

Special Lesson

DEA Regulations for Community and Long-Term Care Pharmacies

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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 nor 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.

This program meets requirements for all states where law CE is required.

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 and corresponding 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;
4. Schedule II controlled substance, and,
5. Schedule III to V controlled substances,
6. Describe DEA's periodic inventory requirements;
7. 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;
8. 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;
9. Discuss the basis, procedures, and limitations for partial dispensing of Schedule II controlled substances to terminally ill or long-term care facility residents;
10. Recall two examples of when a pharmacy distributes rather than dispenses a controlled substance;
11. Explain what a pharmacy must do if it distributes more than 5% of the total number of controlled substance dosage units (instead of dispensing);
12. 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;
13. Describe DEA security requirements and recommendations for storing and handling controlled substances;
14. List what actions the DFA can take against a pharmacy;
15. Describe how the DEA generally conducts a pharmacy audit in terms of what records are typically examined and the meaning of "readily retrievable;" and
16. Describe what is meant by a DEA-type accountability test.

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), which replaced the Bureau of Narcotics and Dangerous Drugs (BNDD) 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.

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

The regulations that implement the CSA affect every aspect of manufacturing, packaging, repackaging, distributing, storing, ordering, receiving, prescribing, compounding, dispensing, and transporting controlled substances. 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 pharmacies), the DEA focuses major attention on pharmacies in order to ensure that pharmacists are complying with handling and record-keeping requirements. Although the DEA does not routinely audit community pharmacies, they have that right. It is better to be in compliance.

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.

Controlled substance prescriptions may be issued only for legitimate medical purposes by medical practitioners acting in the course of their professional practice. This 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 a pharmacist 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. 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. 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. 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.

Handling 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 alterations, 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 filling of a line item) and the date the partial shipment is received at the pharmacy in the space provided on copy 3. If and 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.

Because of their importance and interest to regulators, it is 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.

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.

Handling 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 inch 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 inch C does not have to be stamped on the lower right corner of hardcopy 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.

Review of Required Records

Each pharmacy registered to handle controlled substances must maintain records that include the following information for each controlled substance:

- a) Name of the controlled substance;
- b) Each finished form, e.g., capsule, tablet, or concentration per unit volume, e.g., 10 mg. per ounce or 2 mg. per ml., and the number of units or volume of finished form in each commercial container, e.g., 100 tablet bottle or 3 ml. vial;
- c) The number of commercial packages of each finished form received from other persons, i.e., other DEA registrants, including the date and number of containers in each receipt, and the name, address, and DEA registration number of the person IDEA registrant from whom the containers were received;
- d) The number of units or volume of each finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed the substance; and,
- e) The number of units or volume of such finished forms and/or commercial containers disposed of in any manner by the registrant, including the date and manner (method) of disposal and the quantity of the substance in finished form disposed.

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. If used, either must be kept locked when not in use.

Inventorying 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 (un-saleable 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 has been **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.

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.

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 can not 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 7days) 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 before actual dispensing occurs.

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, 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, and 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 **hand-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 20 doses plus five refills, which only authorized a total of 120 dosage units.

LTCF or Terminally-Ill Patients

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.

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 inch 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 inch C does not have to be stamped on the lower right corner of hard-copy Schedule III to V prescriptions.

NOTE: Realize that some prescription files may need to be kept for 30 months (two years + 6 months) in order to ensure that all authorized refills of Schedule III to V prescriptions that were originally filled longer than two years ago, but refilled within the past two years. *[State requirements may be longer; be sure to check carefully.]*

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 not 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 — any 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 DFA 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 warrantless 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 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 has "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 DEA Audit

Though relatively 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, and 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 (dose 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.

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