DRUG ENFORCEMENT ADMINISTRATION

Pharmacy Presentation

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HISTORY OF THE DEA

- 1970-The Comprehensive Drug Abuse Prevention and Control Act signed
- 1971-War on Drugs was coined
- DEA formed on July 1, 1973

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STRUCTURE OF THE DEA

Four Core Series Employees

- Special Agents
- Intelligence Research Specialists
- Diversion Investigators
- Chemists

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RESPONSIBILITIES OF THE DEA

- Enforces the Controlled Substances Act
- Title 21 of the United States Code (USC)
- Code of Federal Regulations Title 21 Part 1300 to End

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Updated Guidance for Pharmacies

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Updated Guidance

What's New: Transfer of Electronic Prescriptions

The Drug Enforcement Administration (DEA) is amending its regulations to allow the transfer of electronic prescriptions for schedules II-V controlled substances between registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis. This amendment specifies the procedure that must be followed and the information that must be documented when transferring such electronic controlled substance prescriptions between DEA-registered retail pharmacies.

DEA regulations require that an EPCS be transferred in its electronic form and may not be converted to another form (e.g., facsimile) for transmission. Moreover, the contents of the prescription must not be altered during transfer between retail pharmacies. Otherwise, DEA regulations do not specify the form of communication that must be utilized by the two pharmacists to communicate the transfer of an EPCS from one pharmacy to another for initial dispensing. The communication must, however, be made directly between two licensed pharmacists, which includes any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State. Diversion Control Division | Electronic Prescriptions for Controlled Substances (EPCS) Q&A (usdoj.gov)

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Guidance Document

Disposal of Controlled Substances

Under 21 CFR 1317.05(a), practitioner registrants may dispose of their inventory in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of 21 CFR 1317 using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: the registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Request assistance from the Special Agent in Charge (SAC) of DEA in the area in which the practitioner is located. A copy of the DEA-Form 41 must be sent to the SAC for consideration, which lists the controlled substances the practitioner wants to dispose of. The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners:

- Transfer the controlled substances to a registrant authorized to transport or destroy the substances;
- Deliver the controlled substances to an agent of the Administration or to the nearest office of DEA; or
- Destroy the controlled substances in the presence of an agent of the administration or other authorized person.

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Guidance Document

Requirement to Use Multiple Single-Sheet DEA Form 222s (Order Forms) When Transferring Schedule I or II Controlled Substances Upon Termination or Transfer of a DEA Registration, or Discontinuing Business Altogether

Question: Can a DEA registrant-transferor attach an itemized list or an inventory of schedule I or II controlled substances to a single-sheet DEA Form 222 in lieu of completing multiple DEA Form 222s when the number of items to be transferred to a DEA registrant-transferee exceeds the number of lines on the form?

Answer: No. When transferring inventory from a registrant-transferor to a registrant-transferee upon the termination of registration, transfer of registration, or discontinuance of business, transfers of schedule I or II controlled substances require the use of order forms in accordance with 21 CFR 1305. See 21 CFR 1301.52(e)(1). Under 21 CFR 1305.03, the completion of DEA Form 222 is required for each distribution of a schedule I or II controlled substance. Neither the Controlled Substances Act nor its implementing regulations authorize adding attachments or itemized lists to DEA Form 222s. Rather, DEA regulations state, in relevant part: "Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided." 21 CFR 1305.12(b). In addition, Part 1 of the Instructions for the DEA Form 222 states: "The purchaser fills out no more than twenty line items in this section. If more items are needed, use another form." When the registrant-transferor adheres to the requirements of 21 CFR 1301 and 1305, and follows the instructions set forth on the DEA Form 222, there is no discrepancy between the number of items ordered, the number of lines completed, and the controlled substances transferred. Diversion Control Division | DEA Form 222 Q&A (usdoj.gov)

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DEA Inspections

Title 21 United States Code Section 822(f) The Attorney General [DEA] is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

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DEA Inspections

What to Expect:

- We will conduct regulatory inspections during a registrant's normal business hours
- Diversion Investigator (DI) must present government issued credentials
- Will present a Notice of Inspection (NOI)
- After you sign the NOI, DIs are permitted to inspect controlled substance records and review security
- May conduct a CS audit and count the CS drugs you have on hand
- Will explain what they are doing, and notify you of any violations
- Will explain potential administrative, civil, or criminal action
- DEA will not ask for Controlled Substance Sales Data
- You should read over the statement of rights on the NOI
- You may refuse an inspection & have the DI obtain an Administrative Inspection Warrant from a Magistrate
- Inspections are a unannounced, we don't make appointments
- We aim to be efficient and courteous to limit interruptions

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DEA Inspections

IF – you are in violation, now what?

- On-site correction
- Letter of Admonition, 30 days to file written response
- Memorandum of Agreement
- Order to Show Cause or Voluntary Surrender
- Civil Fines through United States Attorney's Office
- Criminal Action
- Referral to Boards

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DEA Criminal Investigations-Registrants

May not involve an on-site inspection at all, no NOI

Could involve a criminal search warrant or administrative inspection warrant at your registered location, a copy of SW or AIW will be left for your review

Involves violations of the Controlled Substances Act, not just the Code of Federal Regulations

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AREAS OF CONCERN

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AREAS OF CONCERN

- Corresponding Responsibility 21 CFR 1306.04(a)
- CSOS
- POAs
- Recordkeeping
- Reconciling records
- Biennial Inventory Date
- C2 & C3-5 separate

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SECURITY

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SECURITY

Title 21, CFR SECURITY REQUIREMENTS Section 1301.71 Security requirements generally.

- (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

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SECURITY

TITLE 21, CFR 1301.75 PHYSICAL SECURITY CONTROLS FOR PRACTITIONERS

(a) Controlled Substances listed in Schedule I shall be stored in securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances through the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

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WHAT DOES YOUR SECURITY LOOK LIKE?




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FEDERAL PRACTITIONER SECURITY REQUIREMENTS

TITLE 21, CODE OF FEDERAL REGULATIONS SECTION 1301.76 - OTHER SECURITY CONTROLS FOR PRACTITIONERS.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

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FEDERAL PRACTITIONER SECURITY REQUIREMENTS

TITLE 21, CODE OF FEDERAL REGULATIONS SECTION 1301.76 - OTHER SECURITY CONTROLS FOR PRACTITIONERS.

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of upon discovery of such loss or theft. The registrant shall also complete and submit DEA Form 106 regarding the loss or theft.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

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IN THE NEWS

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Current Cases Against Pharmacies

Federal Court Orders San Antonio-Area Pharmacy and Pharmacist to Pay $275,000 Civil Penalty in Case Alleging Unlawful Opioid Distribution

The order resolves a civil complaint the government filed on Jan. 21, 2022, in the Western District of Texas. The complaint alleged that the defendants repeatedly dispensed opioids and other controlled substances in violation of the Controlled Substances Act by filling prescriptions while ignoring "red flags" – that is, obvious indications that the prescriptions were not for any legitimate medical use. The complaint also alleged that the defendants altered prescriptions that lacked required information in order to make them appear to be in compliance with DEA regulations.

Pharmacist Convicted for Conspiring to Unlawfully Dispense Over 100,000 Opioid Pills

According to court documents and evidence presented at trial, from January 2014 to January 2018, Deanna Winfield-Gates, 54, of Houston, was a relief pharmacist at Health Fit Pharmacy (Health Fit), a cash-only, pill-mill pharmacy. Health Fit dispensed controlled substances to drug traffickers in exchange for hundreds of dollars, often based on prescriptions that were fraudulent and issued in the names of physicians whose identities were stolen. Winfield-Gates filled large volumes of cookie-cutter prescriptions for the opioids hydrocodone 10-325mg and oxycodone 30mg and for carisoprodol, alprazolam, and promethazine with codeine, often in combination, knowing these controlled substances were likely to be diverted or abused.

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Updated Fines

Current Fines for Violation of The CSA and CFR

21 U.S.C. 842(c)(1)(A)	Controlled Substances Act ("CSA"); Violations of 842(a)—other than (5), (10), (16) and (17)—Prohibited acts re: controlled substances (per violation)	Current Fine Per Violation	$78,312
21 U.S.C. 842(c)(1)(B)(i)	CSA; Violations of 842(a)(5), (10), and (17)—Prohibited acts re: controlled substances	Current Fine Per Violation	$18,170

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CURRENT TRENDS

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PROMETHAZINE W/ CODEINE

- Currently one of the most concerning diversion issues in the State of Florida
- Numerous "rings" of individuals operating in Florida by sending fraudulent prescriptions to pharmacies in targeted areas
- Be sure to verify ALL Promethazine prescriptions with the prescriber
- Do not call the phone number on the prescription as they are being altered
- Report any known fraudulent prescriptions to local law enforcement and the doctor whose DEA Number is being used.

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PHARMACIST RESPONSIBILITIES

The misuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. As healthcare professionals, pharmacists share responsibility for preventing prescription drug misuse and diversion.

1. Pharmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion. They need to know of the potential situations where drug diversion can occur, and establish safeguards to prevent drug diversion.

2. The dispensing pharmacist must maintain constant vigilance against forged or altered prescriptions. 21 CFR 1301.71(a), 1306.04(a). The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued for a legitimate medical purpose and in the usual course of professional practice. 21 CFR 1306.04(a).

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TYPES OF FRAUDULENT PRESCRIPTIONS

Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing. Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the practitioner's prescription. They may have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Individuals may also call in their own prescriptions and give their own telephone number as a call-back for confirmation. Individuals sometimes steal legitimate prescription pads from practitioner's offices and/or hospitals and prescriptions are written using fictitious patient names and addresses.

In addition, individuals may go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for non-existent doctors or to copy legitimate doctors' prescriptions. The quantity of drugs prescribed and frequency of prescriptions filled are not lone indications of fraud or improper prescribing, especially if a patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of a patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

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IDENTIFYING OUT OF SCOPE PRESCRIPTIONS

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose:

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the same specialty in the area.
- The patient appears to be returning too frequently. A prescription which should last for a month in legitimate use is being refilled on a biweekly, weekly, or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community show up with prescriptions from the same physician.

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IDENTIFYING FRAUDULENT PRESCRIPTIONS

The following criteria may indicate a forged prescription:

- Prescription looks "too good." The prescriber's handwriting is too legible.
- Quantities, directions, or dosages differ from usual medical usage.
- Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears to be photocopied.
- Directions are written in full with no abbreviations.
- Prescription is written in different color inks or written in different handwriting

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PREVENTION TECHNIQUES

- Know the prescriber and his or her signature.
- Know the prescriber's DEA registration number.
- Know the prescriber's authorized agents and request a copy of any written agreement between prescriber and their agent.
- Know the patient.
- Check the date on the prescription order to determine if it has been presented in a reasonable length of time since being issued by the prescriber.

When there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification.

If at any time a pharmacist is in doubt, they may ask (thought not a DEA requirement) for the patient to provide proper identification. Although this procedure is not foolproof (identification papers can also be stolen/forged), it does increase the risk to the individual trying to fill the fraudulent prescription. If a pharmacist believes the prescription is forged or altered, they should not dispense it and should call the local police. If a pharmacist believes they have discovered a pattern of prescription abuse, they should contact the state Board of Pharmacy or the local DEA Diversion Field Office. Both DEA and state authorities consider retail-level diversion a priority issue.

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PROPER CONTROLS

Dispensing procedures without control and professional caution are an invitation to those individuals seeking to fill fraudulent prescriptions. Proper controls can be accomplished by following common sense, sound professional practice, and proper dispensing procedures. In addition, pharmacy staff should have knowledge of these safeguards, as it will help prevent and protect the pharmacy from becoming a source of diversion.

Individuals attempting to fill fraudulent prescriptions often seek out areas where communication and cooperation between health care professionals are minimal because it makes it easier to avoid detection. Thus, a pharmacist should encourage other local pharmacists and physicians to develop a working relationship which will promote teamwork and camaraderie. In addition, the pharmacist should become familiar with those controlled substances that are popular for abuse and resale on the streets in the area and should discuss those findings with other pharmacists and practitioners in the community.

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QUESTIONS

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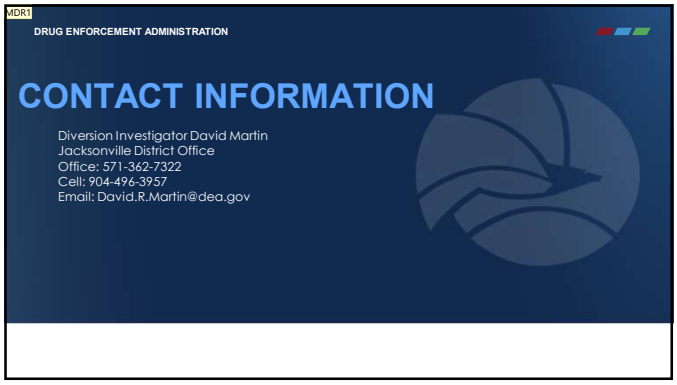
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