DRUG ENFORCEMENT ADMINISTRATION

Supply Chain Conference

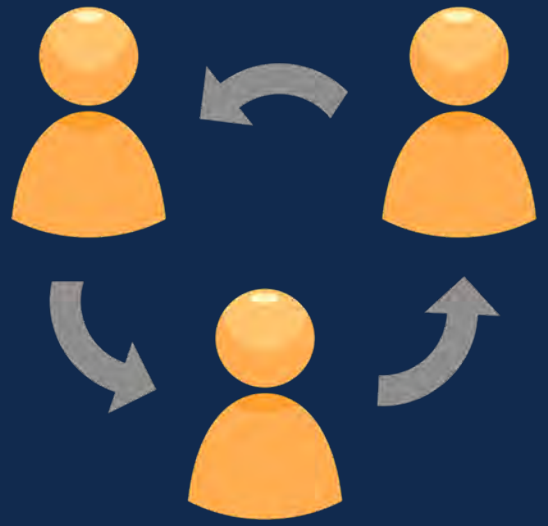
Little Rock, Arkansas

April 30 – May 2, 2024

DRUG ENFORCEMENT ADMINISTRATION

Preparing for a DEA Inspection:

What to expect and how to better prevent diversion



Niketa Prince

Staff Coordinator
Diversion Control Division, Liaison Section

May 2, 2024

Disclaimer

The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way.

This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I have no financial relationship to disclose.

Copyright Disclaimer

The presentation is for educational purposes. Materials, images, or sounds authored or created by parties other than DEA may be subject to copyright and are used herein in accordance with the fair use provision of Title 17 United States Code Section 107. DEA's use of these materials does not authorize persons outside of DEA further distribute of use copyrighted materials.

Diversion Control Division

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

REGULATORY

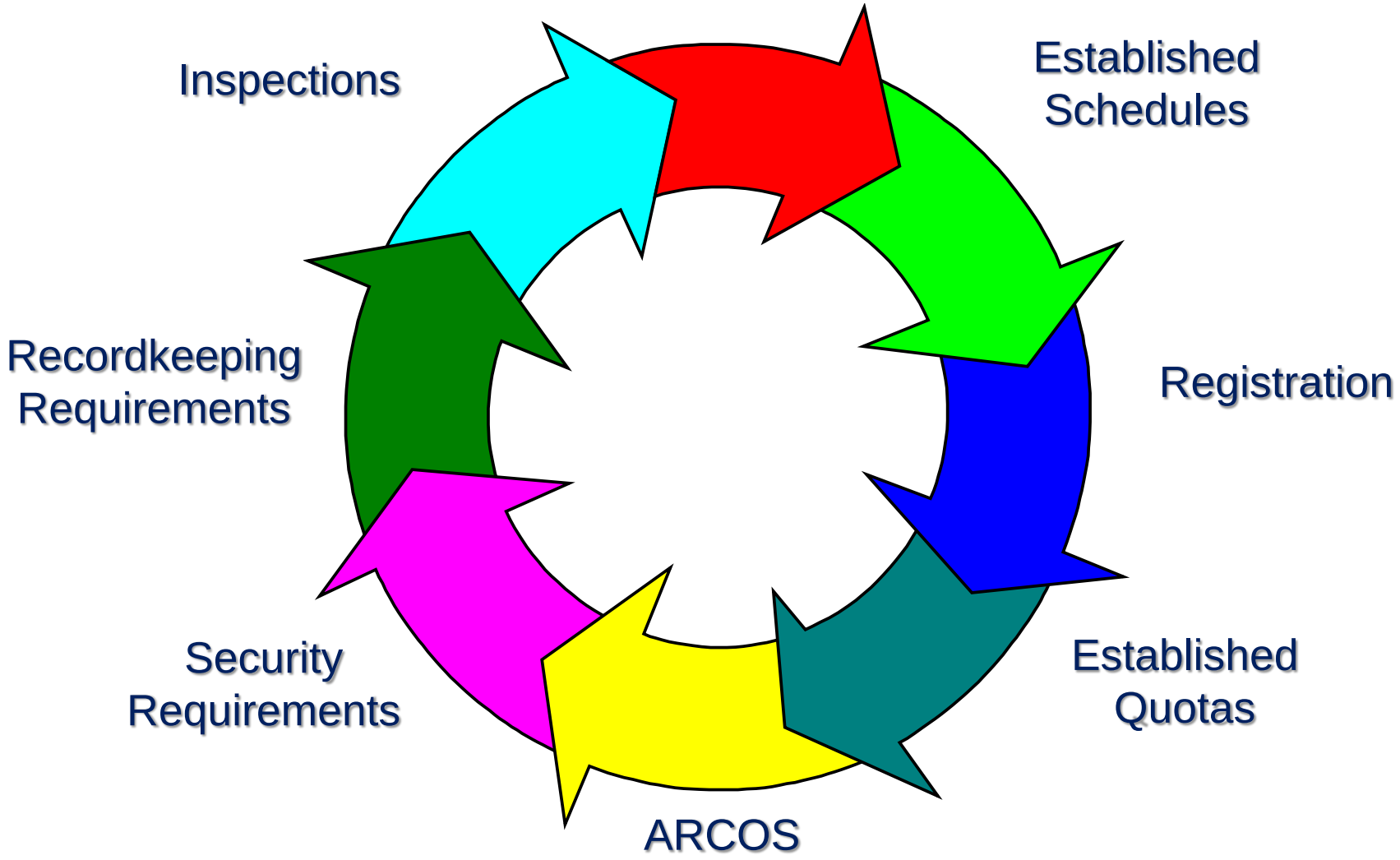
CRIMINAL DIVERSION

COMPLAINTS ON REGISTRANTS

OUTREACH
- REGISTRANT
- COMMUNITY

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

Maintaining the CSA's
Closed System of Distribution



Why is the DEA-Diversion Team on-site?

- Scheduled Inspections
- Theft/Loss
- Patient Complaint
- Suspicious Order Report
- DEA Registrant Request

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)

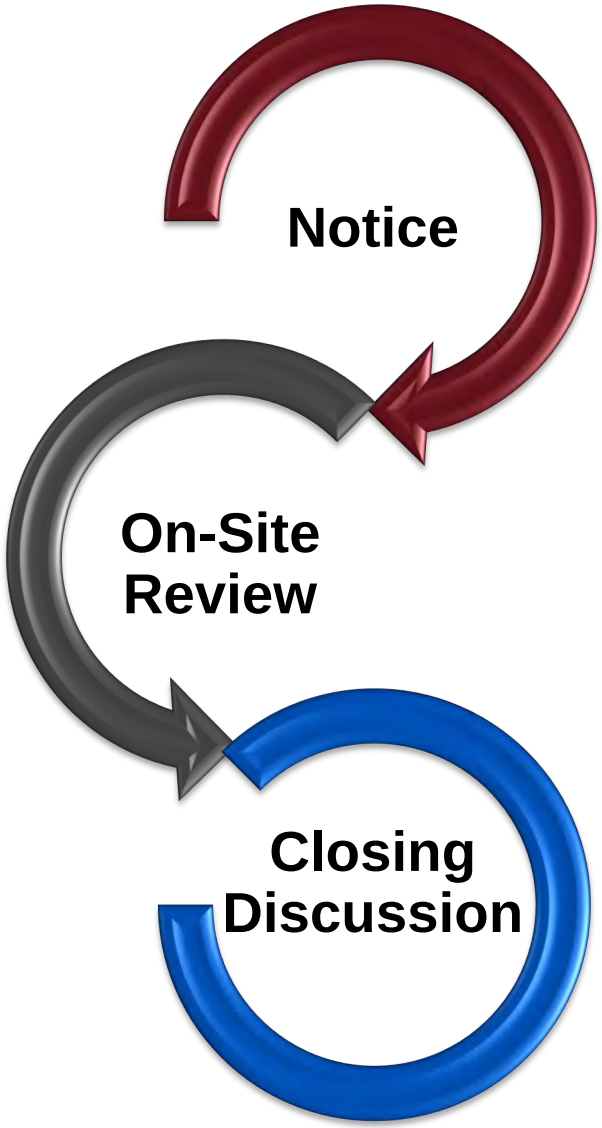
DEA has the authority to enter a controlled premises to conduct an **administrative inspection.**

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)

General Process on-site



Types

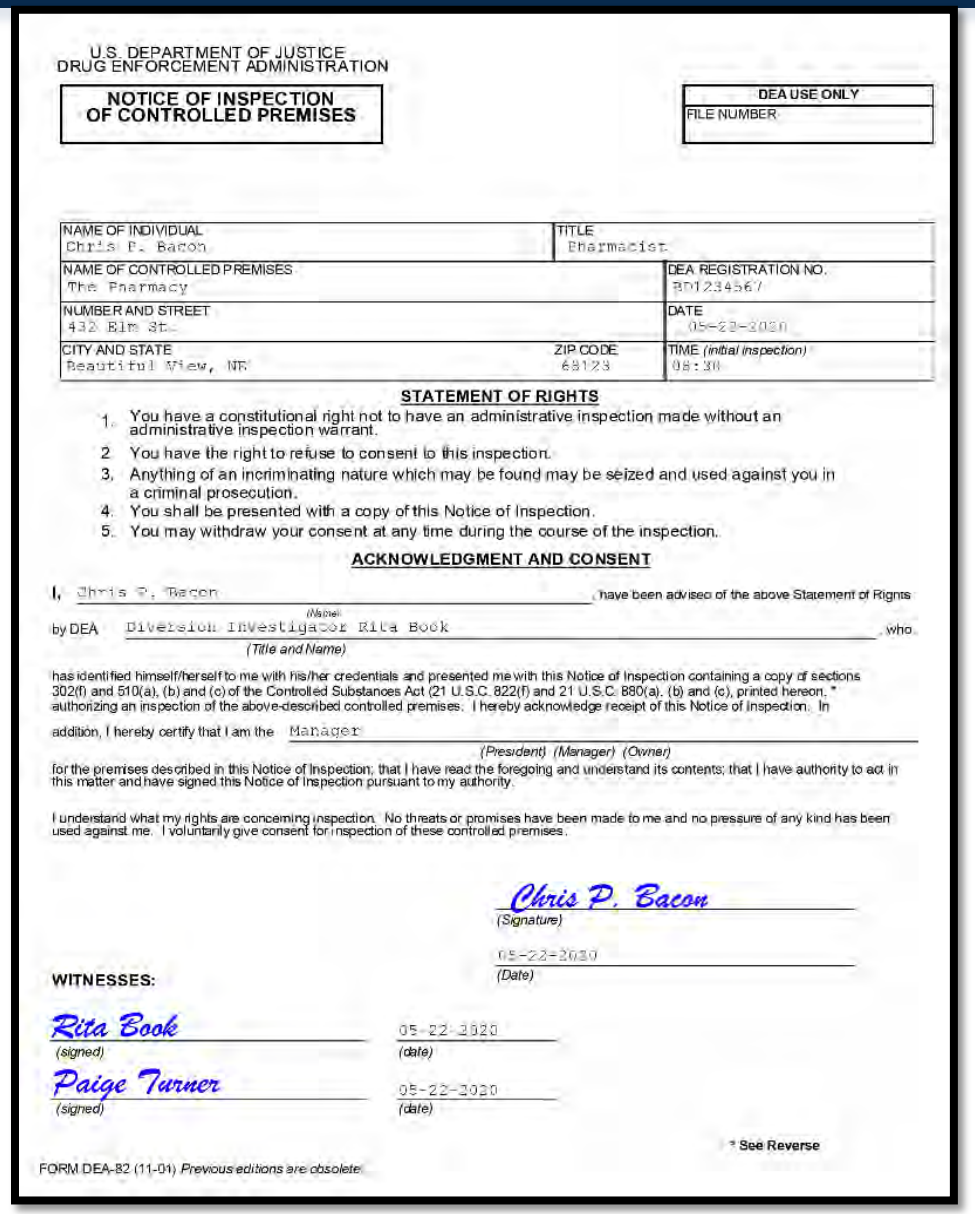
(1) Regulatory
(2) Complaint
(3) Criminal

Notice of Inspection

Unannounced

Two or more DEA Personnel

“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: Chris P. Bacon	TITLE: Pharmacist	
NAME OF CONTROLLED PREMISES: The Pharmacy		DEA REGISTRATION NO.: BP1234567
NUMBER AND STREET: 432 Elm St.		DATE: 05-22-2020
CITY AND STATE: Beautiful View, NE	ZIP CODE: 68123	TIME (initial inspection): 08:30

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.

ACKNOWLEDGMENT AND CONSENT

I, Chris P. Bacon (Name), have been advised of the above Statement of Rights by DEA Diversion Investigator Rita Book (Title and Name), who has identified himself/herself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections 302(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c), printed hereon, * authorizing an inspection of the above-described controlled premises. I hereby acknowledge receipt of this Notice of Inspection. In addition, I hereby certify that I am the Manager (President) (Manager) (Owner) for the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.

I understand what my rights are concerning inspection. No threats or promises have been made to me and no pressure of any kind has been used against me. I voluntarily give consent for inspection of these controlled premises.

Chris P. Bacon (Signature)

05-22-2020 (Date)

WITNESSES:

Rita Book (signed) 05-22-2020 (date)

Paige Turner (signed) 05-22-2020 (date)

* See Reverse

FORM DEA-82 (11-01) *Previous editions are obsolete*

DEA On-site (Cont'd):

- Meet with management and controlled substance handler
- Tour of Facility: Specifically where controlled substances are kept
- Review Standard Operating Procedures of controlled substance handling
- Controlled substance document request (i.e., POAs, Key Control Logs, Spill logs, Inventories and more)
- Physical count of Controlled Substances on hand

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

Security

Records & Inventories

Medical Records

Drug Disposal/ Destruction

Licensing

Reporting

§1316.03 Authority to make inspections.

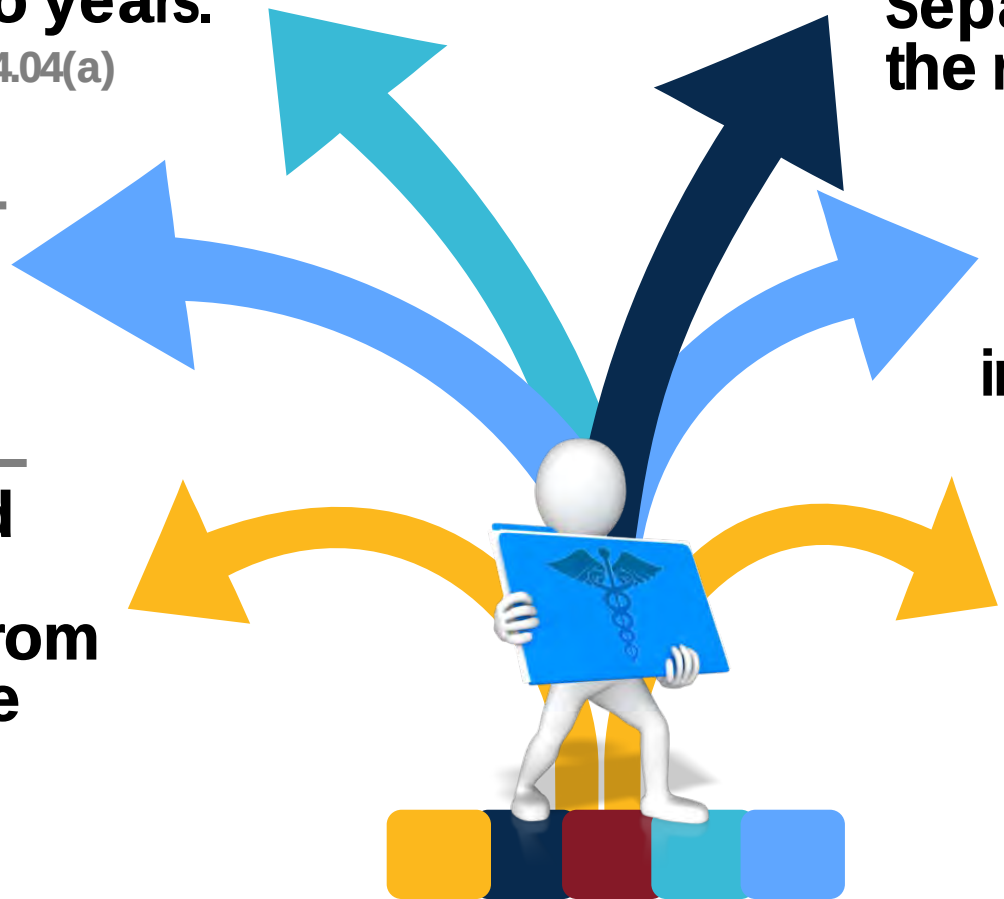
General Requirements
CONTINUING RECORDS

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 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)

Controlled Substance Records

- Most recent Biennial Inventory
- Reconciliations
- Receiving Records
  - DEA-222 Forms
    - Invoices
- Distribution Records
  - Dispensing
  - Disposal & destruction Records
  - Theft/Loss Reports

Power of Attorney

21 CFR 1305.05(a)

- A Power of Attorney may be used to execute a DEA Form 222

- 21 CFR 1305.05(d) requires that a POA be signed by four (4) people
  - The Registrant
  - The Designated Power of Attorney
  - Two Witnesses

How Can You Help?

- Ensure Personnel are familiar with DEA records and knowledgeable of software system/how to run reports
- Have all DEA records readily retrievable
- Ensure all DEA registrations and state licenses are current

Controlled Substance Inventory

A physical inventory count of ALL controlled substances on-hand:

- Automated Dispensing Machines
- Vault/Safe
- Disposal/Expired

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.

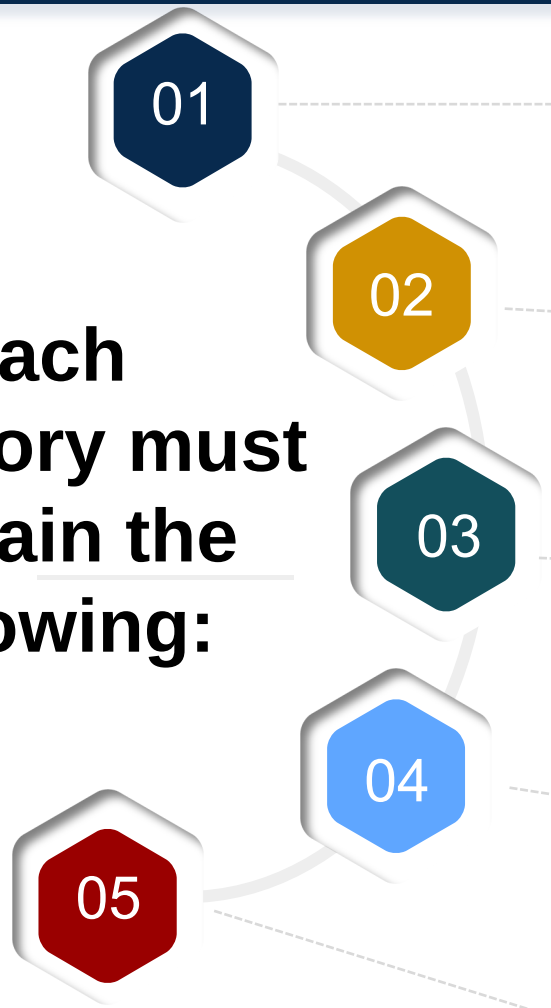
An inventory taken by use of an oral recording device must be promptly transcribed.

§ 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.

Inventory Components

Each Inventory must contain the following:



01 When was it taken: beginning or close of business

02 Name of controlled substances.

03 Each finished form of substances (e.g. 100 milligram tablet).

04 The number of dosage units of each finished form in the commercial container (e.g. 100 tablet bottle).

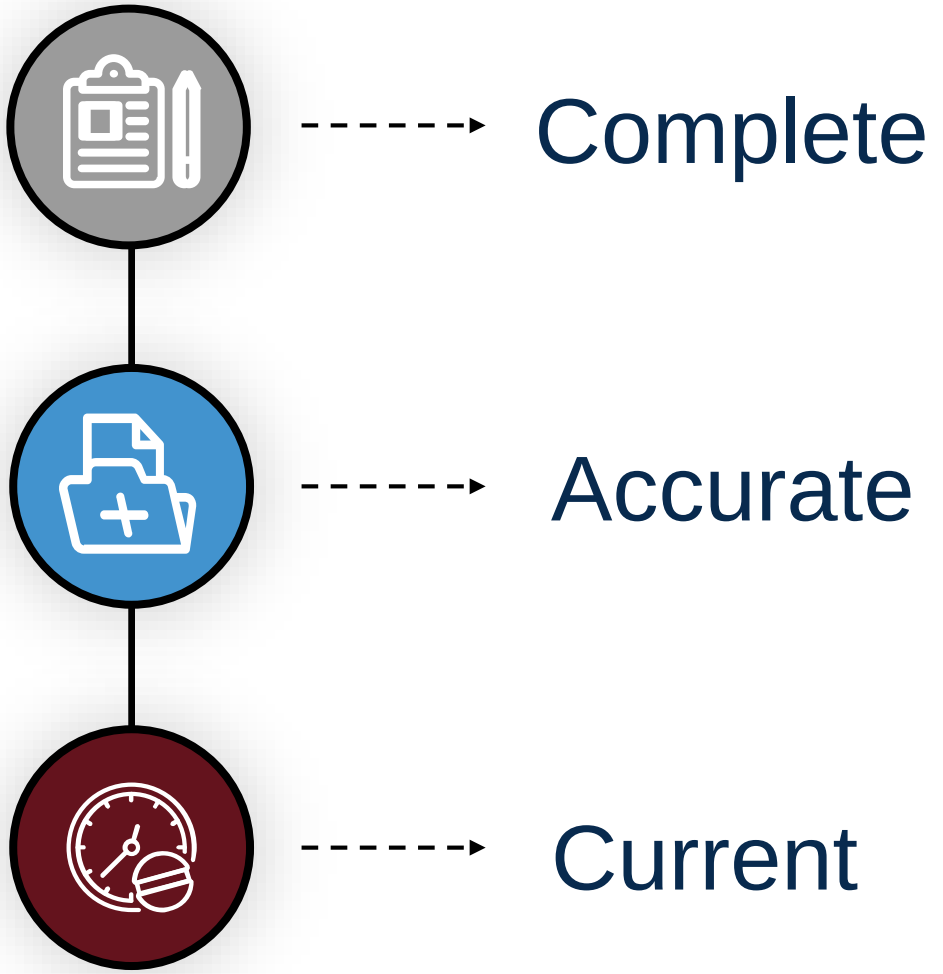
05 The number of commercial containers of each finished form (e.g. four 100 tablet bottles).
Disposition of the controlled substances.

Audit

Audit of Controlled Substances

"21 CFR 1304 and 21 U.S.C. 827"

Every registrant must maintain complete and accurate records on a current basis for each controlled substance received, sold, delivered, or otherwise disposed of.

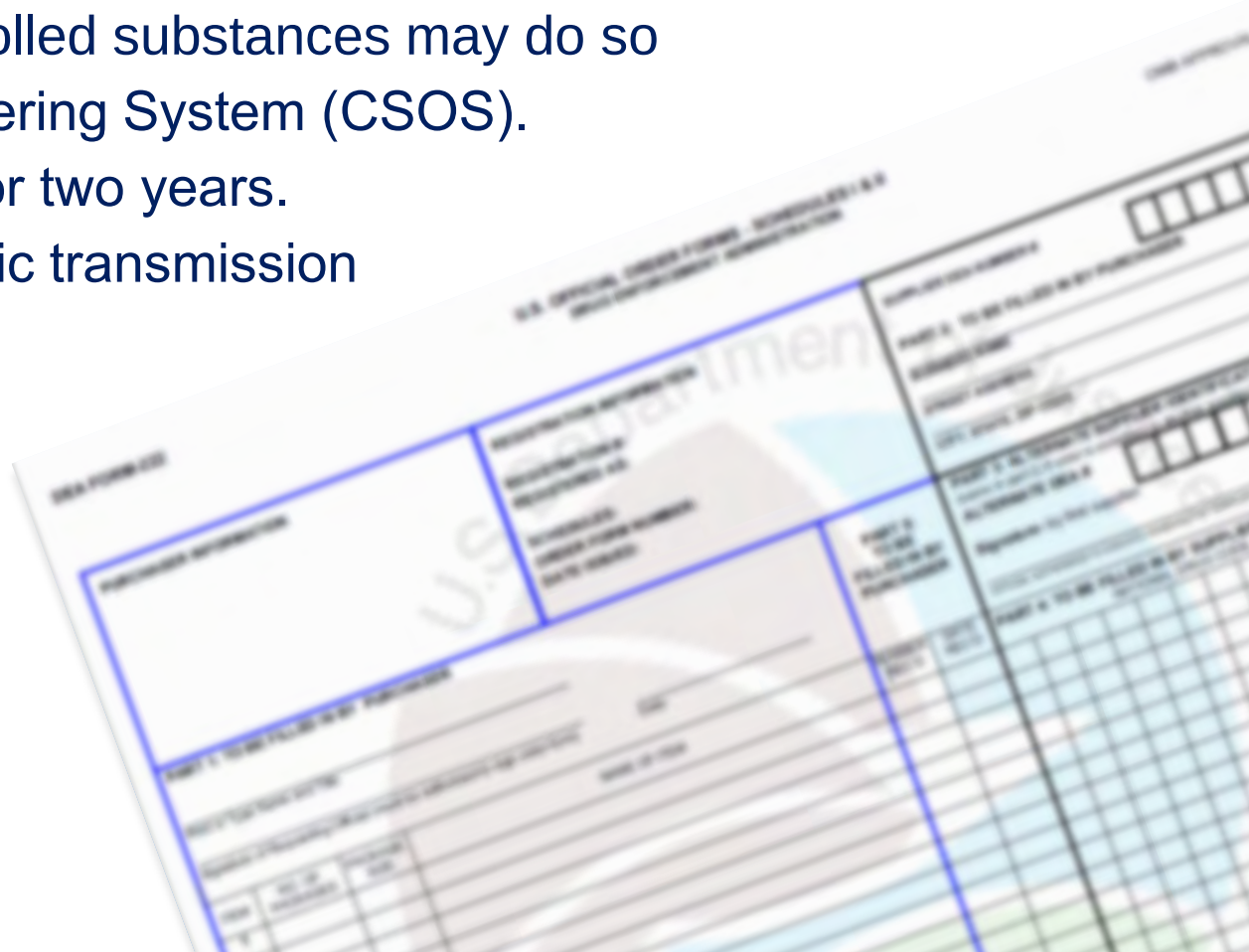


Receiving Records

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 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 Part 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)

Corresponding Responsibility

"21 CFR 1306.04(a) and 1306.06"

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility rests** with the pharmacist who fills the prescription.

A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

Theft & Significant Loss

Factor to considering when determining whether a loss is significant loss:

- Actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances;
- 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;
- 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
- Whether the specific controlled substances are likely candidates for diversion; and
- Local trends and other indicators of the diversion potential of the missing controlled substances.

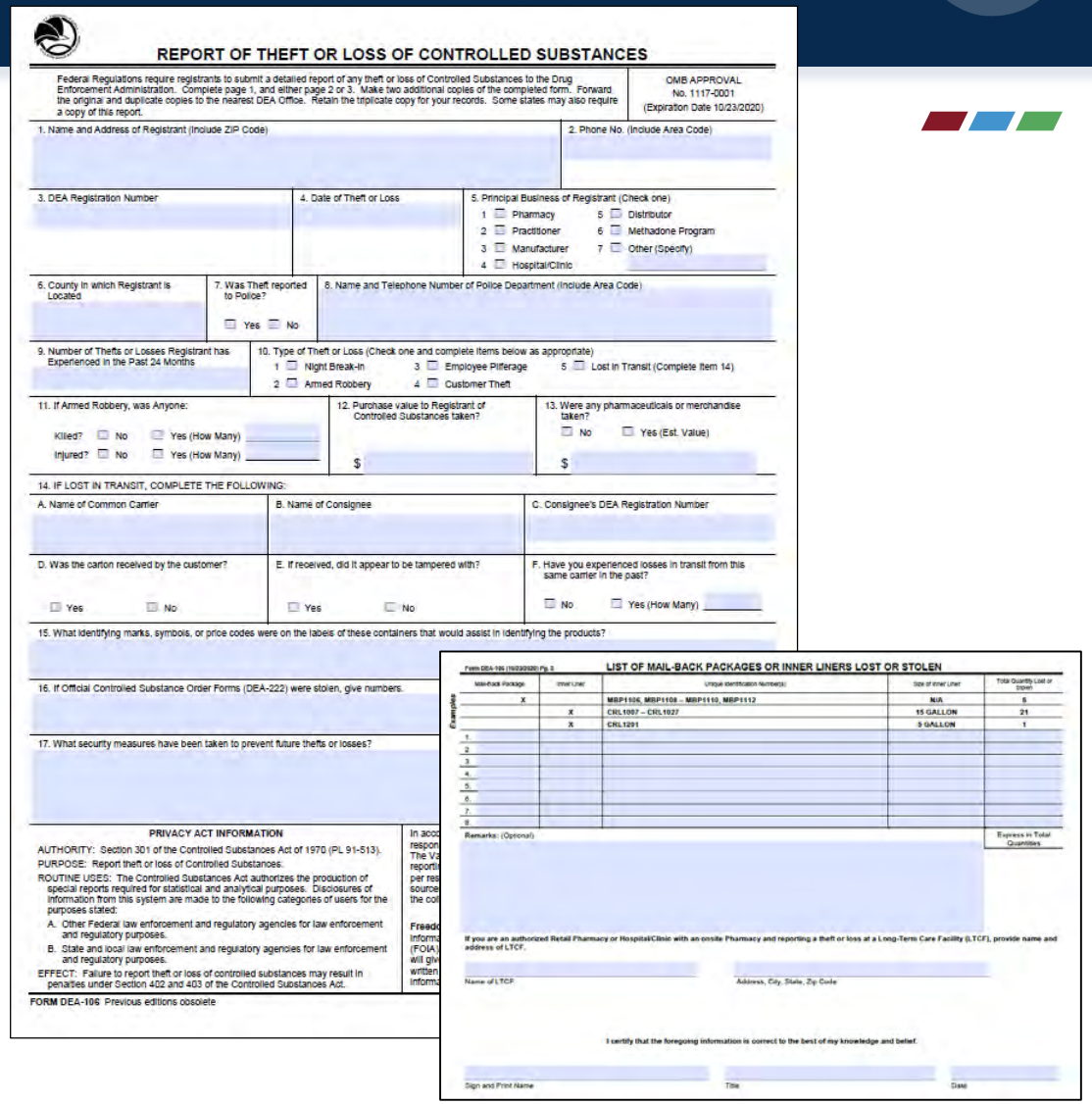
Must notify the local DEA Diversion Field Office in writing, within one business day of discovery of a theft or significant loss of a controlled substance.

21 CFR 1301.76(b)

Theft and Loss Reporting

- **Registrant must notify the DEA in writing within ONE BUSINESS day of discovery.**
- **All in-transit losses must be reported**
- **Must complete a DEA form 106, online, once your investigation is complete.**
- **Registrants are encouraged to immediately report theft and losses to your local law enforcement and state regulatory agency.**
- **DEA regulations specify that you keep a copy of this report for two years.**

21 CFR 1301.76(b)



REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete page 1, and either page 2 or 3. Make two additional copies of the completed form. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL No. 1117-0001 (Expiration Date 10/23/2020)

1. Name and Address of Registrant (Include ZIP Code)
2. Phone No. (Include Area Code)
3. DEA Registration Number
4. Date of Theft or Loss
5. Principal Business of Registrant (Check one)
1 Pharmacy 2 Practitioner 3 Manufacturer 4 Hospital/Clinic 5 Distributor 6 Methadone Program 7 Other (Specify)
6. County in which Registrant is Located
7. Was Theft reported to Police? Yes No
8. Name and Telephone Number of Police Department (Include Area Code)
9. Number of Thefts or Losses Registrant has Experienced in the Past 24 Months
10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 Night Break-in 2 Armed Robbery 3 Employee Pilferage 4 Customer Theft 5 Lost in Transit (Complete Item 14)
11. If Armed Robbery, was Anyone: Killed? No Yes (How Many) Injured? No Yes (How Many)
12. Purchase value to Registrant of Controlled Substances taken? $
13. Were any pharmaceuticals or merchandise taken? No Yes (Est. Value) $
14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:
A. Name of Common Carrier
B. Name of Consignee
C. Consignee's DEA Registration Number
D. Was the carton received by the customer? Yes No
E. If received, did it appear to be tampered with? Yes No
F. Have you experienced losses in transit from this same carrier in the past? No Yes (How Many)
15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?
16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.
17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report theft or loss of Controlled Substances.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

FORM DEA-106 Previous editions obsolete

LIST OF MAIL-BACK PACKAGES OR INNER LINERS LOST OR STOLEN

Mail-Back Package	Inner Liner	Unique Identification Number(s)	Size of Inner Liner	Total Quantity Lost or Stolen
X		MBP1106, MBP1108 – MBP1110, MBP1112	N/A	5
	X	CRL1007 – CRL1027	15 GALLON	21
	X	CRL1291	5 GALLON	1
1				
2				
3				
4				
5				
6				
7				
8				

Remarks: (Optional) Express in Total Quantities

If you are an authorized Retail Pharmacy or Hospital/Clinic with an on-site Pharmacy and reporting a theft or loss at a Long-Term Care Facility (LTCF), provide name and address of LTCF.

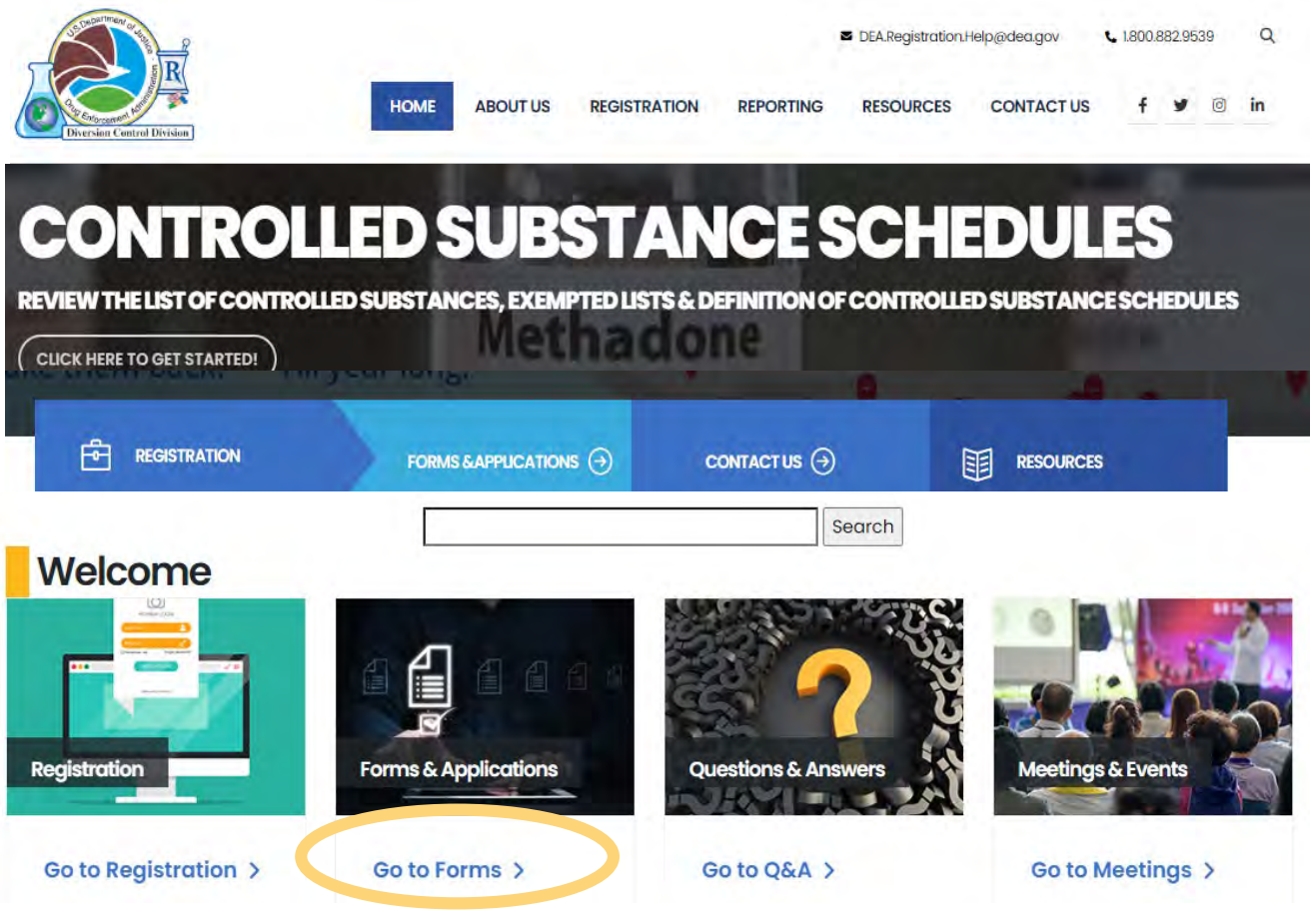
Name of LTCF Address, City, State, Zip Code

I certify that the foregoing information is correct to the best of my knowledge and belief.

Sign and Print Name Title Date

DO NOT use this form to correct minor inventory shortages.

Reporting Theft and Loss DEA Form 106



www.deaDiversion.usdoj.gov

Disposal of Controlled Substances

21 CFR 1317.40

Registrants authorized to collect and authorized collection activities

- Final Rule Published September 9, 2014, in the Federal Register
- Patients now have expanded options to safely and responsibly dispose of unused/unwanted medications – through collection receptacles and mail-back packages
- Establishes “Authorized collectors”
- LTCF may dispose on behalf of resident/former resident in accordance with 1317.80 ONLY.

Collection by registrants shall occur only at the following locations:
(1) Those registered locations of manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that are authorized for collection; and
(2) Long-term care facilities at which registered hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles.

Refer to 21 CFR 1317.75 for guidance on collection receptacle specifications.

Disposal of Controlled Substances

21 CFR 1317.05

Registrants have the option of destroying controlled substances at their registered location provided the destruction method meets the non-retrievable standard 21 CFR 1317.05(a)(1)

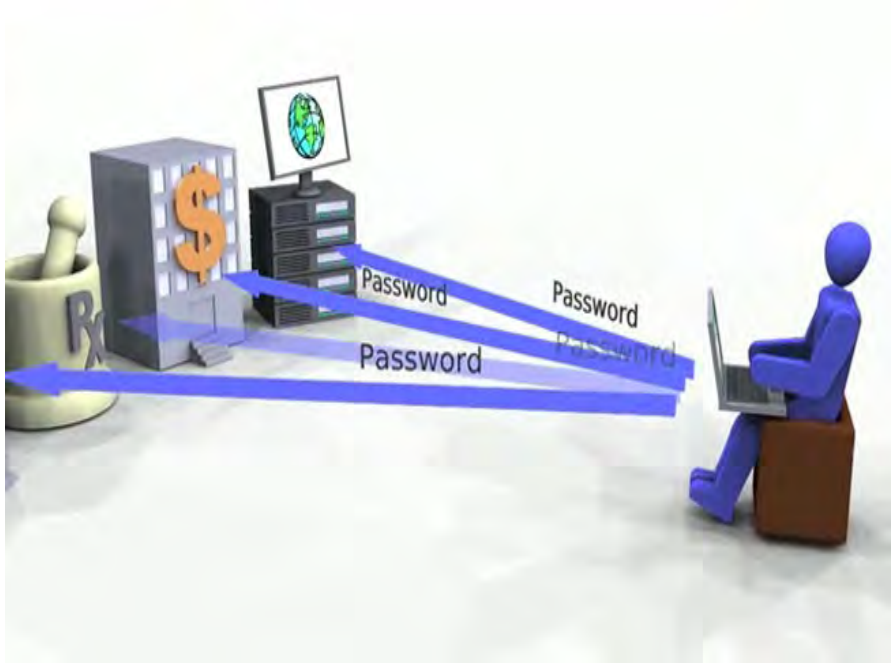
DEA registrants seeking destruction of controlled substances from its inventory should contact a reverse distributor for final destruction 21 CFR 1317.05(a)(2)

DEA is aware that there are companies that claim their products can render controlled substance inventories non-retrievable and claim to have DEA approval…

DEA HAS NOT APPROVED ANY SUCH PRODUCTS FOR THE DISPOSAL OF PRACTITIONER INVENTORY

Review Security

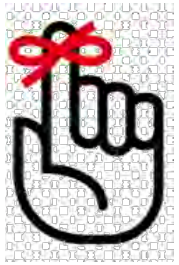
- Safe
- Alarm System
- Camera System
- Access to Controlled Substance List



Reference 21 CFR 1301.71, et al. for guidance on security regulations

Security

Required to **provide effective controls and procedures to guard against theft and diversion** of controlled substances. 21 CFR 1301.71(a)



- If a practitioner maintains a stock of controlled substances at their DEA registered office, the controlled substances must be stored in a securely locked, substantially constructed cabinet.

21 CFR 1301.75(b)

Other security controls for practitioners

- Registrant **cannot employ anyone who has a felony drug conviction** who will have access to controlled substance, **without** a DEA approved employment waiver. 21 CFR 1301.76(a)

Closing Discussion

- Summary of inspection
- Clarify discrepancies
- Ask questions

Legal Recourses

Administrative

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

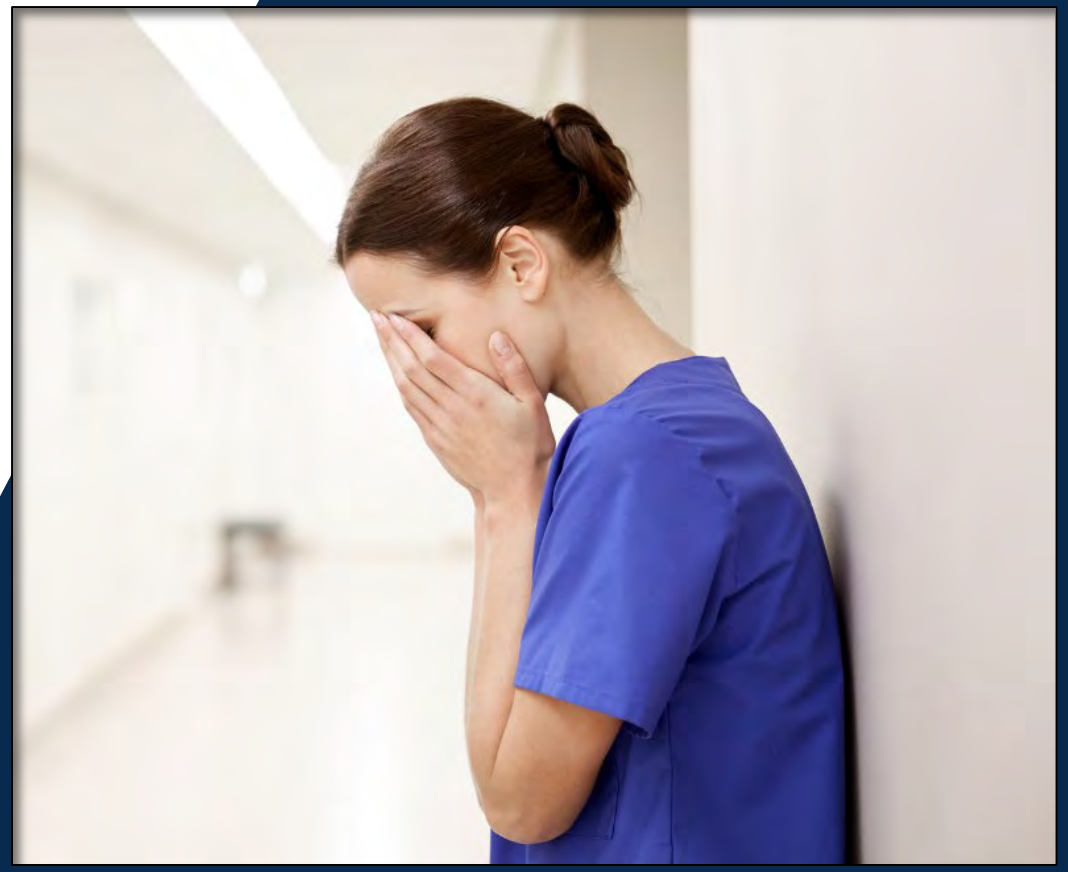
Civil

- Fines

Criminal

- Consent Decree
- Arrest/Prosecution
- Criminal fines

Drug diversion can occur anywhere controlled substances are located, but many incidents occur in healthcare settings by healthcare workers due to availability and access.



RECOMMENDATIONS

- **Conduct mandatory training to include:**

  Duty to report loss or suspected misuse or abuse

  The signs of substance abuse

- **Take complaints seriously, do follow up**

- **Have a progressive discipline policy in place for staff who lose controlled substances or who cannot explain drug count discrepancies, and adhere to it**

- **Regular and surprise hand counted audits**

  Have witness when auditing, change witness

- Whenever possible, include public safety officers when interviewing employees suspected of diversion
- Random urine screens of employees
- **Assign a drug diversion team to rapidly respond and fully investigate incidents**
- Report incidents to the state for tracking
- **Be curious, ask questions, and always watch for ways to improve security and handling of controlled substances**
- Address poor controls (e.g., expired drugs in unlocked areas, not changing passwords, not controlling access to keys)

See Something….Say Something!

- Poor judgment
- Poor/fraudulent documentation
- Erratic performance and suspicious excuses for poor performance
- Change in personality, appearance, or demeanor
- Always offering to help others, coming in early to “lend a hand”
- Overly concerned with helping patients “stay ahead of the pain”
- Patients complaining of unrelieved pain
- Signs of tampering (e.g., holes in packaging, re-glued packages)
- Scheduling issues (e.g., always late, unusual arrival/departure times, LOTS of OT)
- Prolonged or frequent bathroom breaks
- Strange wasting patterns
- Frequent withdrawal of larger doses than needed
- Pattern of removal or wasting near the end of a shift
- Hanging around med rooms, following people in/out
- Life changes (e.g., financial, divorce)
- Illness/injury
- Seeking access to EMR/ prescription pads

Risks: Is it worth it?

Corporate Risks:

- **Risk of civil fine exposure**
- **Risk of civil lawsuits by patients and family members**
- **Risk of lawsuit for fraudulent charges (when charts were falsified and patient and insurance were billed)**
- **Risk of bad publicity: name of hospitals in newspaper**

Risks: Is it worth it?

Individual Risks:

- **Risk of criminal charges**
- **Risk of civil lawsuits by patients and family members (malpractice)**
- **Risk of losing job**
- **Risk of losing state/federal licenses**
- **Risk of bad publicity: ruin your reputation**
- **Risk of addiction/overdose/death**

In Conclusion

No single approach will mitigate all risks of diversion.

A multi-layered approach that addresses processes, practices, culture, security and strategy is recommended.

DIVERSION RESOURCES

Conference Materials And Resources

Questions & Answers

Publications & Manuals

DEA Diversion

DIVERSION CONTROL

Comments / Questions?

ODLL@dea.gov

THANK YOU !!