or dispensing buprenorphine with their DEA registration *as long* as *there are no state regulations that prohibit (or limit) them from participating in this activity*. DEA Registration numbers no longer indicate DATA-waivers, and prescriptions for buprenorphine no longer require the DATA-waivered or "x" waivered number on them, with the elimination of the DATA-waivered requirement in the CAA, 2023.

Both the CSA and the DEA regulations continue to require that a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a).

Some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. As noted above, the intent of the MAT Act was to expand patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine that in previous years.

While the practitioner is responsible for the proper prescribing and dispensing of controlled substances, a corresponding responsibility rests with the pharmacist who fills the prescription. <u>21</u> <u>CFR 1306.04(a)</u>. <u>21 CFR 1306.06</u>.

Additionally, prescribers and pharmacists should check state laws or contact their state pharmacy board for any limitations.

DEA Registrant

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies.

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