



**Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality**

**Module 2  
Controlled Substances Management**




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**Objectives**

At the conclusion of "Module 2: Controlled Substances Management," the learner will be able to:

- Differentiate practices that help improve physical security of the pharmacy from those that increase physical security vulnerability
- Differentiate practices that help prevent theft of medication from the pharmacy by pharmacy staff or store employees from those practices that may increase vulnerability to employee theft
- Recall four Federal controlled substances inventory requirements

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**Self-Audit Process**

Use of the self-audit process allows pharmacy staff to:

- Evaluate daily practices
- Pinpoint audit triggers
- Address vulnerabilities



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## Controlled Substances Self-Audit

### Materials

- Licenses—pharmacist, intern, and technician
- Pre-hire screening and background check materials
- U.S. Drug Enforcement Administration (DEA) Forms 106 and 222
- Reverse distributor records
- Spare key logs
- Security camera and surveillance maintenance logs
- Controlled substance inventory records
- Law enforcement or State pharmacy board alerts

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## Hiring Pharmacy Employees

- Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE)
- Criminal background check
- National Association of Boards of Pharmacy (NABP) disciplinary clearinghouse
- Financial background check

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## Internal Diversion Cases

- Detected by surveillance
- Personal belongings
- Trash containers



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### Minimize Internal Diversion Schemes

- Prohibit storage of personal belongings in the pharmacy and conduct bag checks
- Require box breakdown inside the pharmacy
- Dispose of all regular pharmacy trash in clear bags
- Store all waste in secured trash bins
- Return unwanted filled prescription medications to stock in a timely manner
- Account for outdated drug inventory until removed from the premises

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### Controlled Substance Inventory Management

- Schedule II perpetual inventory
- Random counts Schedule III, IV, V
- Document!



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### Federal Physical Controlled Substance Inventory Requirements

- Conduct every 2 years
- Perform at beginning or close of business
- Keep for 2 years
- Verify inventory requirements

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## Theft or Loss of Controlled Substances

How is theft or loss reported?

- Use DEA Form 106, Report of Theft or Loss of Controlled Substances
- Keep for 2 years



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## Pharmacist-in-Charge Responsibilities

- Staff licensure accountability
- Change in pharmacist-in-charge (PIC) inventory
- Compliance with Federal and State laws
- Claims billing accuracy

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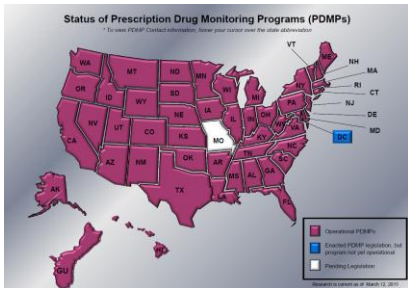
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## Prescription Drug Monitoring Programs



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## Lock-In Programs

- Single pharmacy
- Single prescriber
- Single pharmacy and single prescriber

Do not bill for cash at patient request if the patient is locked in to any pharmacy.



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## Physical Security

- Restrict pharmacy access
- Assign unique security alarm code for each pharmacist
- Examine security logs
- Create only pharmacy keys that clearly state, "Do not duplicate"
- Place any spare pharmacy key inside a tamper-evident container within a locked safe outside of the pharmacy
- Use a key log
- Re-key the pharmacy in the event of a security breach

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## Communications

- Maintain a list with current contact information
- Retain all communications received from outside providers
- Maintain one convenient "go-to" place to retrieve this information
- Ask pharmacy staff to review and initial after reading notices daily

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**Knowledge Check**

Carefully read each statement. Answer false if the practice does not help manage physical security, otherwise answer true.

1. Restrict pharmacy access to authorized pharmacy personnel by key or key code.  
A. True  
B. False
2. Allow guests to visit secure areas of the pharmacy.  
A. True  
B. False

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**Knowledge Check**

3. Place the security code for the pharmacy door on the bulletin board for floating pharmacist access.  
A. True  
B. False
4. Place any spare pharmacy key inside a container within a locked safe outside of the pharmacy and affix a tamper-evident seal to the key container.  
A. True  
B. False
5. Do not check the key log on a regular basis. Only perform a key log check if you discover a loss.  
A. True  
B. False

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**Correct Answers**

1. True
2. False
3. False
4. True
5. False

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### Knowledge Check

Carefully read each statement. Answer true if you think the practice listed will help prevent theft of medication from the pharmacy by pharmacy staff or store employees. Answer false if you think the practice will increase vulnerability to employee theft.

1. Allow storage of personal belongings in the pharmacy.
  - A. True
  - B. False
2. Require boxes to be broken down inside the pharmacy.
  - A. True
  - B. False

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### Knowledge Check

3. Dispose of all regular pharmacy trash in clear bags, and store all waste in secured trash bins.
  - A. True
  - B. False
4. Return unclaimed drug inventory to the shelf within 15 days.
  - A. True
  - B. False
5. Account for outdated drugs removed from the pharmacy shelf by inventory of outdates at the time the drug is pulled from the shelf.
  - A. True
  - B. False
6. Store outdated prescription drugs in an open box under a counter within the pharmacy.
  - A. True
  - B. False
7. Use a tamper-evident or resistant receptacle for drugs awaiting transport.
  - A. True
  - B. False

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### Correct Answers

1. False
2. True
3. True
4. False
5. True
6. False
7. True

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## Knowledge Check

Which of the following instructions listed are consistent with Federal controlled substances inventory requirements?

- A. Use electronic Form DEA-106 to report controlled substance theft within 1 week of discovery.
- B. Separate CSA II records (including inventory records) from other controlled and non-controlled records.
- C. Indicate whether the inventory was conducted at the beginning or close of the business day.
- D. Provide an estimated count of CSA Schedule II medications in 100 count bottles.
- E. Count on effective date of rule for controlled substances that have a change in scheduling.
- F. A and D
- G. B, C and E

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## Correct Answer

G: B, C and E

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## Questions



Please direct questions or requests to: [MedicaidProviderEducation@cms.hhs.gov](mailto:MedicaidProviderEducation@cms.hhs.gov)

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