

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: Delivery of a Prescribed Controlled Substance by a Drug Enforcement Administration (DEA)-Registered Pharmacy to a Practitioner for Direct Administration to the Patient under Power of Attorney (POA)

Summary: This guidance document addresses the limited circumstances in which a DEA-registered pharmacy may deliver a prescribed controlled substance to a practitioner for direct administration to the patient. In those circumstances, ultimate users may execute a POA consistent with state law, designating an administering practitioner as their agent for the limited purpose of accepting delivery of a prescribed controlled substance. See [21 U.S.C. 903](#); [21 CFR 1307.02](#). This guidance document does not apply to the two classes of controlled substances that are currently authorized under the Controlled Substances Act (CSA) to be delivered by a pharmacy to the administering practitioner. Those two classes of controlled substances are: (1) schedule III–V controlled substances administered by injection or implantation for the purpose of maintenance or detoxification treatment (see [21 U.S.C. 829a\(a\)\(2\)\(A\)](#)); and (2) schedule III–V medications that are subject to a Food and Drug Administration (FDA) risk evaluation and mitigation strategy (REMS), if the REMS requires the patient using the drug to be subject to certain monitoring to ensure safe use (under [21 U.S.C. 355-1\(f\)\(3\)\(E\)](#)), including a requirement for post-administration monitoring by a health care provider (see [21 U.S.C. 829a\(a\)\(2\)\(B\)](#)).

This guidance document provides an option for controlled substances that either must (pursuant to FDA requirements) or should (for quality control or other reasons) be delivered directly to a practitioner, rather than the ultimate user, for administration in a healthcare setting. Additionally, the guidance recommends best practices for pharmacies and practitioners to adopt when a patient has executed a POA.

Activity: Delivery of a Prescribed Controlled Substance by a DEA-Registered Pharmacy to an Administering Practitioner under POA.

To Whom it Applies: DEA-registered Pharmacies and Individual Practitioners

Background: Under the CSA, a controlled substance must be dispensed by a pharmacy directly to the ultimate user (*i.e.*, the patient or a member of the patient’s household). A pharmacy generally may not dispense a controlled substance to the prescribing practitioner, as the practitioner is not the ultimate user. Congress has created two limited exceptions to this requirement as described in the Summary section above.

DEA is aware that certain controlled substances, other than those that fall within the exceptions that Congress created, either must (pursuant to FDA requirements) or should (for quality control or other reasons) be delivered directly to the administering practitioner. These controlled substances include, but are not limited to, controlled substances for delivery via an intrathecal pump, which is a pump surgically inserted under the skin that delivers medicine into the

intrathecal space of the body (*i.e.*, the fluid-filled area surrounding the spinal cord). Often these medications are prescribed for the treatment of intractable pain. Sterility is an important issue for these medications.¹

The CSA requirement that these prescriptions be delivered only to the ultimate user has created complexities for patients, pharmacies, and administering practitioners. While alternative options, including the following, remain available to registrants, DEA understands that such alternatives can pose challenges:

- Practitioners may purchase controlled substances from a DEA-registered distributor to have as office stock and administer the substances from that stock instead of receiving patient-specific controlled substances from a pharmacy pursuant to a prescription. Practitioners may utilize this method if (1) the practitioner is registered with DEA at the physical address where the controlled substances are stored and administered, as printed on the practitioner's DEA certificate of registration, and (2) it is permissible under state law. See [21 U.S.C. 822\(a\)\(2\)](#) and [823\(g\)](#); [21 CFR 1301.11\(a\)](#) and [1301.12\(a\)](#).
- A dispensed controlled substance may be delivered to the location of the prescribing practitioner when the patient is physically present in the practitioner's office. Neither the CSA nor its implementing regulations specify where an ultimate user must be in order to receive his or her prescribed controlled substance medications.

Accordingly, DEA believes that the interest of patient safety and a potential reduction in the risk for diversion warrant this guidance.

Question: May a DEA-registered pharmacy deliver a prescribed controlled substance, other than controlled substances currently authorized for such delivery under [21 U.S.C. 829a\(a\)\(2\)\(A\)](#) and (B), to a practitioner for direct administration to the patient?

Answer: Yes, if the patient executes a POA as described below. However, this option is limited to those controlled substances that either must (pursuant to FDA requirements) or should (for quality control or other reasons) be delivered directly to the administering practitioner for administration in a healthcare setting.²

If a patient is issued a prescription for a controlled substance that fits these criteria, the patient may execute a POA, consistent with state law, that designates the administering practitioner as the patient's agent for the limited purpose of accepting delivery of the patient's prescribed medication from the dispensing pharmacy. The practitioner, as the patient's agent, cannot legally take any actions involving the dispensed medication that a patient cannot take. Nor can the practitioner take any actions other than those specifically authorized by the patient in the POA.

¹ [FDA alerts doctors, patients about risk of complications when certain implanted pumps are used to deliver pain medications not approved for use with the devices | FDA.](#)

² The delivery by a pharmacy of a prescribed buprenorphine (MOUD) product to a practitioner for direct administration to the patient, as authorized by [21 U.S.C. 829a](#), is the subject of a separate [guidance](#) document.

Once dispensed to a patient, a prescribed controlled substance has left the closed system of distribution established by the CSA and generally may not re-enter the closed system. Under this POA option, the practitioner receives the dispensed controlled substance as the patient's agent, not as a DEA registrant. Furthermore, if the dispensed controlled substance becomes waste or is unwanted, it cannot be returned to a DEA registrant but must be disposed of by the ultimate user through a mail-back package or collection receptacle. See [21 CFR 1317.30\(b\)\(1\)](#), [1317.70](#), [1317.75](#).

This guidance is limited to prescriptions for controlled substances that either must (pursuant to FDA requirements) or should (for quality control or other reasons) be delivered directly to the administering practitioner for administration in a healthcare setting. This guidance does not impose any requirements regarding the content or structure of the POA between the patient and the administering practitioner, other than the POA be compliant with state law.

Both practitioners and pharmacies retain their continuing responsibility to ensure proper prescribing and dispensing of controlled substances under [21 CFR 1306.04\(a\)](#). A valid POA relating to the delivery of a prescription does not alter this obligation. Additionally, all activities must be carried out in compliance with applicable state law and regulations.

If a practitioner issues a prescription for a controlled substance that will be delivered to an administering practitioner pursuant to a POA:

- The prescription should be for a dose of the controlled substance for direct administration to a named patient, not a take-home supply for that patient and not for the practitioner's office stock. See [21 CFR 1306.04\(b\)](#).
- The administering practitioner must keep the dispensed medications separate from any controlled substances held under the practitioner's DEA registration.
- The prescribing practitioner must adhere to [21 CFR 1306.04\(a\)](#), which requires that a prescription must be written for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. Prescriptions must contain the required information as set forth in [21 CFR 1306.05\(a\)](#) or, if the prescription is electronic, the information set forth in [21 CFR 1311.120\(b\)\(9\)](#).
- Practitioners are responsible for providing effective controls and procedures to guard against theft and diversion of controlled substances. [21 CFR 1301.71\(a\)](#).
- The controlled substance can be administered only to the patient named on the prescription. See [21 CFR 1306.05\(a\)](#).
- The administering practitioner named in the POA should consider maintaining a copy of the POA for a minimum of two years after the last delivery or administration under the POA, or longer if required by applicable law.

If a pharmacy fills a controlled substance prescription for delivery to the administering practitioner pursuant to the POA option discussed in this guidance:

- The pharmacy must comply with all requirements applicable to dispensing under the CSA and DEA regulations. These include, but are not limited to, maintaining records that indicate that the controlled substance was delivered to the practitioner. Such records should indicate the practitioner's name and the address of the location to which it was delivered. *See* [21 CFR 1306.05\(a\)](#).
- The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the address specified in the POA.
- The pharmacy should take steps to assure the existence and validity of any purported POA prior to dispensing a controlled substance to the prescribing and/or administering practitioner. This does not negate the pharmacy's obligation to ensure that they are first dispensing a valid prescription. Moreover, failure on the pharmacy's part to adequately verify the POA may risk diversion and expose the pharmacy to potential violations of state and federal law.
- The pharmacy should also consider maintaining a copy of the POA for a minimum of two years after the last delivery or administration under the POA, or longer if required by applicable law.

Nothing in this guidance changes, limits, or adds POA requirements to deliveries already authorized under [21 U.S.C. 829a](#).

The POA pathway described in this guidance document is an additional option. It is not a preferred or exclusive pathway.

As guidance, this information is non-binding. No patient or DEA registrant is required to implement a POA program. Dispensing registrants can continue to deliver dispensed controlled substances directly to the patient or a member of the patient's household. DEA intends this to be a helpful alternative that allows for the safe and secure handling of controlled substance medications that is consistent with applicable FDA requirements, the CSA, and state law.

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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