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NEW DEA PHARMACIST'S MANUAL: TOP FIVE CHANGES PHARMACIES NEED TO KNOW

The Drug Enforcement Administration ("DEA") recently released the 2020 edition of the Pharmacist's Manual, replacing all previous versions. Since 2010, the Pharmacist's Manual ("Manual") has aided pharmacies and pharmacists in understanding how to apply requirements under the Federal Controlled Substances Act ("CSA") and related DEA regulations. As an agency guidance document, the Manual offers insight into how the DEA may view or interpret the CSA or its regulations. The new 2020 edition of the Manual features various regulatory updates regarding CSA requirements and will almost certainly impact aspects of ongoing operations. While pharmacies and pharmacists should carefully review the entirety of the 2020 Manual, we detail below five noteworthy changes as compared to the 2010 version.

1. **Guidance Concerning "Significant Loss" Determinations**

The regulatory definition of "significant loss" has been an open question, with neither the CSA nor its implementing regulations specifically defining the term. While the new Manual makes changes to the sectional numbering in which it addresses significant loss determinations, it unfortunately does not provide any further guidance to registrants for identifying significant losses of controlled substances beyond previously established regulatory considerations. Accordingly, under existing DEA regulation 21 C.F.R. §1301.76(b), it remains the registrant's responsibility to determine whether a loss of a controlled substance is significant in consideration of the facts and circumstances surrounding the loss and in accordance with the agency guidance maintained in the Manual.[1],[2]

2. **Professional Standards as an Additional Basis for Evaluating the Legitimacy of Prescriptions for Controlled Substances**

Most pharmacists are well aware that valid controlled substance prescriptions must have been issued for a legitimate medical purpose in the usual course of professional treatment. While a prescribing practitioner is responsible for the proper issuance of a prescription, dispensing pharmacists also have a similar, corresponding responsibility.[3] To ensure that pharmacists fulfill this responsibility within the meaning of the CSA, in the past, DEA has advised that pharmacists should exercise sound professional judgment to make a determination about the legitimacy of a controlled substance prescription before dispensing it.[4]

However, in its new Manual, DEA has further specified professional standards as an additional basis for making this determination, advising pharmacists to decline to dispense a prescription of doubtful, questionable or suspicious medical legitimacy.[5] The failure of a pharmacy or pharmacist to ensure that orders are properly filled within the meaning and intent of the CSA may implicate a host of penalties. These include criminal fines and imprisonment, civil enforcement actions for monetary penalties or injunctions, revocation of DEA registration and even revocation of the state licenses of both the pharmacist and the pharmacy, as was the situation in a 2018 case.[6] In light of this guidance, pharmacies should reassess and update policies and procedures for evaluating "legitimate medical purpose" and monitoring pharmacists' compliance.

3. **State Requirements and Considerations**

In addition to federal requirements, pharmacists and pharmacies need to be mindful of applicable state legislation, rules and guidelines which may stipulate additional requirements, considerations or limitations concerning controlled substances. For example, in the context of a Schedule II controlled substance, federal law does not place limits on either the time frame within which a Schedule II prescription must be filled or the quantities of drugs that may be dispensed through a valid prescription. However, some states do limit the quantity of controlled substances dispensed to a 30-day supply or limit initial opioid prescriptions. As such, consistent with the federal requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose, a pharmacist's determination about the legitimacy of a Schedule II prescription must consider (among other things) whether the prescription is still needed by the patient at the time of the requested filling and whether any state laws, rules or professional standards impose limitations on dispensed amounts. In situations in which state law differs from federal law, the stricter provision applies.

4. **An Additional "Partial Dispensing" Exception for Schedule II Prescriptions**

While pharmacists must generally dispense a Schedule II controlled substance in accordance with its prescribed quantity (and subject to evaluation for a legitimate medical purpose and other applicable state law), previously established DEA regulations allowed pharmacists to dispense partial orders for Schedule II prescriptions under specified circumstances.[7] In addition, the Comprehensive Addiction and Recovery Act of 2016 ("CARA") created a new partial dispensing exception which is now included in the Manual. The CARA exception permits the partial dispensing of Schedule II prescriptions at the request of the patient or the prescribing practitioner if all the following criteria are met:

- The partial filling is not prohibited by state law;
- The prescription is written and filled in accordance with the CSA, DEA regulations and state law;
- The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
- The remaining portions of a partially filled prescription in Schedule II, if filled, shall be filled not later than 30 days after the date on which the prescription was written.[8]

The Manual clarifies that the DEA views CARA's partial fill exception to be in addition to the previously established exceptions under DEA regulations. Accordingly, prior DEA regulations will continue to permit a Schedule II prescription to be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral prescription, as long as the pharmacist documents the quantity supplied on the written prescription, on a written record of the emergency oral prescription or in the electronic prescription record.[9] Likewise, the 72-hour rule under the regulation will continue to permit the remainder of the prescription to be filled within 72 hours of the first partial filling.[10] However, pharmacists must continue to notify the prescribing practitioner if the remaining portion is not or cannot be filled within the 72-hour period.[11] Although the regulation prohibits further quantities from being supplied beyond 72 hours without a new prescription, the new Manual has also clarified that DEA views the regulation only as to require a pharmacy to have the remainder of the prescription ready for dispensing prior to the 72-hour limit. Thus, a patient is not required to pick up the prescription remainder within that 72-hour limit.[12] Given the CARA exception update and interpretation as well as the clarification regarding the existing 72-hour rule, pharmacists should reassess and update their partial dispensing procedures accordingly.

5. **New Guidance Regarding Patients Who Bring Medications from Home to the Hospital**

In acknowledging the fact that hospital patients can be admitted by emergency medical services with controlled substances in their possession, DEA has set forth new guidance regarding compliance with CSA requirements. This guidance is particularly noteworthy since an unlawful distribution in violation of the CSA may occur when a hospital takes possession of a patient's home-brought controlled substances.[13] For situations in which the treating practitioner deems it medically appropriate for the patient to continue taking any controlled substance medications brought from the patient's home to the DEA-registered hospital, the Manual recommends that the hospital secure the controlled substances in his or her hospital room, such as by a small safe or secured lockbox. In doing so, DEA posits that since the hospital has not taken possession of the controlled substances, it would not be considered an unlawful distribution by the ultimate user under the CSA.[14] On the other hand, holding and securing a patient's home-brought controlled substances in this manner presents other risks, and hospitals should accordingly consider this option for only a limited set of circumstances. The Manual also outlines various options for situations in which the practitioner deems it medically inappropriate for the patient to continue taking home-brought controlled substances, or if it is the hospital's policy not to permit patients to bring already dispensed controlled medications into the hospital. For example, one option includes turning over the patient's medications to a member of the patient's household. Other options may include implementing disposal procedures, including procedures that apply to hospitals that are authorized collectors; procedures for mailing controlled substances to the authorized DEA-registered reverse distributor; and procedures for abandoned controlled substances. In considering this guidance, hospitals should assess the risks associated with securing and holding a patient's home-brought controlled substances and explore available alternatives for appropriately removing such prescriptions from hospital premises.

PRACTICAL TAKEAWAYS

Pharmacy professionals should carefully review the new 2020 edition of the Pharmacist's Manual together with appliable state legislation and guidance and update their policies and practices accordingly.

To view a redlined version of the changes to the Manual, or for other questions or concerns, please contact:

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- Brian Jent at (317) 977-1402 or bjent@hallrender.com; or
- Your regular Hall Render attorney.

[references]

[1] *See* 21 C.F.R. §1301.76(b) (listing various factors for consideration in determining significant loss).

[2] Under 21 C.F.R. §1301.76(b), registrants must also continue to expediate written notification of a significant loss of any controlled substance to the DEA Diversion Field Office within one business day of discovery.

[3] 21 C.F.R. § 1306.04(a).

[4] *See* Drug Enforcement Admin., U.S. Dep't of Just., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (2010).

[5] Drug Enforcement Admin., U.S. Dep't of Just., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (2020) (interpreting 21 C.F.R. §§ 1306.04(a), 1306.06).

[6] 21 U.S.C. §§ 841, 842, 843; 21 C.F.R. § 1306.04(a); *Jones Total Healthcare, L.L.C. v. DEA*, 881 F.3d 823 (11th Cir. 2018).

[7] *See* 21 C.F.R. § 1306.13.

[8] 21 U.S.C. § 829(f).

[9] 21 C.F.R. § 1306.13(a).

[10] *Id.*

[11] *Id.*

[12] Drug Enforcement Admin., U.S. Dep't of Just., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (2020).

[13] *See* 21 U.S.C. 841(a)(1).

[14] *See id.*

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