# Records, Inventories, and Reports

## Who must keep records?

- A practitioner who handles controlled substances, other than prescriptions (21 CFR § 1304.03(b))—except electronic prescribing of controlled substances (EPCS) prescriptions (21 CFR § 1304.03(c))
- A practitioner who prescribes an FDA-approved CIII-V narcotic controlled substance for opioid maintenance and/or detoxification (21 CFR § 1304.03(c) & (d))

The **DEA registrant** is the person who is responsible for keeping controlled substance records—not a nurse, office manager, corporation, vendor, or employer.

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

## Controlled Substance Records

Schedule II controlled substance records shall be maintained separately from all other 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)
- Some examples of ways to render your records readily retrievable include but not limited to (21 C.F.R. § 1300.01):
  - Items asterisked
  - Redlined
  - Or in some manner which sets them visually apart

Questions regarding records, inventories, and reports:
**Diversion Control Division**
**Liaison and Policy Section**
**(202) 307-7297**

FIND MORE INFORMATION AT WWW.DEADIVERSION.USDOJ.GOV:

*Controlled Substance Schedules*
*Significant Guidance Documents*
*DEA Forms and Applications*
*DEA Laws and Regulations*
*DEA Mailing Addresses*
*Electronic Ordering (CSOS)*
*Electronic Prescribing (EPCS)*
*Sign up for Email Updates*
*Drug Disposal*
*FAQs*
*Meetings and Events*
*Publications and Manuals*
*Registration Support*
*Reporting*

# Records, Inventories, and Reports

## EPCS Prescribers

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

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

## Maintenance and Detox Prescribers

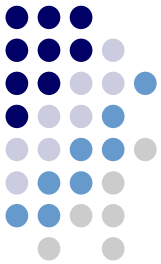
- Prescription records are required for prescribers who issue controlled substance prescriptions for maintenance or detoxification (21 C.F.R. § 1304.03(c))
- Records of prescription information must be maintained separate from all other required records and readily retrievable (21 C.F.R. § 1304.04(g))
- 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))

## Inventories

“Physical Count”

- Must include all controlled substances “on hand” (in possession/under the control of; 21 CFR §1304.11(a))
- 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 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))
- 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”

# Records, Inventories, and Reports



### 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

## 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
- The signer of the DEA application or renewal is the individual authorized to execute DEA Form 222s
- All others authorized who wish to execute a DEA Form 222 must first obtain a Power of Attorney from the signer
- Power of Attorney authorizing who may execute a DEA Form 222

## 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 following 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 for CII (21 CFR 1307.11(a)(1)(iii))
- Must use a sales invoice for CIII-CV (21 CFR 1307.11(a)(1)(ii))
- 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))

# Records, Inventories, and Reports

## Theft and Loss Reporting

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

- 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))
    - Do not use a DEA Form 106 if:
        - You have not previously registered with the DEA;
        - The theft or loss you are reporting is not of a controlled substance; or
        - You want to correct minor inventory shortages
- Registrants are encouraged to immediately report theft and losses to your local law enforcement and state regulatory agency

## Destruction of Controlled Substances

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

- Consult your state regulating agency for stricter recordkeeping requirements (e.g., some state boards require records be kept for 7 years)