

# DEA In a Community Pharmacy

## Part 2

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### 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.

### Dispensing Schedule III to V Controlled Substances

Schedules III to V prescriptions can be dispensed on the basis of—

1. Written;
2. Oral (if the oral prescription is promptly reduced to writing and contains all necessary information); **or**
3. Facsimile (if the state allows it and it contains all necessary information) authorization.

Some pharmacists are under the mistaken notion that because of pharmacy computers, the DEA no longer requires that oral Schedule III to V prescriptions be reduced to writing when first dispensed. Further, that the DEA allows the information to be entered directly into a pharmacy system and that no physical record need be made. **There is no such exemption!** Every Schedule III to V prescription must have an original physical record that is filed and kept for the required time to meet DEA and state requirements (if they are longer).

However, an oral order may be key entered directly into a pharmacy system, then the information may be printed out as the physical representation of the order, instead of hand-writing or typing out a prescription. Either way, **a hard-copy original is required to be retained.**

Schedules III to V prescriptions may be refilled up to five times within six months of the date they are **written, if and only if** the prescriber authorizes refills. Refill quantities can not exceed the amount originally prescribed, unless the pharmacist contacts the prescriber directly and obtains permission to increase the amount dispensed on refill in cases of travel or location hardship.

If the prescriber wishes to increase the quantity authorized above the original amount, a new prescription is required. For example if the situation were as follows:

Original prescription quantity =	20
Five refills authorized =	5 x 20
Total authorized =	120

If the prescriber later wants the patient to get 150 doses, a new prescription is required that authorizes 150 doses. The 150 doses cannot be dispensed from the original prescription for 15 doses plus five refills, which only authorized a total of 120 dosage units.

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### Terminally-Ill or LTCF Patients

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- A Schedule II prescription written for a patient in a long-term care facility (LTCF) or with a documented terminal illness may be filled in partial quantities, even down to individual doses.
  - If there is any question that the patient is terminally ill, the pharmacist must contact the prescribing practitioner **prior to** filling the prescription partially. Both the practitioner and pharmacists have a corresponding responsibility to ensure that the Schedule II prescription is for a terminally-ill patient.
  - The dispensing pharmacist must record on the prescription whether the patient is “**terminally ill**” or a “**LTCF patient.**” If a pharmacist fills such a prescription partially and fails to make the proper notation, the partial dispensing is considered a violation of the Controlled Substance Act.
  - For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record that is uniformly maintained and readily retrievable for inspection) the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.
  - Before any subsequent partial filling, the pharmacist is to determine whether there is a need for any additional partial fillings.
  - The total of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.
  - Unless terminated sooner by discontinuance of the medication, such prescriptions are valid for 60 days from the date they are issued.
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Prescriptions for Schedules III to V controlled substances are to be filed separately for a period of two years, **or** they may be filed in sequential serial order with non-controlled substance prescriptions, provided that each prescription is clearly identified by marking a red letter “C” of at least 1” height on the lower right hand face of the prescription.

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.

Refills (date, amount, and dispenser’s initials) must be recorded on the back of the original prescription, in a separate patient medication record, **or** a computer information system.

If requested by DEA or state officials, the following information must be readily retrievable by prescription serial number:

1. Name and dose/strength of the controlled substance;
2. Date originally filled and refill dates;
3. Quantity dispensed;
4. Identity of dispensing pharmacist; **and**
5. The total number of refills authorized and used to date.

If a pharmacy uses a computer to store prescription records, the system (by screen or printed, hard copy) must be able to provide the same types of information that is required of manual records.

### **Distribution of Controlled Substances**

A DEA-registered pharmacy may distribute limited amounts of controlled substances to other DEA registrants (without becoming registered as a distributor) by means other than dispensing. Examples of such distributions include:

1. Return of overstock, outdated, or unsaleable inventory to the original supplier;
2. Transfer of unsaleable inventory to a DEA-registered returned goods processor;
3. Drug recalls and market withdrawals; **and**
4. Distribution to another practitioner (pharmacy, prescriber).

DEA Form 222 must be used to distribute Schedule II products in the manner above. In such cases (which the pharmacy “supplies” controlled substances to another registrant), the form is executed by the other party and the pharmacy retains copies 1 (pharmacy copy) and 2 (DEA copy, which is sent at the end of each month to the local DEA office).

A pharmacy may distribute a limited quantity of controlled substances to another practitioner without

being registered separately as a distributor. The other practitioner must be registered with the DEA to dispense or administer the controlled substance being supplied, and the distribution must be recorded in a proper manner by the pharmacy, including the use of DEA Form 222 if a Schedule II drug is involved or by proper invoice if a Schedule III to V product is distributed.

To avoid having to become registered separately as a distributor, the amount of controlled substances distributed by a pharmacy in this manner must not exceed **five percent (5%)** of the total number of dosage units distributed and dispensed by the pharmacy during the **same calendar year**. If during the calendar year, the pharmacy expects to exceed the five percent limitation, it must register with the DEA also as a distributor to avoid violations.

### **DEA Reporting Requirements**

Pharmacy handlers of controlled substances are required to report certain events to their local DEA office. Notification is required when:

1. A prescriber fails to provide a written, signed prescription for an oral, emergency dispensing within 7 days;
2. An executed DEA Form 222 is lost or fails to reach a supplier;
3. Unexecuted DEA Form 222s are lost or stolen;
4. The pharmacy discovers significant loss or any theft of controlled substances (reported on DEA Form 106);
5. The pharmacy wishes to dispose of unsaleable controlled substances (reported on DEA Form 41);
6. Pharmacy wishes to store permitted CSA records off site; and
7. A pharmacist observes a suspicious or fraudulent controlled substance prescription.

The prescribing physician must deliver a written, signed prescription within 7 days after issuing an oral emergency prescription for a Schedule II drug. If this does not occur, the DEA requires that the registrant pharmacy report the deficiency. If the pharmacy reports the failure to obtain a written, signed prescription, there is no violation on the part of the pharmacy. Failure to report means that the pharmacy has in effect dispensed a Schedule II product without a prescription!

CSA regulations require that a pharmacy report the loss of an executed (used) DEA Form 222 or a failure of such a form to reach the supplier. A pharmacy also is required to report the loss or theft of any unused DEA Form 222.

If a pharmacy discovers significant loss of controlled substances, it must report the loss to the DEA. To date, the DEA has not defined what it means by a

significant loss. It is widely understood, however, that it does take much for the DEA to become concerned about diversion and there is less tolerance when Schedule II and narcotics are lost, missing, or unaccounted.

The reporting requirement for theft of controlled substances is unambiguous; therefore, every theft is reportable. Both significant losses and theft of controlled substances are to be reported to the DEA on Form 106.

Though almost non-existent today, some pharmacies still dispose of out-dated or unsaleable controlled substances (rather than return them to a supplier or return goods processor). In such cases, the pharmacy must complete and send in DEA Form 41 beforehand. Also, some states have additional notification and witnessing requirements.

Certain DEA pharmacy records may be stored off site, i.e., not at the registered location, so long as the pharmacy provided written notification to the DEA of its intention to do so at least 14 days ahead of time. No Schedule II records may be stored off site.

### **DEA Investigations and Enforcement Actions**

In order for DEA officials (typically diversion investigators, rather than agents) to enter a DEA-registered pharmacy for official purposes, they must present their credentials and state their purpose. Regulations provide that DEA inspectors must obtain informed consent of the pharmacy or obtain an administrative inspection warrant from a judge or magistrate. As a practical matter and because of the power of the federal government, few if any pharmacies are in a position to resist or refuse a DEA inspection.

Under certain conditions—an initial registration inspection or when dangerous or emergency health conditions exist—the DEA can obtain criminal search warrants. In these situations, the DEA has powers to act quickly and decisively, but rarely does so.

Some states have authorized warrant-less administrative inspections of pharmacies in the absence of informed consent. Most states, however, still limit access to prescription records to a defined few and require pharmacists to ensure that the consumer's right to privacy is not violated. In such cases, the board of pharmacy has the right to inspect for regulatory compliance.

The DEA has a number of actions it can take against a pharmacy held in violation of CSA requirements. These include —

- ◆ Administrative,
- ◆ Civil, and
- ◆ Criminal

—and range from official letters citing the violations to fines and legal actions.

A common result of a DEA audit is for the pharmacy to receive an official letter from the DEA outlining its findings and instructing the pharmacy what changes have to be made or what actions the DEA is planning. It is always a good idea to pay quick and thorough attention to such letters, and to seek advice and counsel if such a letter contains anything more than minor deficiencies and required changes.

Three features of DEA enforcement make regulatory compliance very important. First, the DEA has independent authority to levy fines for violations. This feature puts the burden on the pharmacy once it is cited. The DEA does not have to go through a long, involved process in order to cite or fine a pharmacy, and maximum fines have tended to become minimums.

The second is the fact that the DEA can fine a pharmacy up to the maximum for each and every violation that it finds—the so-called “repeated violation” exposure. There is no upper limit on the total amount of fine, i.e., # violations x maximum \$ fine, and DEA fines have been escalating for some time.

Third, though recent policy changes have softened the DEA approach to fining pharmacies, the DEA still does not have to find or prove diversion in order to cite a pharmacy for regulatory noncompliance. Record-keeping mistakes are sufficient to be cited.

Individual pharmacists, even though they are not owners or managers, also should be concerned about DEA compliance, because the professional impact and stigma of being cited by the DEA are not insignificant. State boards of pharmacy can (and do) take independent action against the cited pharmacy **and** the pharmacists involved. It is possible to be “involved” simply by working at a pharmacy, even on a part-time or temporary basis. Both pharmacies and pharmacists can face various licensing actions, including suspension or revocation.

Because of CSA requirements, pharmacies cannot easily (and prefer not to) hire pharmacists who have had their licenses affected or DEA registrations denied or revoked. All pharmacists—owners, partners, manager, staff, part-time, temporary—must take DEA regulatory requirements and inspections very seriously. Even if nothing ever comes of a DEA audit and subsequent letter or citation, there is always the possibility of lingering negative effects and stigma of being associated with a pharmacy that was “*had problems with the DEA.*”

Too many pharmacists believe that DEA requirements are for someone else, namely, owners and managers. That perception is 100% wrong!

### **A TYPICAL DEA AUDIT**

Though infrequent, the DEA may (and does) conduct audits of registrant pharmacies. The purpose of

such audits is to ensure compliance with all aspects of the CSA and/or to confirm or reject a suspicion or report about CSA compliance problems. An audit can last anywhere from an hour (or even less) to a week or more. The more time the DEA spends auditing, the higher the possibility that errors and deficiencies will be discovered.

Typically (but not always), the DEA investigator will ask (and expect) to see and will examine in detail any to all of the following:

1. DEA registration certificate—in date, properly displayed on the premises?
2. Power-of-attorney (if one exists); revocation of powers-of-attorney —proper format, stored in correct place on the premises?
3. Un-used DEA Form 222s—stored properly, on the premises?
4. Executed DEA Form 222 file—no missing forms, completed correctly, readily retrievable, stored properly on the premises?
5. Supplier invoice file that reflects executed DEA Form 222s—no invoices missing, readily retrievable, stored properly on the premises?
6. Supplier invoice files for all other schedules—no invoices missing, readily retrievable, stored properly on the premises?
7. Distribution and return records—complete, accurate, none missing, readily retrievable, stored properly on the premises?
8. Controlled substance prescriptions—required information, none missing, readily retrievable, stored properly (Schedule II records segregated) on the premises?
  - a) Schedule II—Oral emergencies proper in all regards, signed prescription received within 7 days, attached to back of oral emergency, partial dispensing for terminally ill and LTCF residents proper in all regards)
  - b) Schedules III to V—originals exist in physical form, stored properly?
9. Refill records—conform to limits, recorded, readily retrievable on the premises unless proper prior written notification to the DEA?
10. Daily computer dispensing printouts—complete, signed and dated by pharmacist?
11. Biennial inventory record—proper form and information, timely, date, when done and by whom, listed as trade packages, Schedule II items listed separately, readily retrievable, stored properly, on the premises?
12. Storage of controlled substances—secured or dispersed?

13. Pre-employment screening practices—to help ensure that drug felons are not hired for jobs with access to controlled substances.
14. Physical counts and accountability measures of selected controlled substances—a DEA-type accountability.

To avoid what can be serious consequences, it is essential that these records be current, correct, complete, **and** easily produced if requested. Not only must a pharmacy produce these items, they must conform to DEA regulatory requirements. Each violation that the DEA finds can result in a fine of up to \$25,000 and other actions, and the DEA has independent authority to take such actions on its own.

Pharmacies that have the least problems with DEA audits are those where everyone understands the importance of serious attention to following DEA regulations and record-keeping requirements. Sloppy, incomplete, misplaced records send the wrong signal to DEA diversion investigators, the same way that poor records peak the interest of IRS agents. Pharmacies with very neat, complete, accurate, and readily-produced records have a decided edge when it comes to DEA audits.

DEA may also conduct selected inventory accountability tests to determine whether purchasing receiving, dispensing, distribution, and inventory records are accurate and correctly account for the amount of controlled substances that a pharmacy handles.

An accountability test is the most powerful measure of record accuracy and involves a detailed (does by dose) comparison of the last physical inventory for a sample of controlled substances, all receipts of those products, dispensing and distribution records, and a current inventory of the products being tested. The DEA uses accountability tests as a measure of whether drug diversion has occurred in a pharmacy.

A pharmacy's records and inventories are accurate if the sum of what was on hand when the controlled substance was last inventoried plus what has been purchased and received equals what has been dispensed and distributed plus the ending inventory, i.e., on hand at the end of the audit period.

### **Absolute Accuracy is Very Important**

DEA records and inventories must be very accurate; the consequences are simply too costly. One of the best ways to improve and ensure compliance is to conduct a systematic self-assessment of a pharmacy's complete controlled substance handling procedures and records once or even twice a year. Even better, CSA compliance should be part of every affected employee's periodic review.