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Growth. Performance. Success.

2024 ANNUAL CONVENTION

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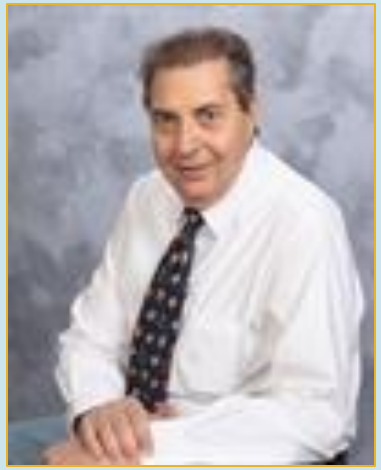
How to Survive a DEA Inspection

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

Speakers



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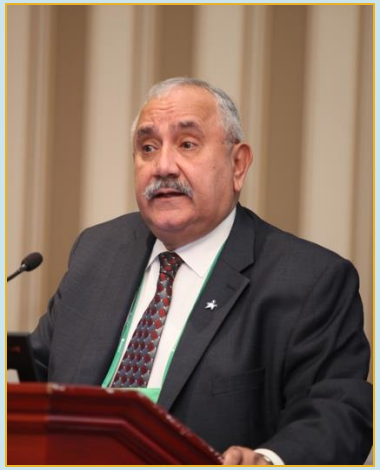

Carlos M. Aquino
Compliance Consultant &
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PharmaDiversion, LLC

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Pharmacist and Technician Learning Objectives

1. Describe the types of DEA civil and administrative actions that can be imposed by a federal prosecutor's office on a pharmacy.
2. Summarize inventory best practices for controlled substances.
3. Discuss the pharmacy Due Diligence Policy and its role in determining the legitimacy of medical necessity for the dispensing of controlled substances as part of a patient's treatment plan.
4. Identify what pharmacy records are required by DEA Diversion as part of an on-site pharmacy audit and best practices for maintaining these records.

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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who is in control of the content of the activity.

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DRUG ENFORCEMENT ADMINISTRATION ("DEA")

DIVERSION CONTROL DIVISION ("DIVERSION")

www.deadiversion.usdoj.gov
(Answer to a Sleepless Night)

RESOURCES

Title 21 Code of Federal Regulations
Title 21 USC Codified CSA
Federal Register Notices
EPCS Guidance – Transfer of an eScript
Pharmacist Manual - Revised 2022
Practitioners Manual – Revised 2023
Narcotic Treatment Program – Revised 2022
Under Pharmacy Tab – "Pharmacist's Guide to Rx Fraud"

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- Administrative Actions
- Chemical Control Program
- CMEA (Combat Meth Epidemic Act)
- Controlled Substances Schedules
- DEA Regulatory Priorities
- DEA TOX
- Drug Disposal Information
- Drug & Chemical Information
- EPCS (Electronic Prescriptions for Controlled Substances)
- Federal Register Notices
- Guidance Document Portal
- Medications for Opioid Use Disorder
- National Prescription Drug Take Back Day
- NFLIS
- OPIOID (PHE) Information
- Pharmacy
- Publications & Manuals
- Questions & Answers
- Telemedicine
- Title 21 Code of Federal Regulations
- Title 21 USC Codified CSA

REGISTRATION | FORMS &APPLICATIONS | CONTACT US | RESOURCES

We are resolving an issue with the NFLIS DQS functionality. We anticipate the problem will be resolved soon.

AUTHORIZATION TO INSPECT

PURPOSE – To inspect, copy, verify correctness of records, reports, or other documents required to be kept or made under the Act or regulations including inventory (excludes financial data, sale data other than shipping data, and pricing data).

- Notice of Inspection (DEA Form 82)
- Administrative Inspection Warrant
- Search & Seizure Warrant

Title 21, United States Codes Section 880 & 965
Title 21, Code of Federal Regulations Part 1316

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DEA ACTIONS AGAINST A PHARMACY

Administrative Action

- Letter of Admonition (LOA)
- Memorandum of Agreement (MOA)
- Voluntary Surrender of DEA Registration
- Order to Show Cause (OTSC)
- Immediate Suspension
- Revocation

Civil Action

- Financial Civil Fine
- Annual Cost of Living Adjustment
- Per Violation (Update 02/12/2024)
- $18,759.00 for Each Record Violation
- $80,850.00 for Each Rx Violation

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DEA RECORDS OF CONTROLLED SUBSTANCES

Control Substance Ordering System (CSOS) (Results in Largest DEA Civil Fines)

- **Sharing/Posting Passwords**
- **Not Confirming CSOS Order**
- **No Power of Attorney Letter**
- **No DEA Form e222 Records (must be readily retrievable)**

Title21, Code of Federal Regulations Part 1311.60 RECORDKEEPING

CSOS APPLICATIONS COST NOTHING

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ORDER FORMS
(DEA Form 222)

“Must be Available for Inspection”
Electronic vs. Paper DEA 222

<u>Proper notation includes</u>:

- Date Drugs were Received

- Quantity Received

- Initials of Person Verifying the Order
(Not Required by DEA)

Title 21, Code of Federal Regulations Part 1305
ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

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Title 21, Code of Federal Regulations Part 1305.22 – Procedure for Filling Electronic Orders

“(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.”

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Title 21, Code of Federal Regulations
Part 1305.27 – Preservation of Electronic Orders

“(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years.”

“(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location”

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POWER OF ATTORNEY

"(a) A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."

21CFR Section 1305.05 - Power of Attorney

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C-III THROUGH C-V INVOICES

“Must be Available for Inspection”

<u>Proper notation includes</u>:

-Date Drugs were Received
-Quantity Received
-Initials of Person Receiving the Drugs
(Not Required by DEA)

Title 21, Code of Federal Regulations
Part 1304.21 (d) & 1304.22 (a)(2)

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THEFT & LOSS REPORT

-Any Theft or Significant Loss Should be Reported Within One Day of Discovery

- A DEA Form 106 Must be Submitted on the DEA Diversion Website Within 45 Days

- Records Must Be Readily Retrievable

Title 21, Code of Federal Regulations Part 1301.76(b)
DEA Pharmacist's Manual Revised 2022

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DRUG DESTRUCTION

- Use of Reverse Distributors

- Required Records for DEA Inspection

- Keep Each Destruction Folder

- Original Single Sheet DEA Form 222
(Copy to “DEA.Orderforms@usdoj.gov” by End of Month)

- Invoices for Schedules III to V

Remember: Quantity Shipped & Date Shipped on the DEA FormS 222 and on the Schedules III to V invoices

Title 21, Code of Federal Regulations Part 1318 - Disposal

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INVENTORY RECORDS FOR CONTROLLED SUBSTANCES

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TITLE 21 CODE OF FEDERAL REGULATIONS
Part 1304.21 (A)
GENERAL REQUIREMENTS FOR CONTINUING RECORDS

“ Every registrant required to keep records pursuant to Part 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her ..... except that no registrant shall be required to maintain a perpetual inventory.”

RECOMMEND DOING A PAPER OR ELECTRONIC PERPETUAL INVENTORY FOR ALL CONTROLLED SUBSTANCES

Shortages = Theft or Diversion
Overages = Failure to Maintain Complete & Accurate Records

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TITLE 21, CODE OF FEDERAL REGULATIONS
Part1304.11 (e)(6)
INVENTORY OF DISPENSERS AND RESEARCHERS

"(i) If the substance is listed in Schedule I or II, make an <u>exact</u> count or measure of the contents; or

(ii) If the substance is listed in Schedules III, IV, or V, make an <u>estimated</u> count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents."

DON'T FOLLOW PART (ii) REGULATION
USE YOUR ELECTRONIC PRESCRIPTION SOFTWARE

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DUE DILIGENCE

PHARMACY – Registrants are responsible to determine that any controlled substance prescriptions filled by their staff pharmacists are done for legitimate medical purpose.

PHARMACIST – DEA has placed the "corresponding responsibilities" on all pharmacists to determine that a controlled substance prescription is written for a legitimate medical purpose by a practitioner acting in their usual course of their professional practice.

Title 21 Code of Federal Regulations

Part 1306.04 – Purpose of Issue of Prescription

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Questions?

Thank you for your attendance

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