DRUG ENFORCEMENT ADMINISTRATION

Preparing for a DEA Inspection: What to expect and how to better prevent diversion

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TODAY'S OBJECTIVES

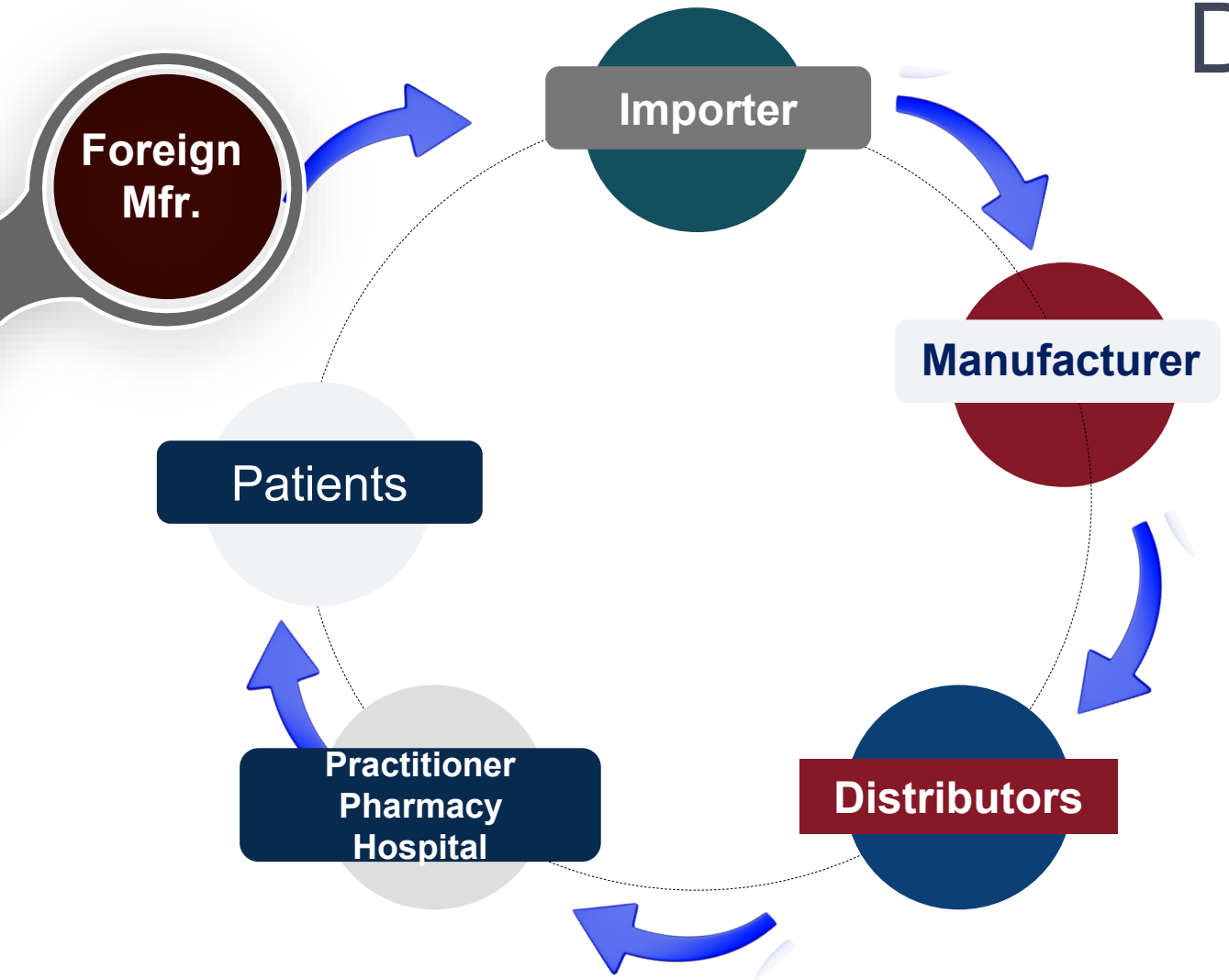
- Overview of Diversion Control
- What to expect during a DEA inspection
- Learn what you can do to:
  - –Better prevent diversion
  - –Better detect diversion
  - –Decrease your liability

Diversion Control Division

To prevent, detect, and investigate the diversion of controlled substances & listed chemicals from legitimate sources

Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes.

Closed System of Distribution

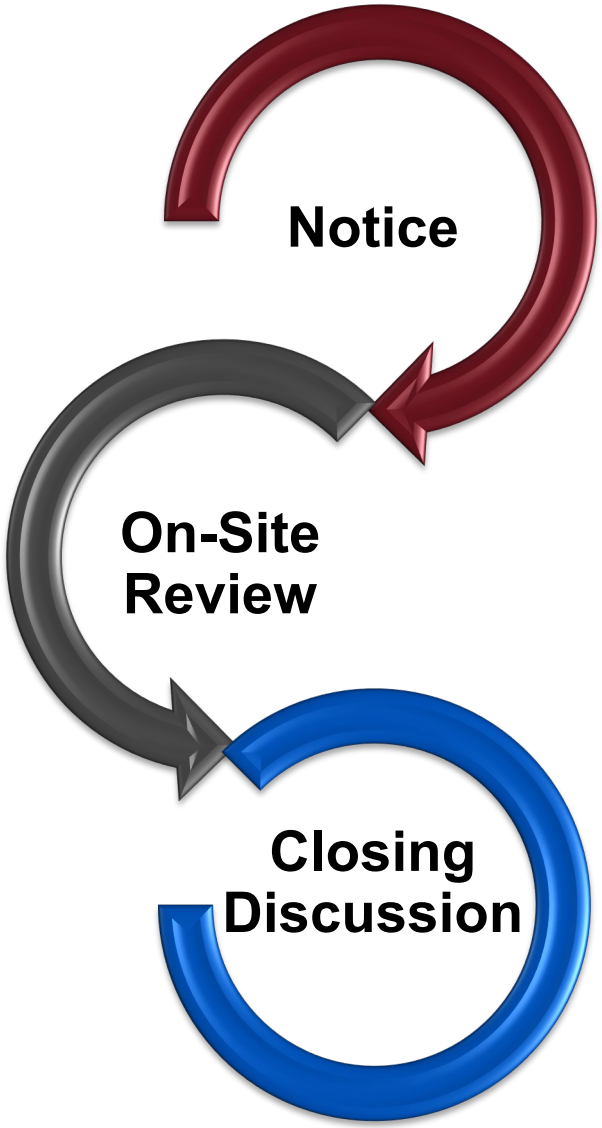


DEA is responsible for:

- oversight of the system
- integrity of the system
- protection of the public health and safety

Oversight of Closed System of Distribution

Inspections



Types

(1) Regulatory
(2) Complaint
(3) Criminal

Inspections
Controlled Premises

The **registered location** of the principal place of business and is a <u>place where original or other records or documents required under the CSA are kept or required to be kept.</u>

21 U.S.C 880(a)(1)-(2)
21 CFR(CFR) 1316.02(c)

DEA has the authority to enter a controlled premises to conduct an **administrative inspection.**

21 U.S.C. 880(b) and 21 CFR 1316.03

Certificate of Registration (DEA Form 223) shall be maintained at the registered location in a **readily retrievable manner** and shall be made available for inspection by DEA or any federal, state, or local agency engaged in the enforcement of laws relating to controlled substances.

21 CFR 1301.35(c)

Primary purpose of the inspection is to ensure compliance with Controlled Substances Act

Security

Records & Inventories

Medical Records

Drug Disposal/ Destruction

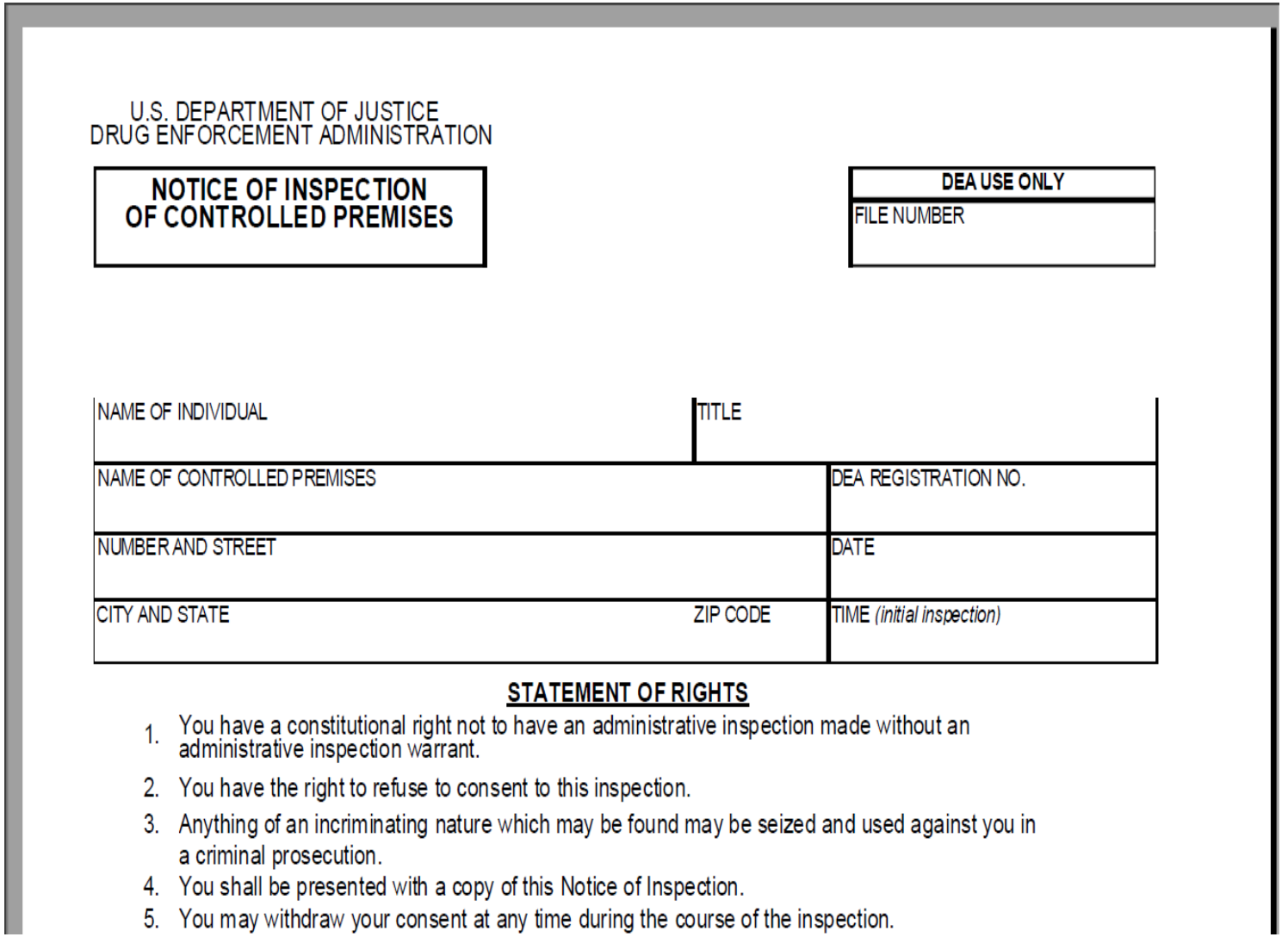
Licensing

Reporting

DEA On-site Investigation

What to expect:

- Present Credentials
- Ask to sign DEA-82, Notice of Inspection



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

NOTICE OF INSPECTION OF CONTROLLED PREMISES

DEA USE ONLY
FILE NUMBER

NAME OF INDIVIDUAL	TITLE
NAME OF CONTROLLED PREMISES	DEA REGISTRATION NO.
NUMBER AND STREET	DATE
CITY AND STATE ZIP CODE	TIME *(initial inspection)*

STATEMENT OF RIGHTS

1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
2. You have the right to refuse to consent to this inspection.
3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.
4. You shall be presented with a copy of this Notice of Inspection.
5. You may withdraw your consent at any time during the course of the inspection.

Steps of an On-Site Inspection

- Meet with Registrant and controlled substance handler(s)
- Tour of Facility: Specifically, where controlled substances are kept
- Discussions of Standard Operation Procedures (SOPs)
- Review Records
- Physical count of Controlled Substances on hand
- Review due diligence/Suspicious Orders

Items Requested During Inspection

- List of Employees with Access to Controlled Substances (Name, Title, Address, DOB)
- Copies of Licenses and Certificates (state/other federal)
- Facility Floor Plan
- Receiving Records (222s, Invoices/purchase orders/ packing slips, CSOS)
- Power of Attorney to order CIIs
- Dispensing/Distribution Records
- Records of Returns (Schedules II-V)
- Records of Destruction (DEA Form-41s, Waste Records, Reverse Distributor)
- Theft/loss reports (DEA Form-106)
- Copy of most recent biennial inventory
- Copy of alarm company contract
- List of Suppliers (Name, address, DEA #)

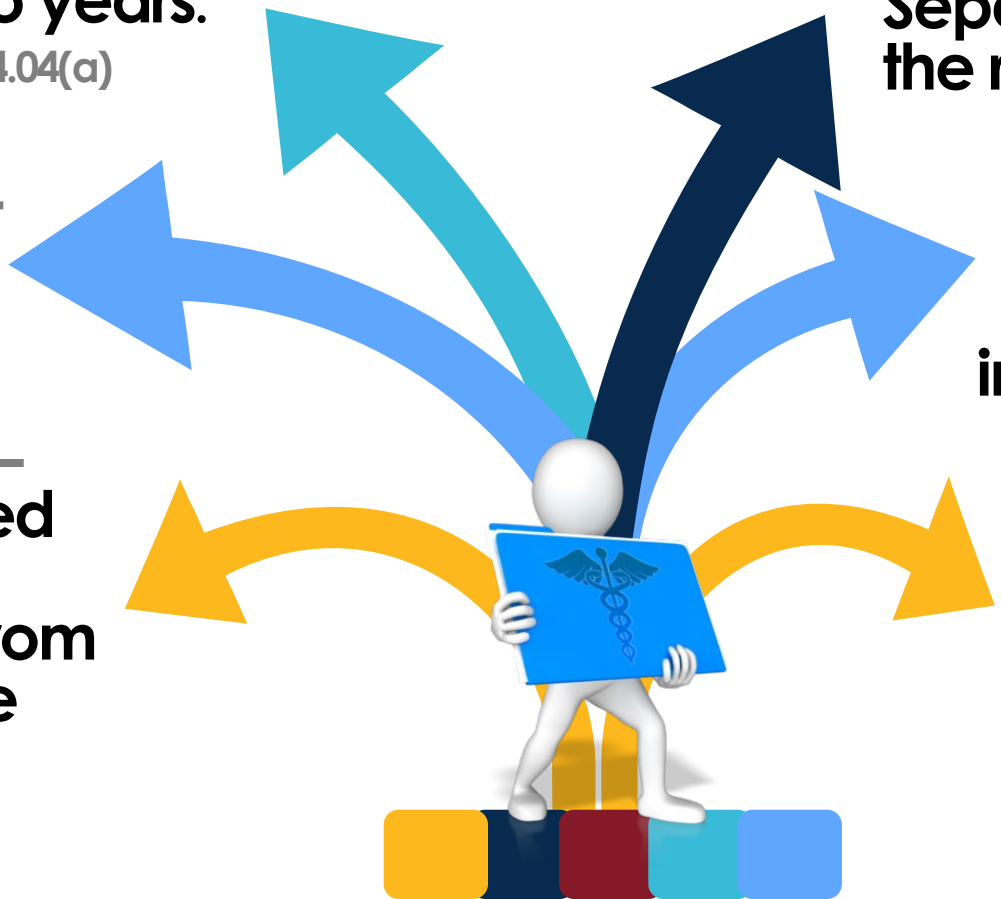
General Requirements
CONTINUING RECORDS

Record requirements are different depending on whether the registrant is handling controlled substances in schedules I and II, or schedules III-V controlled substances. These requirements are also different depending on the type of registrant (business category) taking the inventory.

Kept for two years.
21 CFR. 1304.04(a)

Readily retrievable.
21 CFR 1304.04(f)(2)

Schedule I & II controlled substances must be maintained separately from all other records of the registrant.
21 CFR 1304.04(h)(1)



Separate and stored at the registered location.
21 CFR 1304.21(b)

Separate for each independent activity and collection activity.
21 CFR 1304.21(c)

Complete and accurate.
21 CFR 1304.21(a)

Inventory Requirements

Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location.

An inventory taken by use of an oral recording device must be promptly transcribed.

§ 1304.11 Inventory requirements.

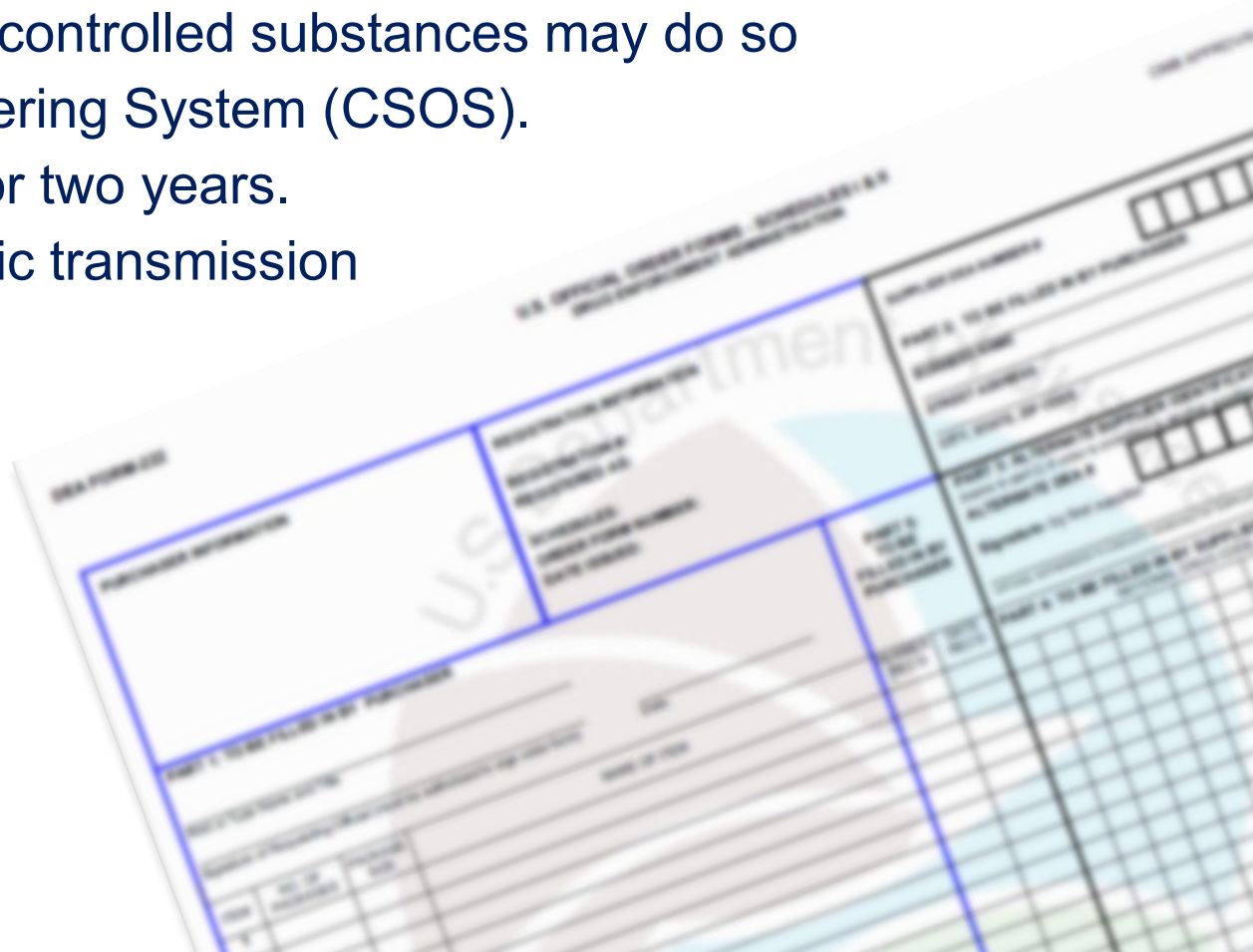
- “Physical Count”
- Must include all controlled substances “On Hand” (In possession/under the control of).
- Inventory date must reflect the date of the actual inventory.
- Maintained in Hand Written, Typewritten, or Printed Form at the Registered Location.
- A separate inventory shall be made for each registered location and each independent activity registered
- Types: Initial / Biennial
- Inventory controlled substances that will be disposed or destroyed.

Receiving Records

The DEA Form 222 (or electronic equivalent) is required for each distribution or procurement of a Schedule II controlled substance, 21 CFR 1305.03.

Any registrant permitted to order Schedule I and II controlled substances may do so electronically via DEA's Controlled Substance Ordering System (CSOS). These records must be maintained electronically for two years. 21 CFR 1305.27. CSOS allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. The use of electronic orders is optional.

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



Dispensing/Distribution Records

Every person registered to manufacture, distribute, dispense, import, and/or export must ***maintain complete and accurate records*** pursuant to their category of registration according to 21 CFR 1304.

Prescription Requirements

21 CFR 1306.05(a), 1306.22(b)

- Must be dated and signed on the date when issued.
- Must include:
  - Patient's full name and address
  - Practitioner's full name, address, and DEA registration number.
- Drug Name, Strength, & Dosage Form
- Quantity & Directions for Use
- Number of Refills Authorized (if any)

Controlled Substance Inventory

A physical inventory count of <u>ALL</u> controlled substances on-hand.

Including:

- Automated Dispensing Machines
- Safes/Vaults
- Disposal/Expired

Accountability Audit

Investigators will:

- count all controlled substances on hand
- review all receipts, invoices and dispensing records for the audit period
- calculate any differences (shortages or overages)
- Verify whether the registrant is maintaining proper records

Disposal of Controlled Substance Inventory

Title 21 Code of Federal Regulations- PART 1317 — DISPOSAL

OPTIONS TO DISPOSE OF

21 C.F.R. § 1317.05(a) and (b)

- Prompt on-site destruction if proper method.
- Prompt delivery to a DEA registered reverse distributor by common carrier or reverse distributor pick-up.

RETURNED OR RECALLED

21 C.F.R. § 1317.05(a) and (b)

- Prompt delivery by common or contract carrier or pick-up at the registered location by:
  - Registrant from whom it was obtained.
  - Registered manufacturer of the substance.
  - Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.

REQUEST ASSISTANCE- SPECIAL AGENT IN CHARGE

21 C.F.R. § 1317.05(a) (4)

Disposal of Controlled Substances

Registrants authorized to collect and authorized collection activities
21 CFR 1317.40

Collectors

Authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies **to collect pharmaceutical controlled substances from ultimate users** by voluntarily administering mail-back programs and maintaining collection receptacles.

Individual practitioners, such as medical doctors, dentists, or veterinarians are not authorized to be collectors.

DISPOSE OF UNNEEDED MEDICATIONS

FREE - ANONYMOUS - SAFE

DEA NATIONAL Rx TAKEBACK

APRIL 26, 2025

10 AM – 2 PM

FIND A COLLECTION SITE NEAR YOU:

www.DEATakeBack.com

Every Day is TAKE BACK DAY

CLEAN THEM OUT

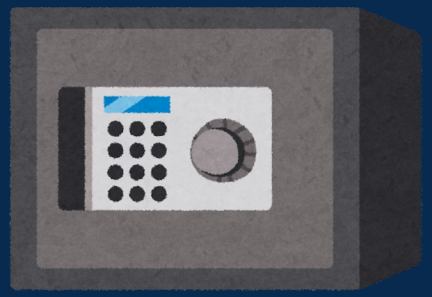
TAKE THEM BACK

ALL YEAR LONG

Dispose of unneeded medication in a collection site near you

SCAN ME

Physical Security



All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. (21 CFR 1301.71)

Practitioners (Pharmacies): See 21 CFR 1301.75b

Non-Practitioners (Controlled Substance Manufacturers, Distributors, Importers, Exporters): See 21 CFR 1301.72-1301.74

Chemical Manufacturers, Distributors, Importers, Exporters: See 21 1309.71

Freight Forwarding Facilities: See 21 CFR 1301.77

Other Security

Practitioners (Pharmacy): 21 CFR 1301.76

Non-Practitioners-Controlled Substances: 21 CFR 1301.74 & 21 CFR 1301.90-93

Chemical Handlers: 21 CFR 1309.72-73

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

1. Name and Address of Registrant [redacted]		**2. Phone No.** [redacted] **Amendment Key / Date Submitted**
3. DEA Registration Number [redacted]	**4. Date of Theft / Loss** 2022-04-27 Amendment # 1 [0] [1]	**5. Registrant's Principal Business** RETAIL PHARMACY
6. Registrant's County MARICOPA	**7. Theft Reported to Police?** Y	**8. Dept. Name, Report #, Officer Name, and Phone of Police Dept.** PHOENIX POLICE DEPARTMENT 22-655180 GONZALEZ 11072 6022626151
9. Number of Thefts /Losses Registrant Has Experienced in Past 24 Months? 0		**10. Type of Theft / Loss** Employee Theft (or Suspected)
11. Killed / Injured Due to Armed Robbery	**12. (Purchase) Value of Substances 106/107** $2 /	**13. Pharmaceuticals or Merchandise Taken?** N
14. The following applies when Type of Theft / Loss (Box 10) is "Lost In Transit":		
A. Name of Common Carrier	**B. Name of Consignee**	**C. Consignee's DEA Registration Number**

Closing Discussion

- Summary of inspection
- Clarify discrepancies
- Ask questions

Registrant Inspections - Common Findings

- Dispensing logs not maintained
- Execution of DEA Form 222
- Lack of required physical inventories such as initial and biennial inventories
- Spill log not accurate
- No checks and balances regarding spills
- Not properly reconciling
- Alarm systems not checked
- Power of Attorney and lack of revocations
- Lack of knowledge of software
- Controlled substance accountability
- Not counting everything on hand
- Take back of controlled substances
- Not notifying DEA of Drug Theft or Loss
- Ordering controlled substances from other entities outside of the closed system of distribution
- CSOS login and CSOS recordkeeping
- Lack of complete and accurate records

Legal Recourses

Administrative

- Letter of Admonition (LOA)
- Memorandum of Agreement (MOA)
- Order to Show Cause (OTSC)
- Immediate Suspension Order (ISO)

Civil

- Fines

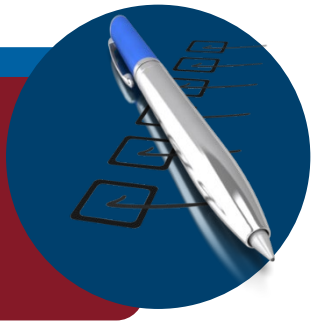
Criminal

- Consent Decree
- Arrest/Prosecution
- Criminal fines

Inspections - BEST PRACTICES

Designate a primary employee (and a back-up) to be responsible for controlled substance management

Conduct periodic internal inspections to stay fresh, identify weaknesses in the processes, and identify any compliance issues



Draft detailed policies and procedures for responding to DEA audits

Keep all controlled substance records in a single, easily-accessible location

Ensure that all controlled substances are maintained in secure areas

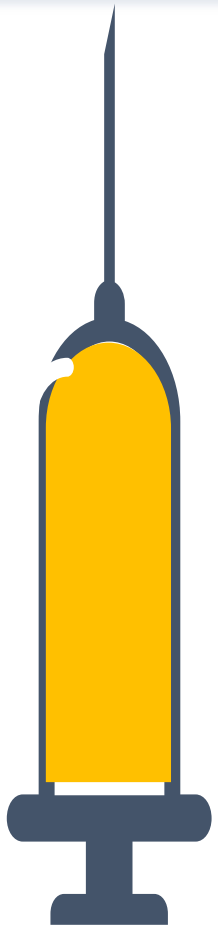
Signs of Drug Diversion

- Suspicious behavior – lethargic, falling asleep at work
- Disappearing for long lengths of time
- Unusual access to the automated dispensing machine
- Disposal of medications with no witnesses
- Poor or no charting of patient medication
- Patients reporting higher pain levels during a specific employee's shift
- Employee always volunteers for overtime / open shifts in the OR
- Employee has excessive no – call / no shows or calls out frequently
- Employee has unexplained wealth or frequent new assets

Diversion Effects All

Patients may receive inadequate pain relief, exposure to infectious diseases, substandard care

Facility/employer bears the cost of diverted drugs, internal investigations, civil fines and negative reputation



Health Care professionals risk overdose and possible death, face criminal prosecution, and malpractice suits

Community suffers though contributory drug misuse and mistrust in healthcare

Best Practices to Prevent Drug Diversion

Strong Medication Management

- Well-defined policies & procedures at registered location
- Secure storage, controlled access, complete records

Staff Education and Training

- Diversion awareness training
- Culture of accountability and vigilance
- Investigating and reporting practices

Audits and Inventory Controls

- Regular audits of controlled substance records
- Utilizing technology to monitor and detect diversion

Secure Medication Storage and Disposal

- Implementing physical security measures
- Proper disposal methods

DIVERSION RESOURCES

DEA Diversion

Questions & Answers

Publications & Manuals

Conference Materials And Resources

Thank You!