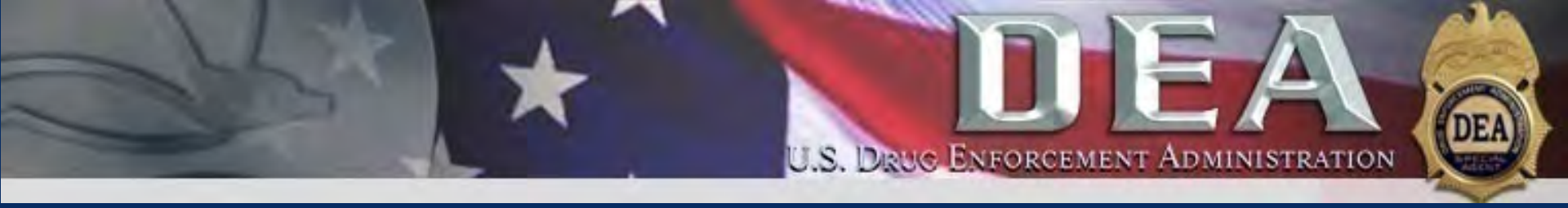


# *Practitioner Diversion Awareness Conference*

## Inventories, Records and Reports

Lynnette Wingert, Unit Chief
Policy Unit

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

fsmb
FEDERATION OF STATE MEDICAL BOARDS

# LEGAL DISCLAIMER

**The following presentation was accompanied by an oral presentation on August 6 & bb7, 2018, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. I have no financial relationships to disclose.**

# Fair Use Act Disclaimer

This presentation is for educational purposes only. This presentation may not be further copied or used, with the embedded images and videos, without an independent analysis of the application of the Fair Use doctrine.

**Fair Use**

Under section 107 of the Copyright Act of 1976, allowance is made for "Fair Use" for purposes such as criticism, comment, news reporting, teaching, scholarship, education and research.

Fair Use is a use permitted by the copyright statute that might otherwise be infringing. Any potentially copyrighted material used in this presentation has been reviewed and found to be used in a manner consistent with Fair Use. A completed Fair Use checklist is attached.

# Course Objectives

- Discuss who is responsible for maintaining controlled substance records.
- General recordkeeping requirements.
- Basic inventory requirements.
- Required records of receipt and distribution.
- Determine when and what reports are required to be submitted.

# Questions To Discuss

**At the completion of this block of instruction you will be able to answer the following questions:**

1. **Practitioners are required to keep records of all controlled substances on hand, to include samples such as Lyrica®?**

2. **Who is ultimately responsible for keeping records of controlled substances at the registered location?**

# Questions To Discuss

3. If a practitioner writes controlled substance prescriptions, using their special “x” identifier for maintenance and detoxification they must keep a record of the prescription information?

4. How many controlled substances can a practitioner distribute in a calendar year to other dispensers before the practitioner must register as a distributor?

5. If a practitioner discovers a theft or significant loss of controlled substances, when must the theft or loss be reported?

# Who Must Keep Records

- **A practitioner who administers, dispenses, procures, or stores controlled substances (including samples).**
  **21 CFR § 1304.03(b)**

**A practitioner is not required to keep records of controlled substances that are:**

- **prescribed unless:**

# Who Must Keep Records

- using EPCS to issue prescriptions

  21 CFR § 1304.03(c)

**or**

- prescribing during the course of **maintenance or detoxification treatment.**

  21 CFR § 1304.03(c) & (d)

# Responsible Party

21 CFR § 1304.03(a)

**The DEA registrant is the person who is responsible for keeping controlled substance records.**

- Not your nurse
- Not your office manager
- Not your corporation
- Not your vendor
- Not your employer

# EPCS PRESCRIBERS

**A practitioner who issues electronic prescriptions for controlled substances (EPCS) must use an electronic prescription application that retains the following information:**

# EPCS Prescribers

- **The digitally signed record of the information specified in 21 C.F.R. Part 1306.**
  **21 C.F.R. 1304.06(a)(1)**

- **The internal audit trail and any auditable event identified by the internal audit as required by 21 C.F.R. § 1311.150.**
  **21 C.F.R. 1304.06(a)(2)**

# EPCS Prescribers

- **An institutional practitioner must retain a record of identity proofing and issuance of the two-factor authentication credential, where applicable, as required by 21 C.F.R. § 1311.110.**
  **21 C.F.R. 1304.06(b)**

- **Must retain a copy of any security incident report filed with the Administration pursuant to 21 C.F.R § 1311.150 and § 1311.215.**
  **21 C.F.R. § 1304.06(d)**

# EPCS Prescribers

- An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by 21 C.F.R § 1311.300.
  21 C.F.R. § 1304.06(e)

- An application provider must retain a copy of any notification to the Administration regarding an adverse audit or certification report filed with the Administration on problems identified by the third-party audit or certification as required by 21 C.F.R. § 1311.300.
  21 C.F.R. 1304.06(f)

# EPCS Prescribers

- **Unless otherwise specified, records and reports must be retained for two years.**
  **21 C.F.R. § 1304.06(g)**

# Maintenance and Detox Prescribers

- **Prescription records are required for prescribers who issue controlled substance prescriptions for maintenance or detoxification.**
  **21 C.F.R. § 1304.03(c)**

- **Records of prescription information must be maintained separate from all other required records and readily retrievable.**
  **21 C.F.R. § 1304.04(g)**

# Maintenance and Detox Prescribers

- **Practitioners who dispense controlled substances for maintenance and/or detoxification must maintain the same records as any other dispensing practitioner.**
  **21 C.F.R. § 1304.22(c)**

# General Recordkeeping

# General Record Keeping Requirements

**Requirements that apply to all controlled substance records required to be kept:**

- **Must be complete and accurate.**
  **21 C.F.R. § 1304.21(a)**
- **Must be stored at the registered location.**
  **21 C.F.R. § 1304.21(b)**
- **Must be kept for two years.**
  **21 C.F.R. § 1304.04(a)**

# General Record Keeping Requirements

- **Must be readily retrievable.**
  **21 C.F.R. § 1304.04(f)(2)**

- **Records must be kept for each separate DEA registered activity.**
  **21 C.F.R. § 1304.21(c)**

- **Must be kept for each DEA registered location.**
  **21 C.F.R. § 1304.21(b)**

# Inventories

# Inventory Requirements

- **Is a “Physical Count”**
- **Must include all controlled substances “On Hand” (In possession/under the control of). (21 CFR §1304.11(a)**

# Inventory Requirements

- **Inventory date must reflect the date of the actual inventory.**

- **Maintained in Written, Typewritten, or Printed Form at the Registered Location.**
  **21 C.F.R. § 1304.11(a)**

# Separate Inventories

- **Separate inventories are required for each registered location.**
  **21 C.F.R. § 1304.11(a)**

- **Must be taken at the Beginning of Business (BOB) or Close of Business (COB).**
  **21 C.F.R. § 1304.11(a)**

- **Separate inventories for each independent activity.**
  **21 C.F.R. § 1304.11(a)**

# Initial Inventories

- Inventory of all stocks of controlled substances.
- On the date you first engage in the manufacture, distribution, or dispensing of controlled substances.
- Best if labeled “Initial Inventory.”
- If nothing on hand record “0.”

# Biennial Inventories

- The biennial inventory is required to be taken on any date within two years of a previous required inventory.
- Best if labeled “Biennial Inventory.”

# Newly Scheduled Controlled Substances

- When a controlled substance is newly scheduled or rescheduled a physical inventory must be taken immediately.
- Must be taken at the Beginning of Business or Close of Business.

# Each Inventory must contain the following:

1. Taken at the beginning or close of business.
2. Names of controlled substances.
3. Each finished form of substances (e.g. 100 milligram tablet)
4. The number of dosage units of each finished form in the commercial container (e.g. 100 tablet bottle
5. The number of commercial containers of each finished form (e.g. four 100 tablet bottles)
6. Disposition of the controlled substances

# Records

# Separate Schedule II Records

- **Schedule II controlled substance records shall be maintained separately from all other records.**

# Separate Schedule III-V Records

- **Records of schedules III-V controlled substances must be kept separate from all other records or readily retrievable.**

- **Records that are readily retrievable can be separated out in a reasonable time.**
  **21 C.F.R. § 1300.03**

# Separate Schedule III-V Records

- **Some examples of ways to render your records readily retrievable include but not limited to:**
  **21 C.F.R. § 1300.01**
  - **Items asterisk**
  - **Redlined**
  - **Or in some manner which sets them visually apart.**

# DEA Form 222

- The DEA Form 222 is used for the acquisition and distribution of schedule II controlled substances.
- The DEA Form 222 must be filled out completely and accurately.
- Power of Attorney authorizing who may execute a DEA Form 222.

# Power Of Attorney

- **The signer of the DEA application or renewal is the individual authorized to execute DEA Form 222's.**

- **All others authorized who wish to execute a DEA Form 222 must first obtain a Power of Attorney from the signer.**

# Purchase Records CIII-CV

- Must immediately inventory all schedule III-V controlled substances when received.
- Annotate the date received on the record of receipt.

# Dispensing Log/Patient File

**Dispensing of controlled substances can be entered in patient chart or can be maintain in a dispensing log with the below information:**

- **Actual Name of Controlled Substance, Form, Quantity, Strength;**
- **Number of Units or Volume of Finished Form Dispensed;**
- **Name, Address of the Person to Whom It Was Dispensed;**
- **Date of Dispensing.**

# Transferring Controlled Substances

**What to do if you need to transfer controlled substances to another DEA Registrant.**

- **Must use a DEA Form 222 (CII).**
  **21 CFR 1307.11(a)(1)(iii)**

- **Must use a sales invoice for (CIII-CV).**
  **21 CFR 1307.11(a)(1)(ii)**

# Transferring Controlled Substances

- 5% of your yearly total.
  21 CFR 1307.11(a)(1)(iv)

- If more you must register as a distributor.
  21 CFR 1307.11(b)

# Reports

# Theft and Loss

- **Theft, or Significant Loss.**
- **Not an Inventory Adjustment.**
- **Loss (Unexplained Disappearance).**
- **Any discovered shortage which the practitioner cannot convincingly establish to have been diverted after reasonable review/investigation should generally be considered a loss.**

# Theft and Loss Reporting

- **Must report a theft or significant loss to DEA in writing within one business day.**
  **21 C.F.R. § 1301.76(b)**

- **Must complete a DEA form 106, online, once your investigation is complete.**
  **21 C.F.R. § 1301.76(b)**

- **Registrants are encouraged to immediately report theft and losses to your local law enforcement and state regulatory agency.**

# Destruction of Controlled Substances

- **DEA Form 41 shall be used to record the destruction of all controlled substances using an on-site method that renders the controlled substances non-retrievable.**

- **DEA Form 41 shall include the names and signatures of the two employees who witnessed the destruction.**
  **21 CFR § 1317.95(d)**

# Destruction of Controlled Substances

- **The DEA Form 41 no longer needs to be sent to the Division Office, maintain with your other records.**

# Destruction of Controlled Substances

**Exceptions for DEA Form 41:**

- **Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a Form 41.**
  **21 C.F.R. § 1304.21(e)**

# Destruction of Controlled Substances

**Exceptions for DEA Form 41:**

- **Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record need not be maintained on a Form 41.**
  **21 C.F.R. § 1304.22(e)**

# Security

- **Registrants are required to provide effective controls and procedures to guard against theft and diversion of controlled substances.**
  **21 C.F.R. § 1301.71(a)**

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

# Security

- **Practitioners are required to store stocks of CII-CV controlled substances in a securely locked, substantially constructed cabinet.**
  **21 C.F.R. 1301.75(b)**

# State Regulations

- Also consult your state regulating agency for more strict recordkeeping requirements.
- Example - some state boards require records be kept for 7 years.
- Stricter Law Provision.

# Post Questions

1. Practitioners are required to keep records of all controlled substances on hand, to include samples such as Lyrica®?

   A. True
   B. False

# Post Questions

2. **Who is ultimately responsible for keeping records of controlled substances at the registered location?**

   A. **Licensed Practical Nurse**
   B. **Office Manager**
   C. **DEA Registrant**
   D. **Corporation**

# Post Questions

3. If a practitioner writes controlled substance prescriptions, using their special “x” identifier for maintenance and detoxification they must keep a record of the **prescription information**?

   A. True
   B. False

# Post Questions

4. How many controlled substances can a practitioner distribute in a calendar year to other dispensers before the practitioner must register as a distributor?

   A. 40%
   B. 20%
   C. 60%
   D. 5%

# Post Questions

5. If a practitioner discovers a theft or significant loss of controlled substances, when must the theft or loss be reported?

   A. On a DEA Form 106 upon completion of the investigation of the theft or loss.
   B. In writing to DEA within 1 business day of discovery of the theft and loss.
   C. DEA must be notified upon completion of the local police departments investigations.
   D. DEA is not required to be notified.

# *Thank-you for your time and attention!*