



A PHARMACY CONTINUING EDUCATION PROGRAM

W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

January 2011 "Part 1--Structure & Process of Controlled Substance Distribution"

33rd Year



THIS MONTH
"Part 1. Controlled
Substance
Distribution"

HAVE YOU RECEIVED YOUR 2010 CE CREDITS? IF YOU HAVE QUESTIONS, PLEASE CONTACT US.

MISSING A LESSON? GO TO OUR WEBSITE, & DOWNLOAD WHAT YOU NEED (www.wfprofessional.com). WE NO LONGER HAVE REPRINTS AVAILABLE.

WHEN YOU SEND IN QUIZZES, ALWAYS KEEP A COPY. EMAIL OR FAX ANSWERS. FAX # IS 847-945-5037. OR SEND A CONVENTIONAL EMAIL WITH YOUR ANSWERS. (INFO@WFPROFESSIONAL.COM).

HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US.

"CONTROLLED SUBSTANCES." Last year we discussed dispensing issues related to controlled substances. In this lesson, and the next, we review matters associated with distribution of controlled substances. This lesson provides 1.5 hours (0.15 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-11-001-H03-P. Pharmacists completing this lesson by January 31, 2014 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the requirements for registration of a pharmacy to dispense controlled substances.
2. Discuss the process of obtaining a waiver from DEA for certain pharmacy employees.
3. List the steps to be taken when controlled substances have been stolen or lost.
4. List the controlled substance records that must be maintained by a pharmacy.
5. Discuss required inventories.

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.

INTRODUCTION

Controlled substances present an extremely significant concern. Have we discussed rules and regulations in the past? Yes. Do we continue to receive requests from you to make clarifications? Yes. This is a didactic and academic topic, and there seem to be continuing areas of misunderstanding. There is special confusion when it comes to controlled substance distribution, recordkeeping, and administrative matters.

In the past we have discussed controlled substances dispensing requirements. In this lesson, and the next, we shall concentrate on issues from ordering controlled substances to online and central fill pharmacies. The goal is to present information that can be a resource for the pharmacy department.

One of the most important responsibilities within pharmacy is to comply with Drug Enforcement Administration (DEA) requirements for the distribution of controlled substances. Not only must pharmacists assure that controlled substance prescriptions are valid, but all valid prescriptions must be filled in a pharmacy that meets the structure and process requirements of the Controlled Substance Act (CSA) and DEA regulations. The structure and process of DEA regulations requires that pharmacies be registered with the DEA and that appropriate steps are taken to assure adequate restrictions on the availability of controlled substances within a registered pharmacy.

Note: The material that follows is based on information provided by the DEA in its publication "The Pharmacist's Manual." This material is not intended as legal advice. Any pharmacist who needs legal advice should consult an attorney.

PHARMACY REGISTRATION WITH DEA

Every pharmacy that dispenses a controlled substance must be registered with the DEA. First, a state license or permit must be obtained. After obtaining a state license or permit, the DEA registration may be obtained. To register as a new pharmacy, DEA Form 224 must be completed. The certificate of registration issued by DEA must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered.

A pharmacy registration must be renewed every three years utilizing DEA Form 224a. To renew a registration, the most current information from the pharmacy's existing registration must be utilized. A registrant can renew online no more than 60 days prior to the current expiration date.

If the registrant has not renewed online approximately 50 days before the registration expiration date, a renewal application is sent to the registrant at the mailing address listed on the current registration. If the renewal form is not received by the 30th day before the expiration date of the current registration, the pharmacy should contact the local DEA Registration Specialist or DEA Headquarters and request a renewal registration form. Once the expiration date has passed and no renewal has been received by DEA, the pharmacy has no authority to handle controlled substances.

Corporations that own or operate a chain of pharmacies may submit a single DEA Form 224b, Retail Pharmacy Registration Affidavit for Chain Renewal. This affidavit, along with a list of the corporation's registrations, is provided in lieu of a separate registration application for each pharmacy registration. No registration may be issued unless the completed affidavit is received by DEA. The corporation should retain a copy of this affidavit with their readily retrievable records for the duration of the registrations covered by the affidavit. A responsible individual must answer the questions listed on the affidavit on behalf of the corporation as they pertain to each registrant.

A pharmacy that moves to a new physical location must request a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA.

A pharmacy that discontinues business activities either completely or only regarding controlled substances must return its DEA registration certificate and unused official order forms (DEA Form 222) to the local DEA Registration Specialist. In addition, DEA may ask for the location of where inventories, prescriptions, and other required controlled substance records will be stored during the requisite two-year retention period.

Unwanted controlled substances in the pharmacy's possession must be disposed of in accordance with DEA regulations.

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January 2011

TRANSFER OF BUSINESS

A pharmacy registrant that transfers its business operations to another pharmacy registrant must submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

1. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed); and
4. The date on which the transfer of controlled substances will occur.

On the day the controlled substances are transferred, a complete inventory must be taken and a copy of the inventory must be included in the records of both the person transferring the business and the person acquiring the business. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. It is not necessary to send a copy of the inventory to the DEA unless requested by the Special Agent in Charge.

To transfer schedule II controlled substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

All controlled substance records required to be kept by the registrant-transferor shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

If the registrant acquiring the pharmacy owns at least one other pharmacy licensed in the same state as the pharmacy being transferred, the registrant may apply for a new DEA registration prior to the date of transfer. DEA will issue a registration which will authorize the registrant to obtain controlled substances at the time of transfer, but the registrant may not dispense controlled substances until the pharmacy has been issued a valid state pharmacy license.

A DEA registration application to transfer ownership of an existing pharmacy can be facilitated if the applicant includes an affidavit verifying that the pharmacy has been registered by the state licensing agency. The affidavit verifying the existence of the state license should be attached to the initial application for registration.

DENIAL, SUSPENSION, OR REVOCATION OF REGISTRATION

Under the CSA, the DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant:

- Has materially falsified the application;
- Has been convicted of a felony relating to a controlled substance or a List I chemical;
- Had a State license or registration suspended, revoked, or denied by a competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or List I chemicals or has had the suspension, revocation, or denial of a registration recommended by competent State authority;
- Has committed an act which would render the DEA registration inconsistent with the public interest; or
- Has been excluded (or directed to be excluded) from participation in a Medicaid or Medicare program.

DENIAL OF REGISTRATION IN THE PUBLIC INTEREST

In determining the public interest, the CSA states the following factors are to be considered:

- The recommendation of the appropriate State licensing board or professional disciplinary authority.
- The applicant's experience in dispensing or conducting research with respect to controlled substances.
- The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
- Compliance with applicable State, Federal, or local laws relating to controlled substances.
- Such other conducts which may threaten the public health and safety.

CHEMICAL REGISTRATION REQUIREMENTS

Registration is not required for regulated sellers of scheduled listed chemical products (SLCPs). However, a regulated seller must self-certify with DEA pursuant to federal law. A regulated seller is defined as a grocery store, general merchandise store, drug store, or other entity engaged in over-the-counter sales of ephedrine (both single-entity and combination products), pseudoephedrine, or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions by direct sales. A mobile retail vendor is defined as a person or entity that makes sales at retail from a stand that is intended to be temporary or is capable of being moved from one location to another.

Federal law requires any person who is engaged in the wholesale distribution of an SLCP to obtain a registration as a chemical distributor. A distributor who does not meet all the requirements for a regulated seller of SLCPs, or who does not meet the requirements for distributors required to submit "mail-order" reports, is a wholesale distributor. This would include those pharmacies that sell quantities of SLCPs to institutions, including long term care facilities, jails, and other institutional-type settings for non-patient specific use. Such pharmacies are often referred to as "closed door" pharmacies.

Retail pharmacies that are registered to handle controlled substances need not obtain a separate DEA chemical registration for retail distribution of SLCPs. If a pharmacy desires to engage in the wholesale distribution of bulk quantities of SLCPs, the pharmacy is required to register with DEA as a chemical distributor because these activities fall outside the definition of a regulated seller. Therefore, the pharmacy would be subject to the registration requirements that apply to wholesale distributors for those distribution activities, and subject to the pharmacy requirements for its pharmacy activities.

TRANSFER OF CONTROLLED SUBSTANCES

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.

To transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

TRANSFER TO A PHARMACY

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to the DEA. The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

TRANSFER TO THE ORIGINAL SUPPLIER OR ORIGINAL MANUFACTURER

Any pharmacy may transfer controlled substances to the original supplier or the original manufacturer that is appropriately registered with the DEA. The pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, dosage form, and quantity of the controlled substance.
3. The supplier or manufacturer's name, address, and registration number.
4. The DEA Form 222 or the electronic equivalent will be the official record for the transfer of schedule II controlled substances.

DISPOSAL OF CONTROLLED SUBSTANCES

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

REVERSE DISTRIBUTORS AUTHORIZED TO DISPOSE CONTROLLED SUBSTANCES

A pharmacy may forward controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 to the DEA when the controlled substances have been destroyed. A DEA Form 41 should not be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

REQUESTS FOR EMPLOYMENT WAIVERS FOR CERTAIN PHARMACY EMPLOYEES

Under DEA regulations, a registrant must not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, the regulations permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances.

A registrant that applies for such a waiver should understand that the following factors will be considered by the DEA in the approval process and should provide details relevant to each factor as part of the waiver request submitted, since a waiver will not be considered unless there are valid reasons to believe that diversion is unlikely to occur:

1. A detailed description of the nature and extent of the individual's past controlled substances violations, including all pertinent documentation;
2. Current status of the individual's state licensure;
3. Extent of individual's proposed access to controlled substances. "Access" is not limited to only physical access to controlled substances, but includes any influence over the handling of controlled substances;
4. Registrant's proposed physical and professional safeguards to prevent diversion by the individual;
5. Status of employing registrant regarding handling of controlled substances;
6. Other pertinent information uncovered by DEA in its investigation of the individual's or registrant's handling of controlled substances; and
7. All other relevant factors or materials.

CONTROLLED SUBSTANCE THEFT OR SIGNIFICANT LOSS

Should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss.

1. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

2. Complete DEA Form 106

A pharmacy must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved.

If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office and keep a copy for its records. The DEA Form 106 must include the following information:

- Name and address of the firm (pharmacy),
- DEA registration number,
- Date of theft or loss (or when discovered if not known),
- Name and telephone number of local police department (if notified),
- Type of theft (e.g., night break-in, armed robbery),
- List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
- A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

3. If Investigation Finds No Theft or Loss

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, the registrant must notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

4. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- The actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances;
- 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;
- 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; and, if known
- Whether the specific controlled substances are likely candidates for diversion; and
- Local trends and other indicators of the diversion potential of the missing controlled substances.

If it is determined that the loss is not significant, the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion.

IN-TRANSIT LOSS

When all or part of an in-transit shipment of controlled substances fails to reach its intended destination, the supplier is responsible for reporting the in-transit loss of controlled substances to DEA. The purchaser is responsible for reporting any loss of controlled substances after he/she has signed for or taken custody of a shipment. If it is discovered after that point that an in-transit loss or theft has occurred, the purchaser must then submit a DEA Form 106. If the purchaser does not take custody of the shipment and instead returns it to the supplier, it is the supplier's responsibility for reporting any loss of controlled substances in the original shipment.

IN-TRANSIT LOSS FROM CENTRAL FILL PHARMACY

When a central fill pharmacy contracts with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting the in-transit loss upon discovery of such loss by use of a DEA Form 106. In addition, when a retail pharmacy contracts with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery using a DEA Form 106.

BREAKAGE AND SPILLAGE

The breakage or spillage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, or spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. When this disposal occurs, it must be reported to DEA. Damaged goods may also be disposed of through shipment to a reverse distributor or by a DEA approved process.

RECORDKEEPING REQUIREMENTS

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. Readily retrievable is defined as:

- Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
- Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

REQUIRED RECORDS

The records which must be maintained by a pharmacy are:

- Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
- Power of Attorney authorization to sign order forms
- Receipts and/or invoices for schedules III, IV, and V controlled substances
- All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
- Reports of Theft or Significant Loss (DEA Form 106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
- Records of transfers of controlled substances between pharmacies
- DEA registration certificate
- Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005

CENTRAL RECORDKEEPING

A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/her intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located. Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification.

PRESCRIPTION RECORDS

Pharmacies have two options for filing prescription records under federal regulations. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be *readily retrievable* for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:

Option 1 (Three separate files):

- A file for schedule II controlled substances dispensed.
- A file for schedules III, IV and V controlled substances dispensed.
- A file for all noncontrolled drugs dispensed.

Option 2 (Two separate files):

- A file for all schedule II controlled substances dispensed.
- A file for all other drugs dispensed (noncontrolled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a **red "C" stamp** not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

CONTROLLED SUBSTANCE INVENTORIES

An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II controlled substances and an estimated count or measure of the contents of a schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made). The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

INITIAL INVENTORY

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory. There is no requirement to submit a copy of the inventory to the DEA. Regulations require that the inventory include:

- The date of the inventory,
- Whether the inventory was taken at the beginning or close of business,
- The name of each controlled substance inventoried,
- The finished form of each of the substances (e.g., 10 milligram tablet),
- The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle),
- The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and
- A count of the substance - if the substance is listed in schedule II, an exact count or measure of the contents or if the substance is listed in schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.

DEA recommends, but does not require, an inventory record include the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

BIENNIAL INVENTORY

Following the initial inventory, the registrant is required to take a biennial inventory (every two years), which requires the same information as the initial inventory (see list above) of all controlled substances on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.

NEWLY SCHEDULED CONTROLLED SUBSTANCE INVENTORY

When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.

***IN THE NEXT LESSON WE'LL DISCUSS:
ORDERING CONTROLLED SUBSTANCES,
CANCELLING ORDERS,
ONLINE PHARMACIES &
LONG TERM CARE FACILITIES & CONTROLLED SUBSTANCES***

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to:
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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Describe registration requirements	Yes	No
Discuss a special waiver for some employees	Yes	No
What's done when controlled substances are lost or stolen	Yes	No
List records that must be maintained	Yes	No
Discuss required inventories	Yes	No

2. Was the program independent & non-commercial Yes No

	Poor			Average		Excellent
3. Relevance of topic	1	2	3	4	5	6 7

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

Please Select the Most Correct Answer

- | | |
|---|--|
| <p>1. DEA registration consists of 2 steps: DEA licensure & state licensure.
 A. Obtain DEA approval first
 B. Doesn't matter which is obtained 1st
 C. Obtain state approval 1st
 D. Obtain both simultaneously</p> <p>2. What form is used to initially register with DEA?
 A. Form 224
 B. Form 224a
 C. Form 222
 D. Form 222a</p> <p>3. How often must DEA registration be renewed?
 A. Annually
 B. Biannually
 C. Every 3 years
 D. Every 5 years</p> <p>4. When Schedule III-V controlled substances are transferred to a reverse distributor for destruction, the reverse distributor must issue an official order form, or the electronic equivalent, to the pharmacy.
 A. True B. False</p> <p>5. Pharmacies registered to handle controlled substances need not obtain a separate DEA chemical registration for retail distribution of SLCPs.
 A. True B. False</p> | <p>6. A pharmacy may not employ a person who has at any time been denied a DEA registration and there are no exceptions to this requirement.
 A. True B. False</p> <p>7. Any pharmacy may transfer controlled substances to the original supplier or manufacturer that is appropriately registered with the DEA.
 A. True B. False</p> <p>8. Which of these factors may give the DEA authority to deny, suspend or revoke registration of a registrant?
 A. Registrant falsified the application
 B. Registrant has been convicted of a felony related to controlled substances
 C. Registrant has been excluded from participation in Medicaid
 D. All of these</p> <p>9. A pharmacy may hire an outside firm to inventory, package & arrange for the transfer of controlled substances to another pharmacy.
 A. True B. False</p> <p>10. A pharmacy must notify, in writing, the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss.
 A. True B. False</p> |
|---|--|

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