



Practitioner Diversion Awareness Conference

Inventories, Records and Reports

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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. Are Practitioners 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

- q A practitioner who administers, dispenses, procures, or stores controlled substances (including samples).

21 CFR § 1304.03(b)

- q A practitioner is not required to keep records of controlled substances that are:
 - q prescribed **unless:**



Who Must Keep Records

q using EPCS to issue prescriptions

21 CFR § 1304.03(c)

or

q 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 and 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!*

