

Controlled Substances Act Compliance for Pharmacies- What to expect at a DEA inspection DPM Dan McCormick – Omaha Field Division

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4. Learning objectives for pharmacists:
 - a. Recite the provisions of the Controlled Substances Act and mandated regulations for pharmacies.
 - b. Discuss the documentation requirements for controlled substance transactions at a pharmacy.
 - c. Summarize a pharmacist's corresponding responsibility when dispensing controlled substances.

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- d. Outline common components of a DEA Inspection at a pharmacy.
- e. Describe examples of the legal actions the DEA may take if a pharmacy is found noncompliant.

5. Learning objectives for pharmacy technicians:

- a. Summarize the basic provisions of the Controlled Substances Act.
- b. Describe the factors or considerations used when placing controlled substances into the respective schedules.
- c. Explain the “Closed System of Distribution” under the framework of the Controlled Substances Act and who must register with the DEA.
- d. List the required components which must be included on a prescription in order for a prescription to be valid.
- e. Give examples of behaviors which may indicate a prescription is fraudulent or was not issued for a legitimate medical purpose.

6. History of Federal Drug Laws in the United States – Controlled Substances Act

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7. The CSA regulates certain drugs—whether they are medical or recreational, legally or illegally distributed—that are considered to pose a risk of abuse and dependence.
 - a. Drug Schedules
 - b. Trafficking Provisions
 - c. Registration Provisions
8. All legitimate handlers of controlled substances must register with the DEA* and maintain a strict accounting for every controlled substance that moves through their system.
9. Controlled Substances Act: protect public health from the dangers of controlled substances while ensuring that patients have access to controlled substances for legitimate medical purposes.
10. In 1973, the Drug Enforcement Administration (DEA) was established and serves as the federal law enforcement agency responsible for enforcing controlled substance laws and regulations of the United States.
11. Two major components of the DEA: Diversion Control Division and Enforcement Division
12. Diversion Control investigates everything related to legitimately used controlled substances and listed chemicals.

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13. Enforcement investigates violators of Schedule I drug laws and clandestinely manufactured pharmaceuticals.
14. Closed System of Distribution
15. 21 CFR Chapter II – Drug Enforcement Administration, Department of Justice
16. Registration Requirements: 21 CFR Parts 1301, 1309, and 1321
17. Ordering Controlled Substances: 21 CFR 1305.03, 1307.11(a)(1)(iii), 1301.52(e)(1)
18. Ordering Controlled Substances: 21 CFR 1304.21(a)(d), 1304.22(c), 1304.22(a)(2),
1304.04(f)(2)
19. Power of Attorney: 21 CFR 1305.05(f)
20. Inventory: 21 CFR 1304.11
21. Recordkeeping Requirements: Must maintain complete, accurate, and current records for every controlled substance purchased, received, sold, stored, distributed, dispensed or otherwise disposed of. 21 CFR 1304.21(a)
22. Prescription Requirements: 21 CFR 1306.05, 1306.22(b)
23. Security: 21 CFR 1301.71(a), 1301.75(b), 1301.76(a)

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24. Theft or Loss – Two Step requirement - Notify their local Field Division Office, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss AND Submit a “Report of Theft or Loss of Controlled Substances,” DEA Form 106, electronically to the agency within 45 days of discovery of a theft or significant loss 21 CFR 1301.74(c) and 1301.76(b)
25. Dispensing and Administration: 21 CFR 1304.22(c)
26. Transferring or Disposing Your Controlled Substances: 21 CFR 1317.05(a)(2)
27. Inspections: The CSA authorizes the DEA to inspect “controlled premises,” where registrants “may lawfully hold, manufacture, distribute, dispense, administer or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.” 21 U.S.C. 880
 - a. Potential Adverse Actions:
 - b. Letter of Admonition
 - c. Memorandum of Agreement
 - d. Civil Fines
 - e. Order to Show Cause

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f. Immediate Suspension Order

28. Criminal Prosecution

29. Drug Diversion: Involves the diversion of drugs from legal and medically necessary uses to uses that are illegal and not medically authorized or necessary

30. Commonly Diverted Drugs:

- a. oxycodone
- b. amphetamine and dextroamphetamine
- c. oxycodone and acetaminophen
- d. diazepam
- e. phenobarbital
- f. alprazolam
- g. methylphenidate
- h. hydrocodone and acetaminophen
- i. alprazolam
- j. promethazine with codeine

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31. Corresponding Responsibility: 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. 21 CFR 1306.04

32. Valid Prescription: 21 CFR 1306.04

33. **“Red Flags” for Pharmacies: This list is not all inclusive or absolute, must exercise due diligence.**

- a. Patient
- b. Prescription
- c. Pharmaceutical or Drug
- d. Practitioner
- e. Payment
- f. PDMP

34. Best Practices

- a. Strong Medication Management
- b. Staff Training

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- c. Audits and Inventory

- d. Securing your medication, Proper storage, Disposal

Omaha Diversion Contact Information

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