Drug Enforcement Administration Diversion Control Division Guidance Document

Title: Applicability of the 8-hour Training Requirement to Medical, Surgical, and other Specialty Residents or Other Individual Practitioners Working Solely under a DEA-Registered Hospital/Clinic Registration

Summary: This guidance document provides information regarding the applicability of the training requirement included in the Consolidated Appropriations Act (CAA) of 2023 to medical residents, surgical residents and other subspecialty trainees, or other individual practitioners, who solely work under a Drug Enforcement Administration (DEA)-registered hospital/clinic registration under 21 <u>CFR 1301.22(c)</u> as an agent or employee of the hospital. This guidance will be sent via email to all DEA-registered hospital/clinics and practitioners and will be posted on the <u>DEA guidance portal</u>.

Activity: Applicability of the 8-hour Training Requirement to Medical, Surgical, and other Specialty Residents or Other Individual Practitioners Working Solely under a DEA-Registered Hospital/Clinic Registration. Such practitioners do not have their own DEA registration and prescribe controlled medications under the DEA Registration of the Hospital/Clinic.

To Whom It Applies: All Medical, Surgical, and other Specialty Residents or Other Individual Practitioners Solely Working under a DEA-Registered Hospital/Clinic Registration

Background: On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act of 2023 (CAA),¹ which included provisions that expanded access to medications for opioid use disorder (OUD). Specifically, the CAA amended the Controlled Substances Act (CSA) by eliminating the "DATA-Waiver" requirement previously codified in 21 U.S.C. 823(g)(2).

By removing 21 U.S.C. 823(g)(2), section 1262(a)(1) of Division FF of the CAA eliminated additional requirements for dispensing narcotic drugs in schedule III, IV, and V for the treatment of opioid use disorders, which required qualifying practitioners to submit a notification of intent to begin dispensing the drugs or combinations thereof to patients for the treatment of opioid use disorders.

Section 1263(a) of Division FF of the CAA also amended the CSA by adding a new requirement for prescribers to complete training on substance use disorders as a condition of registration. Specifically, the new requirement provides that, "[a]s a condition of 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. Section 1263(a) of the CAA 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 21 U.S.C. 823(l)(4)(B). The term "first applicable registration" means the first registration or renewal of registration by a qualified practitioner on or after June 27, 2023, under 21 U.S.C. 823(l)(4)(A).

¹ Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6 § 1263(a), 136 Stat. 4459, 5683-5684 (2022).

As set forth in <u>21 CFR 1301.22(c)</u>, an individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;

(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

While Section 1262 of Division FF of the CAA removed the federal requirement for practitioners to obtain a DATA-Waiver to treat patients with OUD with buprenorphine, section 1263 of Division FF of the CAA requires practitioners to complete Substance Use Disorder (SUD) training before applying for a controlled substance registration or renewing their DEA registration. Individual practitioners operating under the DEA registration of a hospital/clinic do not have to attest to completion of training under 21 U.S.C. 823(l)(1), unless they are applying for or renewing a separate registration. Therefore, it is only when the practitioner applies for an individual DEA registration for the first time that they must attest to receipt of this training.

Question: I am an individual practitioner, or medical, surgical or other specialty resident, who is an agent or employee of a hospital or other institution, acting under the registration of the hospital or other institution pursuant to 21 CFR 1301.22, and I am not separately registered with DEA. Am I required to attest that I completed the 8-hour training requirement in the CAA?

Answer: Individual practitioners, or medical, surgical, or other specialty residents operating under the DEA registration of a hospital/clinic pursuant to <u>21 CFR 1301.22(c)</u> are not required to apply for or maintain a DEA registration on an individual basis. Accordingly, individual practitioners operating under the DEA registration of a hospital/clinic do not have to attest to completing the

CAA training, unless they are separately registered. The new training requirement in section 1263(a) of Division FF of the CAA went into effect on June 27, 2023, and applies to all qualified practitioners "as a condition of registration . . . beginning with the first applicable registration for the practitioner." <u>21 U.S.C. 823(/)(1)</u>. "First applicable registration" is defined as "the first registration or renewal of registration by a qualified practitioner . . . that occurs on or after [June 27, 2023]." <u>21 U.S.C. 823(/)(4)</u>. DEA-registered hospitals may consider providing opportunities for accredited training to residents and other practitioners who may be treating patients and prescribing medications for SUD while operating under the hospital's DEA registration. Section 1263 of the CAA allows for SUD training to count towards meeting the DEA training requirement if it occurred as part of medical school, nursing school, physician assistant school, or dental school within 5 years of an initial DEA registration application. Residency programs are part of training through accredited medical, nursing, physician assistant, or dental schools, and training provided by hospitals would meet the CAA training requirement.

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.

EO-DEA274, DEA-DC-80, February 15, 2024