Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: Drug Enforcement Administration (DEA) Registration Requirements for Practitioners Who Receive Schedule III-V Controlled Substances, Dispensed by a DEA-Registered Pharmacy Pursuant to a Prescription, and Delivered to the Practitioner by the Pharmacy in Accordance with 21 U.S.C. 829a(a).

Summary: The Controlled Substances Act (CSA) allows a pharmacy to deliver a schedule III, IV, or V opioid to be administered for maintenance or detoxification treatment of an opioid use disorder, dispensed by the pharmacy pursuant to a prescription, to the prescribing practitioner or the practitioner administering the controlled substance. (21 U.S.C. 829a(a)). One of the requirements imposed by the CSA is that "the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, *at the location listed on the practitioner's certificate of registration*" issued under the CSA. See 21 U.S.C. 829a(a)(1), 21 CFR 1306.07(f)(1). This guidance clarifies the DEA's registration requirements for practitioners, particularly for those practitioners who may have multiple practice locations.

Activity: Delivery by a DEA-Registered Pharmacy of an Opioid Controlled Medication for Maintenance or Detoxification Treatment for Opioid Use Disorder, Dispensed Pursuant to a Prescription, to a Prescribing Practitioner or a Practitioner Who Will be Administering the Controlled Medication to a Patient by Injection or Implantation.

To Whom it Applies: DEA-Registered Individual Practitioners and DEA-Registered Pharmacies.

Question: Must practitioners who receive controlled medications from a pharmacy, in accordance with 21 U.S.C. 829a(a), be registered with DEA at every location at which they receive such controlled medications?

Answer: Yes. One of the conditions imposed by the statute authorizing the delivery of opioids for maintenance or detoxification treatment of an opioid use disorder is that the controlled medication be delivered to the location that is listed on the practitioner's certificate of registration. 21 U.S.C. 829a(a)(1). Thus, unless the practitioner is registered at a particular location, there is no authorization for delivery of the controlled medication to that location. Moreover, the CSA requires a separate registration "at each principal place of business or professional practice where the [registrant] . . . dispenses controlled substances." 21 U.S.C. 822(e)(1); see also 21 CFR 1301.12(a). The term "dispense," as defined in 21 U.S.C. 802(10), means to "deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance."

Pursuant to 21 CFR 1307.03, the Administrator of DEA may grant an exception to the application of the regulations contained in Chapter II of Title 21 of the CFR. The Administrator cannot, however, use her authority under 21 CFR 1307.03 to grant waivers of the statutory registration requirements of the CSA.

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-DEA285, DEA-DC-82, February 21, 2024