Drug Enforcement Administration
Diversion Control Division
DATA-Waived Guidance Document

Title: Q&A Pharmacy Delivery of Buprenorphine Products under the SUPPORT Act

Question: May a pharmacy deliver a prescribed buprenorphine product to a practitioner for direct administration to the patient?

Answer: Yes, but only in limited circumstances. Ordinarily, a prescription only authorizes a pharmacist to dispense a controlled substance to an ultimate user, which includes a patient or a member of the patient's household. 21 U.S.C. 802(10) and (27); 21 CFR 1300.01 ("[p]rescription means an order for medication which is dispensed to or for an ultimate user"). However, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) permits a pharmacy to deliver a controlled substance prescribed for maintenance or detoxification treatment to a practitioner's registered location for the purpose of direct administration through either injection or implantation to a narcotic dependent person. 21 U.S.C. 829a(a).

The prescription must be issued by a qualifying practitioner who is authorized to prescribe controlled substances for maintenance or detoxification purposes under 21 U.S.C. 823(g)(2) and the prescription must meet the requirements of the Controlled Substances Act and DEA regulations, including the requirement that it may not be used to supply the practitioner with stock for general dispensing to patients. The pharmacy may deliver the controlled substance to the registered location of either the prescribing practitioner or the administering practitioner, and must be administered by injection or implantation only to the patient named on the prescription within 14 days after the date of receipt of the controlled substance by the practitioner. 21 U.S.C. 829a(a)(2)(B) and 829a(a)(5).

Notwithstanding any exceptions under 21 U.S.C. 827, a practitioner administering controlled substances must maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under 21 U.S.C. 829a, including the persons to whom controlled substances were delivered. 21 U.S.C. 829a(a)(6). The pharmacy must maintain, for a period of at least two years, complete and accurate records of all controlled substances received, distributed, dispensed, or otherwise disposed of, including either, where applicable, the original paper prescription or an electronic prescription which is readily retrievable. *See* 21 CFR part 1304. The pharmacy must also comply with all other Federal, State, local and tribal laws in the jurisdiction in which they are licensed. *See, e.g.,* 21 U.S.C. 829a(a)(3). Relatedly, nothing in this guidance document relieves any pharmacy or other entity that dispenses a buprenorphine product from any obligations that might arise under the Federal Food, Drug, and Cosmetic Act, such as those relating to an FDA-approved Risk Evaluation and Mitigation Strategy (REMS).

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