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DEA Updates Year-End Review

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In a flurry of activity in the last months of 2020, the Drug Enforcement Administration (DEA) issued three updates to further the mission of DEA's Diversion Control Division to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. These three developments include an update to the DEA Pharmacist's Manual, a notice of proposed rulemaking (NPRM) for emergency medical services agencies, and an NPRM for suspicious order monitoring.

Updates to DEA Pharmacist's Manual

The DEA updated the Pharmacist's Manual: An Informational Outline of the Controlled Substances Act for the first time in 10 years. The Pharmacist's Manual is designed to help pharmacists understand the provisions of the Controlled Substances Act (CSA) 21 U.S.C. § 801 et seq. and its implementing regulations, 21 C.F.R. Part 1300 et seq. The 2020 edition answers questions that pharmacists may encounter in their pharmacy practice and provides guidance about complying with CSA regulations. The main updates in the 2020 edition include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018.

One highlight of the 2020 Pharmacist's Manual is an explanation of the new single-sheet format order form for Schedule I and II Controlled Substances (DEA Form 222). A final rule, New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222), became effective on Oct. 30, 2019, which included a sunset date of Oct. 30, 2021. This final rule implements a new single-sheet format for the DEA Form 222 instead of a triplicate form that was previously used. The final rule mandates that after Oct. 30, 2021, the triplicate form will no longer be allowed and that all orders for Schedule I and Schedule II Controlled Substances must be placed on the single-sheet DEA Form 222.

The 2020 Pharmacist's Manual also describes the Secure and Responsible Drug Disposal Act of 2010. This Act allows patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with certain controls against diversion. Authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals or clinics with an on-site pharmacy, and retail pharmacies may collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. An outline of the regulations and process for such collection and disposal is provided by the 2020 Pharmacist's Manual.

The 2020 Pharmacist's Manual also explains partial dispensing of Schedule II controlled substances, as provided by the Comprehensive Addiction and Recovery Act of 2016. Pharmacists must check state requirements and restrictions to ensure state law aligns with the federal allowance for partial dispensing.

Another addition is the process set out by the SUPPORT for Patients and Communities Act of 2018, Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, 132 STAT. 3894 (2018), allowing for the delivery of a controlled substance by a pharmacy to an administering practitioner.

Pharmacists and pharmacies, and those working with these individuals and entities, should review the updated manual because it includes many changes in federal controlled substances laws and regulations implemented over the past decade. It is important to note that the 2020 Pharmacist's Manual is simply guidance and sets out recommended practices for complying with federal laws and regulations. Pharmacists and pharmacies are responsible for ensuring federal and state compliance.

NPRM for Emergency Medical Services Agencies

On Oct. 5, 2020, the DEA proposed a rule to implement the Protecting Patient Access to Emergency Medications Act of 2017, which allowed a new registration category for emergency medical services agencies (organizations providing emergency medical services outside a fixed medical facility, e.g., by air or ground ambulance) that handle controlled substances and established standards for registering emergency medical services agencies.

The NPRM addresses emergency medical services vehicles, recordkeeping requirements, records and inventory, restocking, maintenance of records, security requirements, and storage of controlled substances, among other DEA requirements for emergency medical services.

Like all notice-and-comment rulemaking, interested stakeholders were provided the opportunity to comment on the proposed rule. Comments on this NPRM were due Dec. 4, 2020.

NPRM for Suspicious Order Monitoring

On Nov. 2, 2020, the DEA proposed revising its regulations relating to suspicious orders of controlled substances to implement the Preventing Drug Diversion Act of 2018. This proposed rule applies not only to persons who are registered with DEA under the business activity of distributor, but also to manufacturers and importers (who are permitted to distribute controlled substances as a coincident activity to their manufacturer or importer registration), practitioners (who are permitted to distribute controlled substances pursuant to the five percent rule without obtaining a separate registration as a distributor), and Narcotic Treatment Programs (NTPs) distributing in controlled substances in bulk form to other NTPs. Under the NPRM, the DEA also proposed definitions of four critical terms: "due diligence," "order," "order received under suspicious circumstances" and "suspicious order." The DEA also created a two-option framework for registrants to follow for orders received under suspicious circumstances (ORUSCs). The first option is to immediately file a suspicious order report through the DEA centralized database, decline to distribute pursuant to the suspicious order, and maintain a record of the suspicious order and any due diligence related to the suspicious order. The second option involves more investigation but provides an opportunity to fill the order. Before fulfilling the ORUSC, under the second option the DEA registrant may conduct due diligence to investigate each suspicious circumstance surrounding the ORUSC and maintain a record of its due diligence regarding the ORUSC. If through this due diligence process the registrant can dispel each suspicious circumstance within seven calendar days of the order, the order does not need to be reported to the DEA. If all of the suspicious circumstances of the ORUSC cannot be dispelled, then the order is considered a suspicious order, which requires a report. All suspicious order reports must be made to the DEA centralized database.

Under the NPRM, suspicious order reports must include seven pieces of information:

(1) The DEA registration number of the registrant placing the order for controlled substances;
(2) The date the order was received;
(3) The DEA registration number of the registrant reporting the suspicious order;
(4) The National Drug Code number, unit, dosage strength and quantity of the controlled substances ordered;
(5) The order form number for Schedule I and Schedule II controlled substances;
(6) The unique transaction identification number for the suspicious order; and
(7) What information and circumstances rendered the order actually suspicious.

Lastly, the proposed definitions under the NPRM are as follows:

> *Due diligence* means a reasonable and documented investigation into persons and orders (coupled with other appropriate investigations, including previous investigations into persons and orders) that includes, but is not limited to, verification that a person (or a person submitting an order) holds the appropriate DEA registration, verification that a person (or a person submitting an order) holds all licenses required by the state(s) in which a person (or a person submitting an order) conducts business with respect to controlled substances, examination of each suspicious circumstance surrounding an order, and examination of all facts and circumstances that may be relevant indicators of diversion in determining whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances.
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> *Order* means any communication by a person to a registrant proposing or requesting a distribution of a controlled substance, regardless of how it is labeled by the person or the registrant, and regardless of whether a distribution is made by the registrant, except that simple price/availability inquiries, standing alone, do not constitute an order.
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> *Order received under suspicious circumstances* means an order potentially meeting the definition of suspicious order.
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> *Suspicious order* includes, but is not limited to, an order of unusual size, an order deviating substantially from a normal pattern or an order of unusual frequency.

The NPRM is sure to receive several comments from stakeholders. Comments were due Jan. 4, 2021.

Conclusion

Pharmacies and pharmacists should review the 2020 updated version of the Pharmacist's Manual and ensure compliance with the CSA and DEA regulations. The updated Pharmacist's Manual provides a guide for compliance. Emergency medical services agencies and all DEA registrants should remain apprised of recent proposed rules, which would increase flexibility in handling controlled substances. Lastly, all DEA registrants that receive orders should review the NPRM on suspicious orders, which would create two options for the registrant to follow upon receipt of an order under suspicious circumstances.