



EDUCATIONAL RESOURCES

PREPARING FOR AND RESPONDING TO A DEA INSPECTION

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INTRODUCTION



INTRODUCTION

- Having the DEA suddenly appear to conduct an inspection can be intimidating.
- Being prepared is essential to minimizing problems that can result from an inspection.

INTRODUCTION

- Overview
 - What prompts a DEA inspection
 - What to do when DEA agents show up
 - Possible outcomes

INTRODUCTION

- Overview
 - Preparation – Know and comply with the DEA requirements
 - Ordering controlled substances
 - Security Requirements
 - Inventory Requirements
 - Dispensing Requirements
 - Record Keeping Requirements

WHAT PROMPTS A DEA INSPECTION

- 21 CFR §1316.05 allows a DEA inspector to enter premises and conduct inspections at reasonable times and in a reasonable manner upon
 - stating his purpose
 - presenting to the owner, operator or agent in charge of the premises to be inspected with
 - appropriate credentials,
 - written Notice of Inspection, and
 - either receiving informed consent or through the use of an administrative warrant

WHAT PROMPTS A DEA INSPECTION

- Routine to verify compliance and identify potential areas of diversion. All pharmacy purchases of Schedule II and Schedule III drugs get reported to the DEA. Pharmacies which buy the most are more likely to get a visit from the DEA to determine whether the dispensing is legitimate.
- Grievance complaint
- Referral from local, state, or federal authority or agency

WHAT TO DO WHEN DEA SHOWS UP

- The DEA will arrive unannounced
- Upon arrival, the DEA will
 - Identify the decisionmaker
 - Display credentials
 - seek cooperation
 - Obtain informed consent (NOI), or
 - Obtain Administrative Inspection Warrant

WHAT TO DO WHEN DEA SHOWS UP

- Investigators will review
 - State licensure/registration
 - List of owners/corporate officers
 - List of responsible individuals
 - Physical security for drugs
 - Identify persons with access to cage, vault, and controlled substances
 - Recordkeeping compliance
 - Understanding of federal regulations

WHAT TO DO WHEN DEA SHOWS UP

- Investigators will perform records review
 - Immediately secure access to inventory, records, and computers
 - Count inventory with management
 - Get agreement on inventory count
 - Review records and record keeping system (purchases, sales, disposals, etc.)
 - Compare overall purchases to sales
 - Identify suspicious transactions or trends (cash sales, excessive purchases, etc.)

WHAT TO DO WHEN DEA SHOWS UP

- Upon arrival, the Pharmacy should
 - Have a designated Inspection Leader assigned to deal with the DEA. The Inspection Leader should be aware of all aspects of the pharmacy's policies, operations, and record-keeping systems.
 - The Leader should accompany the investigator throughout the inspection and make notes.
 - Have your records readily available.
 - If copies of documents are provided to the investigator, always make a duplicate set of copies for the pharmacy's own records.

WHAT TO DO WHEN DEA SHOWS UP

- After the DEA inspection, the Pharmacy should
 - Create a separate file.
 - This file will include the notes taken during the inspection by pharmacy employees, the forms filled out regarding the inspection, duplicates of the records provided to the investigator, and any subsequent correspondence with the agency.

POSSIBLE OUTCOMES OF A DEA INSPECTION

- Verbal Warning
- Letter of Admonition
- Memorandum of Agreement/Understanding
- Immediate Suspension Order
- Order To Show Cause
- Civil
 - Provides a remedy of maximum \$10,000 USD per violation.
- Criminal
 - Arrest and/or Criminal Fines



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PREPARING FOR A DEA INSPECTION

PREPARING FOR A DEA INSPECTION

- Ordering Controlled Substances

- On September 30, 2019, DEA issued a final rule which implements a new single-sheet format for DEA Form 222, used by DEA registrants to order schedule I and II controlled substances. The rule became effective on October 30, 2019, and provides for a two-year transition period, during which the existing triplicate version of the forms may continue to be used. DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition to using the new single-sheet form. When a registrant's supply of triplicate forms is depleted, DEA will issue new single-sheet forms to the registrant. This rule includes a "sunset date" of October 30, 2021—the date after which use of the triplicate forms will not be allowed.

PREPARING FOR A DEA INSPECTION

- Ordering Controlled Substances
 - Schedule I and II controlled substances are ordered with an official paper order form, DEA Form 222, or the electronic equivalent through the Controlled Substance Ordering System (CSOS).
 - DEA Forms 222 have an order form number and are issued with the name, address, and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant.

PREPARING FOR A DEA INSPECTION

- Completing DEA Forms 222

- A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil. Only one item may be entered on each numbered line. An item must consist of one or more 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.
- The purchaser should record the name and address from whom the controlled substances are being ordered must be entered on the form. If the purchaser does not have this information, then the supplier should ensure it is on the form.
- Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney. The purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier.

PREPARING FOR A DEA INSPECTION

- Completing DEA Forms 222
 - When the items are received, the purchaser must document on the purchaser's copy the actual number of commercial or bulk containers received and the date received.
 - The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.
 - DEA Forms 222 must be maintained separately from all other records of the registrant.
 - DEA Forms 222 are required to be kept available for inspection for a period of two years.
 - If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents at the registered location printed on the DEA Form 222.

PREPARING FOR A DEA INSPECTION

- Controlled Substance Ordering System (CSOS) – Electronic Order Forms
- Any registrant permitted to order Schedule II controlled substances may do so electronically via CSOS and must maintain the records of these orders electronically for two years.
- CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. The electronic orders must be signed using a digital signature issued by the Certification Authority (CA) run by DEA.
- Digital certificates can be obtained only by the person who signed the most recent DEA registration application or renewal application, a person authorized to sign a registration application, or a person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.

PREPARING FOR A DEA INSPECTION

- Ordering Schedules III-V Controlled Substances
- The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. Such receipts must also contain the following information:

PREPARING FOR A DEA INSPECTION

1. The name of the substance;
 2. Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
 3. The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;
 4. The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;
 5. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.
- In addition, these receipts must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

PREPARING FOR A DEA INSPECTION

- Security Issues
 - Locked cabinets
 - Limit issuance of keys
 - Alarms/Security cameras
 - Background checks

PREPARING FOR A DEA INSPECTION

- Inventory Requirements
 - Beginning inventory
 - All CS on-hand (including ordered not yet received, and all invoiced) on the date the pharmacy first dispenses a CS
- Biennial Inventory
 - Must inventory every 2 years on anniversary of beginning/initial inventory date
 - The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.
 - The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

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- Newly Scheduled Drugs
 - Date of inventory specified in Federal Register; thereafter on the biennial inventory date
 - Change in Pharmacist-In-Charge
 - Although the DEA does not require a new inventory when there is a change in PIC, it is required by most state pharmacy boards

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- Inventory for Damaged, Defective, or Impure Substances
 - For damaged, defective, or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings, the inventories must include:
 1. The name of the substance;
 2. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
 3. The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

PREPARING FOR A DEA INSPECTION

- Inventory Requirements
- Required Information Contained in Inventory Record
 - Date and time of inventory
 - Signature of person(s) responsible for taking inventory
 - Name of CS
 - Dosage form/unit strengths/concentration
 - Number of units or volume in each commercial container
 - CI or CII: exact count
 - CIII, CIV, CV: estimate, unless container originally held 1,000 or more

PREPARING FOR A DEA INSPECTION

- Required Information Contained in Inventory Record (cont'd)
 - Number of commercial containers
 - Total quantity of substance in all forms to nearest unit weight
 - Inventory, written or typed, and if done in oral recording must be promptly transcribed
 - Separate inventories required for each separate location
 - The inventory records of Schedule II drugs must be kept separate from all other records of the pharmacy.
 - The inventory records of Schedules III, IV, and V drugs must be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

PREPARING FOR A DEA INSPECTION

- Dispensing Requirements
- A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must also include:
 1. Prescriber's full name, address, and DEA registration
 2. Patient's full name and address
 3. Drug name
 4. Drug strength
 5. Dosage form
 6. Quantity prescribed
 7. Directions for use
 8. Number of refills authorized (if any)

PREPARING FOR A DEA INSPECTION

- Dispensing Requirements
- To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 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. Drug abusers often request prescriptions for “uppers and downers” 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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- Dispensing Requirements
- 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.:
 - The lack of a valid DEA and/or license number
 - Incorrect spelling of drug
 - An improper Sig.
 - Inappropriate erasures or markings
 - A suspicious signature

PREPARING FOR A DEA INSPECTION

- Identifying Fraudulent Prescriptions
 - 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.

PREPARING FOR A DEA INSPECTION

■ Identifying Fraudulent Prescriptions

- 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 should require proper identification.
- 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.

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- Recordkeeping Requirements

- The records which must be maintained by a pharmacy are:
 1. Executed official order forms (DEA Form 222) or the electronic equivalent.
 2. Power of Attorney authorization to sign order forms.
 3. Receipts and/or invoices for schedules III, IV, and V controlled substances.
 4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business.
 5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors).
 6. The Suspicious Orders Report System (SORS) should be accessed on-line and only be used by DEA registrants that distribute controlled substances to other DEA registrants. Reporting a suspicious order to SORS Online constitutes compliance with the reporting requirement under 21 U.S.C. 832. Previously, only manufacturers and distributors were required to report suspicious orders. The SUPPORT Act requires that ALL DEA registrants that distribute controlled substances report suspicious orders to DEA. Reverse distributors and exporters are not affected by this SUPPORT Act requirement.

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- Recordkeeping Requirements

- The records which must be maintained by a pharmacy are:

7. Records of controlled substances dispensed, to include prescriptions or a logbook of controlled substances which may be lawfully dispensed without a prescription.
8. Reports of Theft or Significant Loss (DEA Form 106), if applicable.
9. Registrant Record of Controlled Substances Destroyed (DEA Form 41), if applicable.
10. DEA registration certificate.
11. The self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005.

PREPARING FOR A DEA INSPECTION

- Prescription Record Requirements (Paper)
 - Option 1:
 1. A file for Schedule II controlled substances dispensed.
 2. A file for Schedules III, IV and V controlled substances dispensed.
 - Option 2:
 1. A file for all Schedule II controlled substances dispensed.
 2. A file for all other drugs dispensed (non-controlled and those in Schedules III, IV and V). If this method is used, a prescription for a Schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high.
- If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

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- Prescription Record Requirements (Electronic)
 1. If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.
 2. Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not preempt any longer period of retention which may be required now or in the future, by any other federal or state law or regulation, applicable to pharmacists or pharmacies.
- 3. Records regarding controlled substances must be readily retrievable from all other records.

Electronic records must be easily readable or easily rendered into a format that a person can read. Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of 21 CFR Part 1311 and 21 CFR 1304.04(h)(5). The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by a DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to a DEA or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

ADDITIONAL STEPS TO PROTECT AGAINST DIVERSION

- Perpetual inventory of controlled substances, or conduct inventory more frequently
- Monitor employee behavior and moods
- Division/rotation of job responsibilities
- Know the prescribers, their specialties, and prescribing patterns
- Know your patients and their medical conditions
- If you have questions/concerns about a prescription, utilize published information to contact the prescriber
- If you have concerns about patient, require proper identification
- If you believe the prescription is forged or altered, do not dispense and call the police



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QUESTIONS?

Email us at auweb@achcu.com



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THANK YOU

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