

DEA In a Community Pharmacy Part 1

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Universal Program Numbers:

406-000-08-007-H03P & 406-000-08-007-H03T

The expiration date for this program is 1/31/10.



PLEASE NOTE:

This program does not purport to include all that the DEA may require of pharmacy registrants or pharmacists. Users of this program are reminded that DEA pharmacy registrants are solely responsible for ensuring compliance with DEA regulatory requirements, and that the responsibility for compliance cannot be abdicated or transferred to anyone else. The contents of this program are for educational purposes only. The contents do not constitute or are they offered as legal advice or counsel or as representing official DEA positions or opinions. Only the DEA, or a court, can provide an official position or opinion.

Goals and Objectives

Goals: To provide the pharmacist with current information on what the Drug Enforcement Administration (DEA) generally requires as compliance with the Controlled Substances Act.

Objectives: After completing this article, the pharmacist should be able to:

1. Summarize pharmacist liability when dispensing prescriptions for controlled substances;
2. Recall the three steps the DEA recommends that a pharmacist undertake if confronted with a questionable prescription for a controlled substance;
3. Discuss DEA handling and record-keeping requirements when ordering, receiving, and storing controlled substances in a pharmacy, in situations involving—
 - Schedule II controlled substance, and
 - Schedule III to V controlled substances,
4. Describe DEA's periodic inventory requirements.
5. Describe DEA requirements for Schedule II prescriptions including—
 - How they may be received and required information,
 - Refills, emergency dispensing, partial filling, facsimile prescriptions, and
 - Prescription record requirements;
6. Describe DEA requirements for Schedule III to V prescriptions including—
 - How they may be received and required information
 - Refills and authorized quantities, and
 - Prescription record requirements;
7. Discuss the basis, procedures, and limitations for partial dispensing of Schedule II controlled substances to terminally ill or long-term care facility residents;
8. Recall two examples of when a pharmacy distributes (rather than dispenses) a controlled substance
9. Explain what a pharmacy must do if it distributes more than 5% of the total number of controlled substance dosage units (instead of dispensing).
10. Recall DEA reporting requirements when there is a theft of controlled substances, when a pharmacy does not receive a written, signed Schedule II prescription within 7 days;
11. Describe DEA security requirements and recommendations for storing and handling controlled substances;
12. List what actions the DEA can take against a pharmacy
13. Describe how the DEA generally conducts a pharmacy audit in terms of what records are typically examined and the meaning of "readily retrievable"; and
14. Describe what is meant by a DEA-type accountability test.

There is a long list of requirements for handling controlled substances in a community pharmacy. The foregoing are the most important.

Federal Regulation of Controlled Substances

Federal control of legitimately-produced controlled substances is based on the Controlled Substances Act (CSA) of 1970. The CSA was the basis for the establishment of the Drug Enforcement Administration (DEA) as the federal agency responsible for enforcing the Act.

In order to align enforcement with federal requirements, most states (48) have adopted the **Uniform Controlled Substances Act (UCSA)**. Although the CSA and various UCSAs are in substantial agreement, individual states have additional requirements. If a state requirement conflicts with the federal requirement, the federal requirement takes precedent. If a state requirement is more stringent, it supersedes the federal act. For example, the CSA requires certain records be kept for two years, while a state may require four years. In such situations, four years is the requirement for the state.

The CSA authorizes the Drug Enforcement Administration (DEA) to enforce regulatory requirements for registered handlers of controlled substances, including pharmacies as part of a closed system. The dual goals of the DEA are to prevent the diversion of controlled substances into illicit markets (and for illicit purposes), and to ensure that controlled substances are available for legitimate medical needs.

The regulations that implement the CSA affect every aspect of controlled substances—

- Manufacturing,
- Packaging,
- Prepackaging,
- Distributing,
- Storing,
- Ordering,
- Receiving,
- Prescribing,
- Compounding,
- Dispensing, and
- Transporting.

CSA regulations apply also to samples, drug recalls, returns, and disposal of controlled substances. CSA requirements are in effect irrespective of whether payments or other consideration is involved in handling controlled substances.

Because of the amount of controlled substances handled by pharmacists (especially community pharmacies, which include long-term care and Internet pharmacies), the DEA focuses major attention on pharmacies in order to ensure that pharmacists are

complying with handling and record-keeping requirements.

Dispensing Responsibility and Corresponding Liability

Both federal and state laws require pharmacists to exercise vigilance over controlled substance inventories and prescriptions. DEA pharmacy registrants are required to —

- Keep accurate inventories and records;
- Identify suspicious patients and prescriptions;
- Assess the medical legitimacy of controlled substance prescriptions;
- Report prescriptions that do not comply with the law; and
- Report the theft or significant loss of controlled substances on official order forms.

An important principle of DEA oversight is the following: controlled substance prescriptions may be issued only for legitimate medical purposes by medical practitioners acting in the course of their professional practice. This is a very important statement and means that a physician cannot write a prescription to obtain controlled substances to be used as office supplies, or write a prescription in order to supply controlled substances for illicit purposes, or to treat or maintain an addict. Such orders are not prescriptions under the CSA and cannot be accepted as controlled substance prescriptions.

The responsibility for proper prescribing initially rests with the prescriber. **But**, there is a corresponding liability on the part of pharmacists who fill controlled substances prescriptions that do not conform to DEA regulatory requirements, i.e., if they are not for legitimate medical purposes. The corresponding liability implies efforts to ensure that controlled substance prescriptions are issued by currently-registered medical practitioners acting within the course of their medical practices for legitimate medical purposes.

If pharmacists knowingly dispense prescriptions for controlled substances, which are not for legitimate medical purposes, they can face civil and criminal penalties. The CSA does not apply just to the pharmacy; it is important to every pharmacist who handles controlled substances in the course of his/her practice.

What to Do If Confronted with a Questionable Prescription?

The CSA does not require pharmacists to practice medicine or judge legitimate versus illegitimate medical practices. However, the DEA in the course of interpreting corresponding liability recommends that pharmacists take three steps when confronted with questionable or suspicious prescriptions for controlled substances:

1. Examine the prescription for face validity;
2. Contact the prescriber directly to verify the prescription and patient if the medical practitioner is not known; and
3. Talk directly to, and identify, the patient.

If a pharmacist determines, or has reason to believe, that a prescription written for a controlled substance is not for legitimate medical need, the DEA maintains that such a “prescription” should **not** be filled. State boards of pharmacy agree!

To avoid what can be very serious liability for the illegal distribution of controlled substances without a prescription—which constitutes a **criminal (felony) violation** of the CSA—pharmacists must be vigilant and act in a good faith belief that such prescriptions are for legitimate medical purposes before dispensing them.

A prescription may **not** be issued in order for a medical practitioner to obtain supplies of controlled substances for direct administration or general dispensing to patients, i.e., as office supplies. However, a pharmacy may distribute controlled substances directly to a medical practitioner without registering as a wholesaler so long as the annual total distributed does not exceed 5% of the total that the pharmacy dispenses.

Schedule II to V controlled substances may be distributed to a medical practitioner in the same manner that a drug wholesaler or manufacturer sells such products to a pharmacy. All procedural and record-keeping requirements apply, and the pharmacy must remember to include such transactions in its records and inventories. To be safe a pharmacy should probably avoid distributing controlled substances in any manner other than through dispensing.

Ordering, Receiving, and Storing Controlled Substances

In order to “handle” controlled substances, a pharmacy must be registered with the DEA (and appropriate state agencies). The registration must be in date to be legitimate. Ordering controlled substances also requires that a pharmacy have authority for each schedule that it wishes to handle Schedules II, III, IV, and V. Handling and record-keeping requirements depend partly on which controlled substance schedule is involved. Schedule II requirements are the most stringent, because they have the highest potential for diversion and abuse.

Schedule II Controlled Substances

Schedule II drugs can be ordered **only** by using DEA Form 222, the official order form, which a pharmacy can obtain in limited quantities only from the DEA. To be valid and proper, DEA Form 222 must be filled out in triplicate using the carboning feature between the three copies. It must be legible, correct, and complete, cannot have erasures, cross-outs, or any

alternations, and be pre-printed with the pharmacy’s name, address, DEA registration number, and schedule “2” and “2N” handling authority.

DEA Form 222 must be dated **and** signed by the person who signed the pharmacy’s DEA registration (or re-registration application), or someone who has a proper power of attorney to execute the form. A power of attorney must be signed by the individual who signed the most recent application for DEA registration (or re-registration) and be stored with the pharmacy’s unused DEA Form 222s.

Copies 1 and 2 (intact) are then sent to a DEA-registered supplier (most often a drug wholesaler, sometimes a manufacturer) for filling. A supplier has 60 days from the date the form is first executed to fill the order, though market dynamics materially shorten the allowed time. Copy 3 is retained by the pharmacy in a secure place on the premises.

Though not a federal requirement (but may be a state requirement), Schedule II orders probably should be received by a pharmacist. The number of packages received (for each line ordered) and the date the packages are received on the pharmacy premises must be recorded in the space provided on copy 3 of DEA Form 222 (the pharmacy’s receiving and file record). No “ditto” marks can be used as convenient short-cuts on DEA Form 222 to record receipt of Schedule II controlled substances. Each line listing an ordered product must be “completed” individually, i.e., number of trade packages received and the date received.

Partial filling of a pharmacy’s executed DEA Form 222 by a supplier is permitted. The pharmacist enters the number of packages actually received (which will be less than the number ordered in the case of a partial filing of a line item) and the date the partial shipment is received at the pharmacy in the space provided on copy 3.

If/when the subsequent order amount (up to the number of packages not supplied earlier) is delivered by the supplier, that quantity (the number of packages received subsequently) is entered with the date received (on the same line as the original receipt notation was made).

Completed copy 3s of DEA Form 222 are to be filed in form number-date sequence in a separate file for two years and be “readily available” for inspection. The corresponding supplier’s original (not a copy or photocopy) invoice must also be kept in the same manner for two years. Both records must remain on the registered premises. The easiest and best way to maintain these files is to attach each supplier invoice (or invoices in the case of partial order filling) to the corresponding DEA Form 222 copy, then file them in DEA numerical order.

In cooperation with the DEA, several wholesalers and distributors have developed a system to

make ordering of Schedule II drugs easier and faster. Each of the systems relies on connecting to the DEA web site, deacon.gov, to get an “electronic signature”. The pharmacy gets a “digital certificate” (essentially a number), which is put into the ordering machine (including interpretive software) supplied by the wholesaler/distributor.

Once installed, the pharmacy orders Schedule II drugs as part of its daily ordering. Schedule II drugs are then printed together to obtain a chronological list of each order (which may then be stapled to the corresponding invoice before filing).

In an effort to improve security and to update a form (Form 222) that is more than 30 years old, the DEA announced that it has developed a new form for ordering Schedule II controlled substances. The DEA plans to eliminate the three-part, carbon-paper form and replace it with a single-copy form.

This single form will thwart counterfeiters. It will have an embedded watermark of the DEA emblem on it. Once the form is filled out, pharmacists will photocopy it for their receiving records. An added security feature is that the copy will display “copy” across the face of it.

Once the new single copy form is adopted, the DEA will phase out the current Form 222. Pharmacy organizations are evaluating the new form in terms of its effectiveness at the present time (until January 8, 2008).

Inventories and records of all controlled substances listed in Schedule II must be maintained separately from all other records of the pharmacy, and prescriptions for such substances must be maintained in a separate prescription file. All Schedule II files must be easily retrievable for inspection.

Because of their importance and interest to regulators, it is very, very important that all Schedule II files be up-to-date, complete, accurate, and easy to locate should a DEA or appropriate state official ask to inspect them.

Schedule III to V Controlled Substances

Inventories and records for Schedule III to V drugs must be maintained separately from all other records of the pharmacy **or** in such form that the information that is required is readily retrievable from the business records of the pharmacy, including a pharmacy computer system. Schedule III to V prescriptions must be kept in a separate file **or** in such form that the information that is required is readily retrievable from the business records of the pharmacy. Such prescriptions are considered “readily retrievable” if, at the time they are initially filed, the face of each prescription is stamped in the lower right corner with a red letter “C” at least 1” in height and filed in sequential number order with Schedule II prescriptions **or** in

sequential number order with prescriptions for non-controlled substances.

However, if a pharmacy uses a computer system (or other electronic record-keeping system) that permits identification by prescription serial number and retrieval of original documents by prescriber’s name, patient’s name, drug dispensed, and date filled, a red 1” C does **not** have to be stamped on the lower right corner of hard-copy Schedule III to V prescriptions.

If a pharmacy registrant has authority to handle Schedules III to V controlled substances, they may be ordered from a DEA-registered supplier in the same manner as other pharmaceuticals. Orders containing Schedules III to V products are received and checked against the supplier’s invoice. The supplier’s invoice must indicate in some manner that a product is a controlled substance.

Supplier invoices for Schedule III to V orders also must be filed in a separate file or be readily retrievable for a period of two years. To be considered “readily retrievable,” they must be easily produced should DEA or state officials ask to see them. Again, only original documents are permitted. Photocopies and computer-generated second copies are not acceptable as receiving documents.

Storing Controlled Substances

Schedule II to V controlled substances should be stored in a securely-locked, substantially-constructed cabinet. An acceptable alternative is for pharmacies to disperse Schedule II, III, IV, and V controlled substances throughout the stock of non-controlled substances in a manner so as to discourage their theft or diversion. Individual state boards of pharmacy have stricter storage requirements. In such cases, follow the stricter requirement. Many pharmacies go well beyond the minimum by storing Schedule II drugs in a safe or vault, which must be kept locked when not in use.

Inventoring Controlled Substances

All controlled substances in the possession and control of a pharmacy must be inventoried, i.e., counted or measured, at least every two years (biennially), but may be done more frequently. “Inventory” **includes** normal stock plus supplier deliveries received onto the premises (but not yet checked in and put away), products (unsaleable or otherwise) waiting to be picked up by the supplier (because they were delivered in error and never signed for or checked in), prescriptions which have been partially filled or filled but which have not been recorded as dispensed to the patient, and drugs in emergency kits at long-term care facilities.

Excluded from “inventory” are controlled substance prescriptions that are still on the premises (awaiting patient pickup or pharmacy delivery) but have already been recorded as having been dispensed and any

controlled substances that have been taken “off the book” (because the supplier has given credit for the returns) and are simply waiting to be shipped back to a supplier or returned goods processor.

The **biennial inventory** form must include the name, address, and DEA registration number of the pharmacy. The pharmacist must note on the biennial inventory record the date the inventory is done, whether the inventory was taken at the opening or close of business, and the identity of the pharmacist(s) who took the inventory. Inventory quantities are to be recorded as trade package multiples, e.g., 1.5 x 100 count bottle, rather than 150. The biennial inventory record must be filed in a separate file for two years (on the registered premises) and be easily retrieved if requested by a DEA or state official.

Special Waivers for Certain Employees

A pharmacy registrant may not employ in a position that allows access to controlled substances anyone who can be **convicted** of a felony (relating to controlled substances) **or** anyone who has had an application for DEA registration **denied, revoked, or suspended for cause** (instead of an administrative, civil, or criminal action). Anyone wishing to hire such a person must first obtain a waiver, e.g., request an exemption, from the DEA before hiring. The DEA looks very closely at all requests for waivers.

Dispensing Schedule II Controlled Substances

Except in cases of medical emergency, Schedule II controlled substance prescriptions must be written and signed by a current DEA-registered practitioner. Some states now allow practitioners other than MDs, ODs, and DDSs to prescribe controlled substances. The DEA allows this practice if the state has promulgated regulations. All Schedule II prescriptions, including those received by provider pharmacies from long-term care facilities, **must** contain certain information when presented for filling, including:

- Date;
- Patient name and address;
- Name, strength, and quantity of controlled substance;
- Directions for use; **and**
- Prescriber name, address, and DEA registration number.

As of December 19, 2007, the DEA ruled that prescribers could write prescriptions for Schedule II drugs in quantities up to 90 days supply. This is a reversal of a November 2004 ruling that held that writing multiple Schedule II prescriptions was the same as refilling the prescription, which is illegal.

The latest ruling allows prescribers to write three prescriptions for a Schedule II analgesic. The first prescription of 30-days is available for immediate filling,

the second 30-day supply may be filled in 30 days and the second 30-day supply may be filling 60 days from the first filling. That way the patient receives three 30-day supplies from one writing. All three prescriptions must be dated on the same day that they are written.

Schedule II prescriptions **cannot** be refilled and must be filed in a separate prescription file that is readily available for inspection. Such prescriptions must be kept on file for two years and stored on the registered premises.

Partial filling of Schedule II prescriptions is allowed. Most often this occurs when the pharmacy does not have enough on hand to fill the entire prescription. If partially filling a Schedule II prescription, the pharmacist must make a note **on the face of the prescription** of the quantity supplied and the date. The remaining portion of the prescription can be supplied to the patient only if done so within 72 hours of the initial dispensing. If the remainder will or cannot be supplied within that time, the pharmacist must contact and inform the prescriber and can no longer dispense any amount at all from that prescription.

If a medical emergency exists, a limited amount of controlled substances can be supplied to a patient **without** a written, signed prescription. The basis for dispensing is an oral authorization from a DEA-registered prescriber. The amount that can be dispensed in this fashion is limited to what is required to meet the medical emergency. To provide an emergency supply of a Schedule II drug on the basis of an oral authorization, the following are necessary:

- The prescriber must determine that the patient requires immediate administration of the drug for proper medical use;
- The prescriber must also decide that there is no appropriate alternative therapy available; **and**
- It is not reasonably possible for the prescriber to provide a written, signed prescription beforehand.

A pharmacist may dispense an emergency supply of a Schedule II drug on the basis of oral authority by a prescriber provided that:

1. The amount or quantity prescribed is limited to what is needed to meet the emergency medical need (for the specific situation, not on the basis of an arbitrary period or amount);
2. The oral order is immediately reduced to writing by the pharmacist and contains all necessary information including prescriber information but not the prescriber’s actual signature;
3. The pharmacist makes a reasonable effort to determine the identity of the prescriber, if previously unknown to the pharmacist;

4. The prescriber delivers a written, signed (original) prescription to the pharmacy within 7 days of its creation date;
5. The face of the written prescription must have the date of the oral-authorized dispensing date and the words “**Authorization for Emergency Dispensing**” written on its face;
6. The pharmacist attaches the written prescription (obtained within 7 days) to the previously written down oral authorization; **and**
7. The pharmacist notifies the local DEA office if the prescriber fails to have a written

prescription delivered to the pharmacy within the proper time period.

Unless prohibited by state regulations, the DEA allows that a prescriber can transmit a Schedule II prescription to a pharmacy via facsimile **if:**

1. The state specifically allows facsimile prescriptions; **and**
2. The original, written, signed prescription is presented to the pharmacy before actual dispensing occurs.