CEprn®
A PHARMACY CONTINUING EDUCATION PROGRAM

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

February 2011 "Part 2--Structure & Process of Controlled Substance Distribution"

33rd Year

THIS MONTH "Part 2. Controlled Substances"

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 month we discussed controlled substance distribution. In this lesson we continue the review of controlled substances. Specifically, in this lesson, our goals are to reexamine ordering procedures, cancellation of orders, online pharmacies and procedures for long term care facilities. 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 707-000-11-002-H03-P. Pharmacists completing this lesson by February 28, 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. Discuss the process for ordering controlled substances by a pharmacy.
2. Describe the restrictions placed on internet pharmacies, when it comes to controlled substances.
3. Discuss the requirements for central fill pharmacies that dispense controlled substances.
4. Consider procedures that are considered in long term care facilities.

Last month we discussed controlled substance distribution. In this lesson we continue the review of controlled substances. Specifically, we reexamine ordering procedures, cancellation of orders, online pharmacies and procedures for long term care facilities.

ORDERING SCHEDULE II CONTROLLED SUBSTANCES

Only schedules I and II controlled substances are ordered with an official order form, DEA Form 222, or the electronic equivalent. A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II controlled substance.

When a controlled substance has been moved by DEA from schedule II to another schedule at the federal level, in many states it may remain a schedule II controlled substance pending any legislative or administrative action that may result from the federal action. Many states require transactions that involve substances they classify as schedule II be made via official order forms (DEA Form 222) or the electronic equivalent. When federal law or regulations differ from state law or regulations, a pharmacy is required to abide by the more stringent aspects of both the federal and state requirements. When the use of DEA Form 222 or the electronic equivalent for the transfer of a controlled substance is not required under federal law, its use as mandated by these states does not violate federal law and is therefore permitted.

REQUESTING OFFICIAL ORDER FORMS

The unexecuted DEA Form 222 can be requested initially by checking "block 3" on the application for a new registration (DEA Form 224). Once a registrant has received a DEA registration number, additional DEA Forms 222 may be ordered online. When requesting additional DEA Forms 222 online, a valid DEA registration number, business name, and contact telephone number are required. The registrant may also request DEA Forms 222 by calling the DEA Headquarters Registration Section or by contacting the local DEA Registration Specialist.

Each book of DEA Form 222 consists of seven sets of forms. Each pharmacy is provided a maximum of six books at one time unless its needs exceed this limit. In such a case, the pharmacy should contact the local DEA Registration Specialist to request additional books.

COMPLETING OFFICIAL ORDER FORMS

When ordering schedule II controlled substances, the purchaser is responsible for filling in the number of packages, the size of the package, and the name of the item. Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney. When the items are received, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received.

The executed DEA Form 222 must be maintained separately from the pharmacy's other business records. However, this does not preclude a registrant from attaching a copy of the supplier's invoice to the related DEA Form 222.

DEA regulations require that, for orders using the DEA Form 222, an order must not be filled if the order is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description.

A supplier may refuse to accept an order for specific reasons as set forth in DEA regulations. If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. If an order is refused, the supplier must return copies one and two of the DEA Form 222 to the purchaser with a statement explaining the reason the order was refused. For electronic orders, the supplier must notify the purchaser and provide a statement as to the reason.

DEA policy does not preclude the substitution of identical products differing in packaging size from those initially ordered, provided that the actual quantity received does not exceed the amount initially ordered and that the National Drug Code number reflected is that of the actual product shipped. For example, a distributor may substitute five bottles of 100, 2 milligram tablets for one bottle of 500, 2 milligram tablets or any variation thereof.

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February 2011

CANCELLATION AND VOIDING AN OFFICIAL ORDER FORM

A purchaser may cancel an order (or partial order) on a DEA Form 222 by notifying the supplier in writing. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing "cancelled" in the space provided for the number of items shipped.

A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing. The supplier must indicate the voiding of Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing "void" in the space provided for the number of items shipped.

POWER OF ATTORNEY TO SIGN AN OFFICIAL ORDER FORM

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Form 222.

The power of attorney may be revoked at any time by the person who granted and signed the power of attorney. Only if the renewal application is signed by a different person is it necessary to grant a new power of attorney when the pharmacy completes a renewal registration. The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record. The power of attorney is not submitted to DEA.

LOST OR STOLEN ORDER FORMS

When a pharmacist has not received an expected shipment of controlled substances, he/she should first contact the supplier to determine whether the original DEA Form 222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form's serial number and date, and verify that the drugs ordered were never received. The pharmacy must attach a copy of the statement to the second order form that is sent to the supplier. In addition, the pharmacist must keep a copy of the statement with copy three from the first and second order forms.

A pharmacy, upon discovery of the loss or theft of used or unused order forms, must immediately report the loss to the local DEA Diversion Field Office and provide the serial numbers of each lost or stolen order form. If an entire book

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Total	2700	2700
Percent Paid and/or Requested Circulation	100%	100%

or multiple books of order forms are lost or stolen, and the serial numbers of the missing forms cannot be identified, the pharmacist must report the approximate date of issuance (in lieu of the serial numbers) to the DEA. If an unused order form reported stolen or lost is later recovered or found, the pharmacy must immediately notify the local DEA Diversion Field Office.

PHARMACY CONTROLLED SUBSTANCE DISTRIBUTION – "FIVE PERCENT RULE"

A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:

The pharmacy or practitioner that will receive the controlled substances is registered under the CSA to dispense controlled substances;

The distribution is recorded by the distributing practitioner in accordance with DEA regulations and the receipt is recorded by the receiving practitioner in accordance with DEA regulations;

If the pharmacy distributes a schedule II controlled substance, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent.

Under the "Five Percent Rule" the total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a distributor.

ORDERING SCHEDULES III-V CONTROLLED SUBSTANCES

The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. These receipts must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received. In addition, these receipts must be maintained in a readily retrievable manner for inspection by the DEA.

RESTRICTIONS ON INTERNET PHARMACY

On October 15, 2008, the President signed into law the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, often referred to as the *Ryan Haight Act*. This law amends the CSA by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called "rogue Internet sites" that unlawfully dispense controlled substances by means of the Internet. The *Ryan Haight Act* applies to all controlled substances in all schedules.

This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy. Thus, any person who knowingly or intentionally dispenses a controlled substance by means of the Internet that does not have a modification of DEA registration allowing such activity is in violation of the CSA and subject to potential criminal prosecution and (in the case of DEA registrants) loss of DEA registration.

DEFINITION OF AN ONLINE PHARMACY

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet. Examples of an online pharmacy include (but are not limited to) the following:

- Any website that sells, or offers to sell, any controlled substance or a prescription therefore to a person in the United States.
- Any person who operates such a website.
- Any person who pays a practitioner to write prescriptions for controlled substances for customers of such a website.
- Any person who pays a pharmacy to fill prescriptions for controlled substances that were issued to customers of such a website.
- Any pharmacy that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of such a website.
- Any person who sends an e-mail that:
    - offers to sell a controlled substance or a prescription for a controlled substance in a manner not authorized by the Act;
    - directs buyers to a website operating in violation of the Act;
    - or otherwise causes or facilitates the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by the Act.

ONLINE PHARMACY REGISTRATION EXEMPTIONS

The following are exempt from the Ryan Haight Act's definition of an "online pharmacy" so long as their activities are limited solely to the exemptions provided:

- Manufacturers or distributors registered under the CSA who do not dispense controlled substances to nonregistrants.
- Nonpharmacy practitioners who are registered under the CSA and whose activities are authorized by that registration, provided that any website operated by such nonpharmacy practitioners complies with DEA regulations, which requires the website to post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the website.
- Any hospital or other medical facility registered under the CSA that is operated by an agency of the United States (including the Armed Forces).
- A health care facility owned or operated by an Indian tribe or tribal organization carrying out a contract under the Indian Self-Determination and Education Assistance Act.
- Any agent or employee of any hospital or facility that is operated by an agency of the United States, and any agent or employee of any hospital or facility owned or operated by an Indian tribe or tribal organization carrying out a contract under the Indian Self-Determination and Education Assistance Act, provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of such health care facilities only to the extent such individuals are furnishing services pursuant to those contracts.
- Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance.
- A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States.
- A pharmacy registered under the CSA whose dispensing of controlled substances via the Internet consists solely of filling or refilling prescriptions for controlled substances in schedule III, IV, or V.
- Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by the CSA.
- Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a Long Term Care Facility when the registration of the automated dispensing system is held by that pharmacy and the pharmacy is otherwise complying with the DEA regulations.

NOTIFICATION REQUIREMENTS

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the Internet, the online pharmacy shall notify DEA and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances. Completion of an *Application for Modification of Registration for Online Pharmacies* serves as the notification requirement to DEA.

The online pharmacy must make a separate thirty-day advance notice to the State boards of pharmacy in each State in which it intends to offer to sell, deliver, distribute, or dispense controlled substances. Online pharmacies that apply for the modification of registration are required to certify that the applicable State boards of pharmacy have been notified.

HOW TO REGISTER AS AN ONLINE PHARMACY

To operate legally as an online pharmacy, the online pharmacy must first be registered with DEA as a pharmacy. Once registered with DEA as a pharmacy, the pharmacy may apply for a modification of registration to operate as an online pharmacy. There is no fee to apply to modify a DEA registration to an online pharmacy.

If the modification of registration is approved, the pharmacy will be issued a modified DEA Certificate of Registration with the new business activity listed as online pharmacy. The registrant will keep the same DEA registration number. A pharmacy may perform the activities of a retail pharmacy and an online pharmacy at the same time.

STATE LICENSURE REQUIREMENTS

An online pharmacy must comply with the requirements of all applicable State laws concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses, or offers to deliver, distribute, or dispense, controlled substances by means of the Internet. In addition, online pharmacies must certify they are in compliance with these requirements when completing an *Application for Modification of Registration for*

Online Pharmacies.

The requirement that an online pharmacy list the States in which it is licensed to dispense controlled substances is designed to ensure that an online pharmacy only dispenses controlled substances to patients in States in which it is authorized to practice pharmacy. Dispensing beyond the scope of State licensure is one of the recurring transgressions of some rogue online pharmacies and generally violates State law. Under this Act, a State may bring civil action in federal court to enjoin any violation of the Ryan Haight Act – not merely those violations of State law – and to obtain other appropriate legal or equitable relief.

ONLINE PHARMACY WEBSITE REQUIREMENTS

When a pharmacy applies for a modification of registration to become an online pharmacy, it must display on its homepage a declaration that it has done so. This declaration must state the following:

"In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. § 831 and 21 C.F.R. § 1304.40."

Once approved to operate as an online pharmacy, the online pharmacy must display at all times on the homepage of its Internet site a declaration of compliance with the requirements of the CSA with respect to the delivery or sale or offer for sale of controlled substances. This statement must include the name of the pharmacy as it appears on the DEA Certificate of Registration.

An online pharmacy is required to post Internet Pharmacy Site Disclosure Information on the homepage of each Internet site it operates. It must be posted in a visible and clear manner and contain the following information:

The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.

- The pharmacy's telephone number and e-mail address.
- Name of pharmacist-in-charge, professional degree, States of licensure, and telephone number.
- List of State(s) in which the pharmacy is licensed to dispense controlled substances.
- Certification that the pharmacy is registered to deliver, distribute, or dispense controlled substances by means of the Internet.
- The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.

The following statement must be visible on the website:

"*This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. § 829), or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. § 802(54)).*"

If at any time an online pharmacy should change its Internet site web address, the online pharmacy must notify DEA at least thirty days in advance of this change.

REPORTING REQUIREMENTS

Each online pharmacy must submit a monthly report to DEA of the total quantity of each controlled substance that the online pharmacy has dispensed the previous calendar month. The report is required for every month in which the total amount of dispensing of controlled substances by the pharmacy is either (i) over 100 prescriptions filled or (ii) 5,000 or more dosage units dispensed of all controlled substances combined. Should an online pharmacy's total quantity of dispensed controlled substances fall below both of the thresholds listed above, a report is still required that indicates a negative response for that given month.

The report must include the total amount of such dispensing by any means including all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. It is not required that the online pharmacy identify the means of the dispensing in its report. Reporting will be by National Drug Code (NDC) numbers. The report must also include the total number of dosage units dispensed for each NDC number.

This report is due on or before the 15th day of the following month. For example, an online pharmacy would submit its report for the month of January no later than February 15th. Reports must be submitted electronically via online reporting, electronic upload, or other means as approved by DEA. All reports must be kept for at least two years and be readily retrievable for inspection.

Should an online pharmacy revert back to a retail pharmacy, the pharmacy is still required to report the monthly

sales for the month in which it changes back to a retail pharmacy.

PRESCRIPTION REQUIREMENTS

In order for a prescription to be valid, it must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or by a covering practitioner. An in-person medical evaluation is a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

DEFINITION OF PRESCRIPTION TERMS

A pharmacy website is exempted from the Ryan Haight Act's definition of an "online pharmacy" if its Internet-facilitated activity relating to controlled substances is limited to filling new and/or refilling prescriptions for controlled substances in schedules III, IV, or V. If the pharmacy is so exempted from the definition of an "online pharmacy," it is not required under the Act to obtain a modification of its DEA registration authorizing it to operate as an online pharmacy. Thus, it is important to understand precisely the definitions of the following terms.

FILLING NEW PRESCRIPTIONS FOR CONTROLLED SUBSTANCES—-SCHEDULES III-V

The term "filling new prescriptions for controlled substances in schedule III, IV, or V" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if:

- The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of the CSA and DEA regulations (for purposes of this definition, such a prescription shall be referred to as the "original prescription");
- The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance; and
- The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

REFILLING PRESCRIPTIONS FOR CONTROLLED SUBSTANCES IN SCHEDULES III-V

The term "refilling prescriptions for controlled substances in schedule III, IV, or V" means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of the CSA and DEA regulation; and does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

CENTRAL FILL PHARMACY

A "central fill pharmacy" fills prescriptions for controlled substances on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with pharmacies who share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a "central fill" activity. Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely reflect the disposition of all controlled substance prescriptions dispensed. Central fill pharmacies are required to comply with the same security requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. Retail pharmacies that also perform central fill activities are allowed to do so without a separate DEA registration, separate inventories, or separate records.

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. Both the retail and central fill pharmacists have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. Prescriptions for controlled substances listed in schedules II, III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

- Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

- Ensure that all information required to be on a prescription is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
- Maintain the original prescription for a period of two years from the date the prescription was last refilled;
- Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the retail pharmacy employee accepting delivery;
- For schedules III-V prescriptions, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining (refills for schedule II prescriptions are not permitted).

The central fill pharmacy receiving the transmitted prescription must:

- Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and the DEA registration number of the retail pharmacy transmitting the prescription;
- Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription; and
- Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common, or contract carrier).

Central fill pharmacies must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy. Central fill pharmacies must comply with the provisions of the C.F.R. when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy (and likewise for retail pharmacies retrieving filled prescriptions from a central fill pharmacy) for delivery to the ultimate user.

LONG TERM CARE FACILITIES

A Long Term Care Facility (LTCF) is defined in the C.F.R. as a nursing home, retirement care, mental care, or other facility or institution, which provides extended health care to resident patients. In most cases, these facilities are not registered with DEA, yet these health care facilities routinely maintain controlled substances issued via prescription to their residents. These controlled substances are already outside the CSA's closed drug distribution system since they have been dispensed to the ultimate user.

LTCFs frequently need to dispose of unused medications due to a change in the resident's medication or the resident's death. Accordingly, LTCFs should contact the local DEA Diversion Field Office for drug disposal instructions. The DEA is aware of issues currently facing LTCFs concerning the dispensing and handling of controlled substances, which are affected by a variety of state laws and circumstances. Pharmacists should check with their state agency for guidelines concerning controlled substances at LTCFs.

USE OF AUTOMATED DISPENSING SYSTEMS BY RETAIL PHARMACIES AT LONG TERM CARE FACILITIES

If state law or regulations permit, the DEA will allow a retail pharmacy to register at the site of the LTCF and store controlled substances in an Automated Dispensing System (ADS). In an ADS, a pharmacy stores bulk drugs in the machine in separate bins or containers. The pharmacy programs and controls the ADS remotely. Only authorized LTCF staff is allowed access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a valid prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. A registered retail pharmacy that possesses additional registrations for ADS machines at LTCFs may keep all records required for those additional registered sites at the retail pharmacy or other approved central location.

DEA registered pharmacies wishing to operate an ADS at an LTCF must contact the DEA Office of Diversion Control, Registration Section for registration instructions.

This concludes our annual review of a significant aspect of pharmacy law.

In future lessons this year we will discuss:

- Dry Eye Syndrome
- Restless Leg Syndrome
- New Drugs Released in 2010
- Drug Treatment for Multiple Sclerosis—-Any New Breakthroughs?
- Healthcare Reform & Impact On Pharmacy
- Vaccine Update

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to: *CE PRN*®, 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.

NAME_____(ID # 1st line on label)_____

ADDRESS_____CITY_____STATE_____ZIP_____

CHECK IF NEW ADDRESS **ARE YOU LICENSED IN FLORIDA? IF YES FL LIC** _____

EMAIL Address (we need this)_____

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?

Discuss process for ordering controlled substances for the pharmacy	Yes	No
Describe restrictions placed on Internet pharmacies regarding controlled substances	Yes	No
Discuss requirements for central fill pharmacies regarding controlled substances	Yes	No
Consider procedure considered for LTCFs	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

1. A pharmacy registered with DEA wishes to maintain shipping & financial records at a central location. Written notification is submitted to DEA. After 14 days, the registrant may begin maintaining central records. (Assuming there is no denial).
   A. True B. False
2. How many days prior to offering a controlled substance for sale via the Internet must an online pharmacy notify the DEA & the state boards of pharmacy in any states in which the online pharmacy offers to sell or deliver controlled substances?
   A. 7 days
   B. 14 days
   C. 21 days
   D. 30 days
3. Under DEA rules, a retail pharmacy transmitting prescription information to a central fill pharmacy must maintain the original prescription for 5 years after date of last refill.
   A. True B. False
4. The Ryan Haight Online Pharmacy Consumer Protection Act became effective in which year?
   A. 2007
   B. 2008
   C. 2009
   D. 2010
5. The "5 percent rule" refers to:
   A. Basketball
   B. Registration as a distributor
   C. Number of online pharmacies
   D. None of these
6. To transfer a Schedule II drug, you need:
   A. DEA Form 224
   B. DEA Form 222
   C. UPS Order Book
   D. None of these
7. Executed DEA Form 222s must be kept separate from other pharmacy records.
   A. True B. False
8. To cancel an order on a DEA Form 222, you must:
   A. Contact DEA
   B. Contact state board of pharmacy
   C. Notify supplier
   D. All of these
9. The Ryan Haight Law:
   A. Amends CSA
   B. Only refers to Schedule II drugs
   C. Only applies to foreign pharmacies
   D. All of these
10. A person who operates an Internet pharmacy website is considered part of the definition of an online pharmacy.
    A. True
    B. False

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