

Selected Controlled Substances Laws

Objectives

After reading this lesson, the pharmacist will be able to:

- Describe standards for the mailing of controlled substances
- Describe standards for the destruction of controlled substances
- Describe standards for fax prescriptions for controlled substances
- Describe standards for Nurse Practitioners and controlled substances
- Describe rules for loss and reporting of controlled substances

Introduction

Most pharmacists deal with controlled substances every day. This lesson will review some rules that come up in day to day pharmacy practice. This lesson will not attempt to present all state and federal rules directed to handling controlled substances.

Mailing Controlled Substances

The ability to mail controlled substances can be very helpful in a number of scenarios. A patient may be homebound and unable to physically come to the pharmacy to pick up the medication. Where an agent for the patient cannot be reliably identified by the pharmacist, mailing medication to the patient may be helpful.

The first Postal Service restriction to notice is that it is unlawful to mail a controlled substance that can not otherwise be lawfully distributed. In other words, mailing the controlled substance does not provide an exemption to the general prohibition against distributing controlled substances. This is just common sense. However, if distribution of the controlled substance is otherwise lawful, it may be mailed if:

- a. The inner container of any package containing controlled substances is marked and sealed under the applicable provisions of the Controlled Substances Act (21 USC 801, et seq., and any implementing regulation in 21 CFR 1300, et seq.) and placed in a plain outer mailing container or securely overwrapped in plain paper;
- b. If the mailing includes prescription drugs containing controlled substances, the inner container is also labeled to show the prescription number and the name and address of the pharmacy, practitioner, or other person dispensing the prescription; and
- c. The outer mailing wrapper or container is free of markings that indicate the nature of the contents.

Destruction of Controlled Substances

Undesirable controlled substances must be handled with care. Broken tablets, expired dosage forms, and the like must be disposed of properly. OAC 4729-9-06 provides that any person legally authorized under Chapters 3719 and 4729 of the Revised Code to possess dangerous drugs which are controlled substances may dispose of such drugs by the following procedure. If the person is a registrant or prescriber required to keep records pursuant to Chapters 3719 and 4729 of the Revised Code, the responsible pharmacist or prescriber must send the state board of pharmacy a list of the dangerous

drugs which are controlled substances containing the name and quantity to be disposed of.

If the person is not a registrant or prescriber, the person must submit to the state board of pharmacy a letter stating:

- The name and address of the person possessing the dangerous drugs which are controlled substances to be disposed of;
- The name and quantity of each controlled substance;
- How the applicant obtained the controlled substances; and
- The name, address, and registration number of the person who possessed the controlled substances prior to the applicant, if known.

When the Board receives the list and/or letter, the Board's executive director must authorize and instruct the applicant to dispose of the dangerous drugs which are controlled substances in one of the following manners:

- By transfer to persons registered under Chapters 3719 and 4729 of the Revised Code, and authorized to possess the controlled substances;
- By destruction in the presence of a state board of pharmacy officer, agent, or inspector or other authorized person; or
- By such other means as the state board of pharmacy may determine to assure that the controlled substances do not become available to unauthorized persons.

In the event that a registrant is required regularly to dispose of controlled substances, the executive director may authorize the registrant to dispose of such controlled substances without prior approval of the state board of pharmacy in each instance. The executive director can only do so on the condition that the registrant keep records of such disposals and file periodic reports with the state board of pharmacy summarizing the disposals made by the registrant. In granting such authority, the executive director may place conditions on the disposal of dangerous drugs which are controlled substances. For example, the executive director may specify the method of disposal and the frequency and detail of required reports.

When the pharmacist or pharmacy has controlled substances that need to be disposed of, the controlled substances must be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration. Methods of disposal shall prevent the possession of the drugs by unauthorized persons pursuant to 4729-9-17 (D).

Facsimile Prescriptions for Controlled Substances

Fax machines have become standard equipment in most pharmacies. Fax machines can be time savers when they allow for the exchange of information when the sender and receiver have a difficult time making contact – such as in a busy pharmacy or when a prescriber may want to give information to a pharmacy before the pharmacy is open. One thing that is helpful to keep in mind is that prescriptions for controlled substances must also comply with the requirements for non controlled substances – a.k.a. dangerous drugs.

When the fax machine is used to send a prescription, including a prescription for a controlled substance, the facsimile will only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record. The facsimile must include the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile. The pharmacist must record the prescription in writing or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

The original prescription signed by the prescriber from which the facsimile is produced must not be issued to the patient. Giving the patient the original and faxing the prescription to the pharmacy would, or at least could, result in duplication. This is a particular problem when the medication prescribed and dispensed is a controlled substance. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued. The facsimile of the prescription must include header information identifying the origin of the facsimile.

A little used time-saving provision of the rules provides that a prescription copy, including a copy for a controlled substance, may be transferred between two pharmacists by the use of a facsimile machine. The facsimile may be considered to be a copy of a prescription if all information requirements of 4729-5-24 (A), including invalidation of the original prescription or computer records, are met. A system must be in place that will show on the facsimile positive identification of the transferring and receiving pharmacists which must become a part of the prescription record. Facsimile copies must be recorded in writing or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

(a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code. An original signed prescription for a schedule II controlled substance prepared in accordance with federal and state requirements and issued for a resident in a long term care facility may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription and shall be received and maintained pursuant to rules 4729-5-21 and 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at either the prescriber's office or the long term care facility

(b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule. When the original prescription is a preprinted prescription forms, the original prescription may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to this sheet. However preprinted forms may not

contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber. See rule 4729-5-14 of the Administrative Code.

(c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code. Sterile product prescriptions must meet the requirements of rule 4729-5-30 of the Administrative Code, except that a sterile product prescription prepared in accordance with federal and state requirements that is for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile will serve as the original written prescription and shall be received and maintained pursuant to rules 4729-5-21 and 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent is not be considered a valid prescription. The facsimile of the prescription must include header information identifying the origin of the facsimile.

Nurse Practitioners

In order to prescribe drugs, including controlled substances, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner [collectively "nurse practitioner"] seeking authority to prescribe drugs and therapeutic devices shall file with the board of nursing a written application for a certificate to prescribe. The board of nursing will issue a certificate to prescribe to each applicant who meets the legal requirements.

The nurse practitioner can only prescribe any drug or therapeutic device that is included in the types of drugs and devices listed on the established formulary. The established formulary can be found on line at the State of Ohio Board of Nursing at: <http://www.nursing.ohio.gov/PDFS/AdvPractice/CTPFormularyOct06.pdf>. The established formulary includes medications that the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may initiate as well as those medications that must be initiated by a physician. The nurse practitioner may not prescribe Amphetamines, such as Methylphenidate. The nurse practitioner may prescribe controlled substances, however, the nurse's prescriptive authority shall not exceed the prescriptive authority of the collaborating physician or podiatrist. The nurse practitioner may personally furnish only antibiotics, antifungals, scabicides, contraceptives, and prenatal vitamins – and not controlled substances.

The nurse practitioner may prescribe a schedule II controlled substance but may not prescribe a schedule II controlled substance in collaboration with a podiatrist. The nurse practitioner may prescribe a schedule II controlled substance only in situations where all of the following apply:

(1) A patient has a terminal condition;

- (2) The nurse's collaborating physician initially prescribed the substance for the patient; and
- (3) The prescription is for a quantity that does not exceed the amount necessary for the patient's use in a single, twenty-four hour period.

Report of theft or loss of dangerous drugs, controlled substances, and drug documents
Rule 4729-9-15

Unfortunately, dangerous drugs, including controlled substances do come up missing from time to time. Each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs must notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance. This includes dangerous drugs in transit that were either shipped from or to the prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs.

The Board must be notified by telephone immediately upon discovery of the theft or significant loss. The term "significant loss" is not clearly defined by the Board. The following may be helpful in clarifying "significant loss:"

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
- (5) Whether the specific controlled substances are likely candidates for diversion; and
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

If a controlled substance is stolen or lost, the drug enforcement administration (DEA) must also be notified. See 21 CFR Part 1301. The DEA registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the state board of pharmacy within thirty days following the discovery of such theft or loss. A request for a waiver of the thirty-day limit must be requested in writing.

When details concerning the specific circumstances surrounding the theft or loss are unknown at the time of discovery, DEA recommends initial notice be provided by faxing a short statement to DEA advising of the theft or significant loss. While such initial notice may alternatively be mailed, delays occurring due to the mailing process may hinder investigative efforts by DEA. The DEA Form 106 must document the circumstances of the theft or significant loss and the quantities of controlled substances involved. DEA recognizes that some time may elapse between the time initial notice of a theft or loss is provided and the conclusion of the investigation. DEA suggests that if an

investigation takes more than two months to complete, registrants provide updates regarding the investigation to DEA.

The Controlled Substances Act (CSA) requires “every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of ...” (21 U.S.C. 827(a)(3)). No registrant should disregard any unexplained shortage of controlled substances. Registrants should treat an individual theft or significant loss seriously and should monitor occurrences so that patterns do not remain undetected. Record keeping must be accurate and complete so as to serve as a reliable reporting and recording device.

DEA has become aware of instances in which registrants have used a DEA Form 106 to document minor inventory discrepancies, thereby “balancing the books.” DEA stresses that the DEA Form 106 should be used only to document thefts or significant losses of controlled substances. Minor inventory discrepancies, not attributable to theft, should not be reported to DEA or recorded on a DEA Form 106. Rather, registrants should make appropriate notations of minor inventory discrepancies in their records, indicating the amount of variance between the physical count and the amount accounted for through records. Such discrepancies need not be reported to DEA if they are not significant or actual losses. If a registrant is unsure of the significance of a loss after considering the factors described below, the registrant should file the report.

Law enforcement authorities must also be notified pursuant to section 2921.22 of the Revised Code. Revised Code section 2921.22 provides that, among other things, no person, knowing that a felony has been or is being committed, shall knowingly fail to report such information to law enforcement authorities.

Conclusion

The distribution of controlled substances is highly regulated. This lesson has not presented all the controlled substances regulations implicated in daily pharmacy practice. Instead, the standards for mailing, destruction, faxing, loss reporting, and nurse practitioners have been presented.

Questions

1. Mailing controlled substances is only legal if it is the only way to get a medication to the patient.
a. True b. false
2. The outer mailing wrapper or container for the controlled substances must clearly indicate the nature of the contents.
a. True b. false
3. When the pharmacist or pharmacy has controlled substances that need to be disposed of, the controlled substances must be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.
a. True b. false
4. Methods of disposal of controlled substances may allow for destruction in the presence of a state board of pharmacy officer.
a. True b. false
5. A facsimile for a prescription drug must include the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.
a. True b. false
6. The pharmacist must record the prescription in writing or store the facsimile copy in such a manner that will allow retention of the prescription record for four years from the date of the last transaction.
a. True b. false
7. A prescription copy, including a copy for a controlled substance, may be transferred between two pharmacists by the use of a facsimile machine.
a. True b. false
8. A nurse practitioner may prescribe a schedule II controlled substance in collaboration with a podiatrist.
a. True b. false
9. Thefts of controlled substances must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.
a. True b. false
10. DEA Form 106 should be used only to document thefts or significant losses of controlled substances.
a. True b. false

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 Pharmacy

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Answer Sheet – circle the one correct best answer

Question	Answer	Question	Answer
1	True False	6	True False
2	True False	7	True False
3	True False	8	True False
4	True False	9	True False
5	True False	10	True False

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Please fax, e-mail, or mail [specify one, please] my continuing education certificate to:

Pharmacist Name _____

Street Address _____

City _____ State _____ Zip _____

E-Mail _____

Phone _____

Ohio Pharmacist License Number _____

- Yes, Please e-mail me your **free** pharmacy law newsletter
- No, Do not e-mail me your **free** pharmacy law newsletter

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Suggestions for Future Topics: _____

Approximately How many minutes were required to complete this lesson? _____

What could be done to make presentation of this material clearer?

