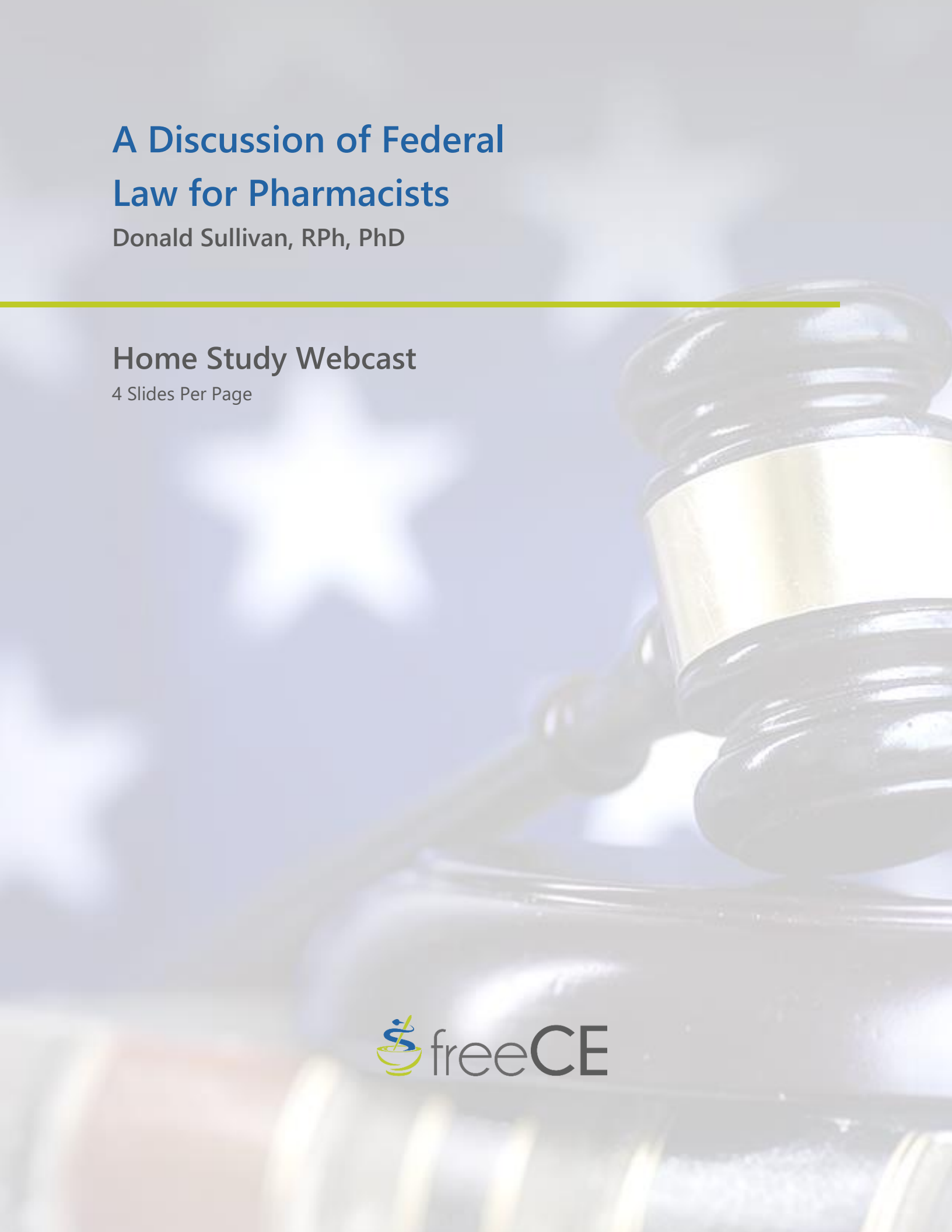
A Discussion of Federal Law for Pharmacists

Donald Sullivan, RPh, PhD

Home Study Webcast

4 Slides Per Page



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A Discussion of Federal Law for Pharmacists

ACTIVITY DESCRIPTION

The program will include information on the faxing of controlled substances and the do not fill until restrictions for controlled substances. It will include a description of new trends in prescription drug diversion and how to combat them. It will also discuss how to handle breakage, spillage, theft, and loss of controlled and non-controlled substances. Finally, it will include other information on pharmacy practice issues including mailing prescription drugs, dispensing related issues, power of attorney for DEA 222s and other practice related topics.

TARGET AUDIENCE

The target audience for this activity is **pharmacists, pharmacy technicians** and **nurses** in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES

After completing this activity, the **pharmacist** will be able to:

- Describe common trends in prescription drug diversion
- Identify pharmacy practice issues that occur when dispensing controlled substances
- Describe the laws related to the practice of pharmacy under federal law

After completing this activity, the **pharmacy technician** will be able to:

- Describe common trends in prescription drug diversion
- Identify pharmacy practice issues that occur when dispensing controlled substances
- Describe the laws related to the practice of pharmacy under federal law

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Knowledge-Based Home Study Webcast

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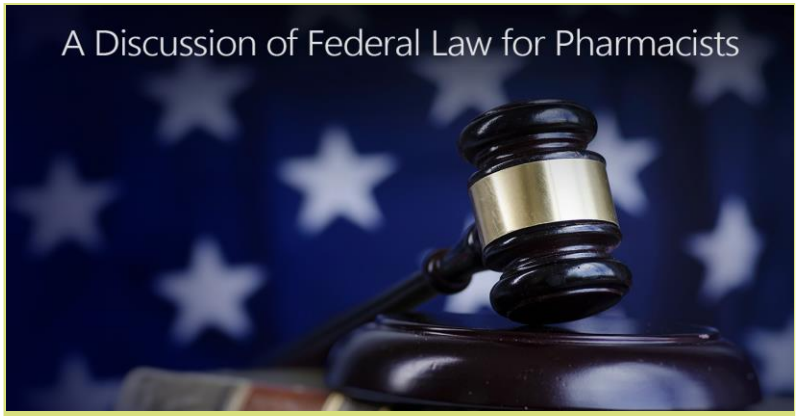


Faculty: Donnie Sullivan, R.Ph, Ph.D.

Objectives

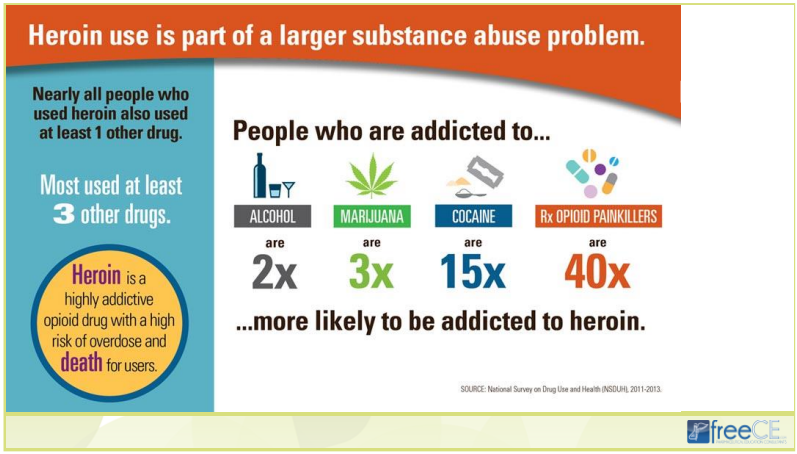
- Describe common trends in prescription drug diversion
- Identify pharmacy practice issues that occur when dispensing controlled substances
- Describe the laws related to the practice of pharmacy under federal law

Federal vs. State Law

- This program focuses on federal pharmacy laws only
- Some states have more restrictive laws than the federal law discussed in this program
- Always be sure to know what the law is in the state you practice, it may be different
- In general, follow the law that is more restrictive
- Reach out to your state board of pharmacy with questions

Resources

- www.deadiversion.usdoj.gov
- Federal controlled substance laws - https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html
- DEA Pharmacists' Manual : https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html
- Regulations on physician's assistants – State Medical Board
- Regulations on nurse practitioners – State Nursing Board
- Regulations on weight loss drugs – State Medical Board



Fentanyl: Home Lab Synthesis

- Two methods used: Siegfried or Janssen method
- Chemicals

25 g N-phenethyl-piperidone (NPP)	= $160.65
25 g Sodium Borohydride	= $ 18.50
25 g Propionyl Chloride	= $ 14.50
500 g Molecular Sieve 4A	= $ 24.50
500 mL THF	= $ 22.65
500 mL Aniline	= $ 69.98
Total	$358.78

18 g of fentanyl produced with a street value of ~$18,000

P.A.J. Janssen, J.F. Gardocki, U.S. Patent 3141823 (1964); http://www.opioids.com/fentanyl/synthesis.html

Street Prices of Prescription Drugs

- Buprenorphine - $2 to $15 per film
- Fentanyl patches - $1/mcg/hr
- Actiq - $20 per lozenge
- Hydrocodone - $2 to $10 per tablet
- Hydromorphone - $9 per tablet
- Methadone 10mg - $10 per tablet
- Oxycodone - $1 per milligram
- Carisoprodol - $3 tablet
- Adderall - $5 to $30 per capsule

www.streetrx.com (Accessed 12/19/16)

New Trends

- Gabapentin is one of the most abused drugs on the street
- Buprenorphine clinics recruiting medical residents for short periods of time for large amounts of cash
- Clonidine being abused by cocaine users
- New "Trinity" – opioid, benzodiazepine, and a stimulant
- Heroin being mixed with fentanyl. Fentanyl is approximately 50 times more potent than oxycodone.
- Carfentanil – "elephant tranquilizer"
- Albuterol inhalers

Corresponding Responsibility

- According to controlled substance act of 1970, to be a valid prescription for a controlled substance it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional practice. The practitioner is responsible for proper prescribing. The pharmacist has corresponding responsibility when dispensing a controlled substance prescription to make sure it is for a legitimate medical purpose.

Corresponding Responsibility

- A prescription for a controlled substance which purports to be a valid prescription, but is not issued for a legitimate medical purpose is not considered a valid prescription according to this Act. The law further states that any individual knowingly dispensing such a purported prescription for a controlled substance will be subject to criminal penalties and administrative sanctions.

Corresponding Responsibility

- The law has been interpreted that a pharmacist has an equal responsibility as the physician in making this determination.
- Just because a prescriber wrote the prescription does not mean a pharmacist can fill it without any regard for appropriateness.

Pharmacist Checklist Before Filling a Controlled Substance Prescription

- Prescription looks authentic
- Prescription has all the legal requirements
- Drug, dose, duration, and quantity seem to be in normally observed prescribing patterns
- Assessment of the patient
- Check patient profile & perform DUR
- Check the state PDMP report
- Call physician to verify information if necessary
- Document, Document, Document!!!!!

Your checklist on PDMP Report

Here is a basic checklist you can use when assessing prescribing and/or dispensing data:

- Type of drugs prescribed (number of CNS depressants and stimulants)
- Duplicate therapy or duplicate classes of drugs
- Strengths of medication prescribed
- Quantity
- Number of physicians the patient is seeing

Your checklist on PDMP Report

- Number of pharmacies the patient is using
- Is the patient using lots of urgent care centers, convenience clinics, ERs, and/or dentists?
- Days supply per prescription
- Is the patient getting things filled early?
- Are doses, quantities, and/or strengths escalating?
- Method of payment by patient
- Beware of possible errors in the report!

Questions to Ask a Physician

- Did you write a prescription for (patient) on (date)?
- What specifically did your write the prescription for?
- Did you authorize any refills?
- Will you please verify their date of birth?
- Will you please verify their address?
- Is this patient new to your practice?
- What is the patient's diagnosis?

Questions to Ask a Physician

- Is this ongoing therapy?
- How long do you think the patient will be taking this drug?
- Will you briefly describe the patient's medical history?
- Does your pain agreement specify the selection of only one pharmacy for the patient?
- Did you counsel the patient on the safe use of this drug?
- Is the patient also using other non-opioid pain therapies?

Examples of Questionable Prescribing

* Multiple controlled substance drug cocktails

Examples: Narcotic pain killer + benzodiazepine + sleeping pill + codeine containing cough syrup + carisoprodol (muscle relaxant) or any combination thereof.

* Length of therapy of codeine or hydrocodone containing cough syrups, anything beyond 3-6 weeks is definitely "suspicious". No clinical rational beyond 6 weeks.

* **Lack of individualization of patient therapy**

Diversion Red Flags

- Almost all patients receive same strength of a drug
- Prescribing drugs with the same directions for use for all
- MDs that give only a 14 or 30 day supply so patients have to come back
- Prescribing large amounts of gabapentin or Lyrica® because it does not show up on a drug screen
- A physician prescribing sub-therapeutic doses or highest strengths at lower doses to "stay-under-the radar"

Diversion Red Flags

- Large influx of patients with oxycodone prescriptions after one "suspicious" patient has one filled
- Syringe sales may indicate heroin abusers
- APN operated clinics that are pill mills
- Controlled substances prescribed with non-controlled substances that patients don't want filled
- Patients unwilling to try other pain therapies

Diversion Red Flags

- The "3 day early" standard????
- Over-documentation by the prescriber
- Office-staff verifying prescriptions when called by the pharmacist. You may need to talk to prescriber directly in some cases.
- Patients traveling long distances

Final Thoughts on Diversion

- Safety of yourself, your staff and your customers comes first
- Experience is on your side
- Prescription diverters are becoming very sophisticated. They know name(s) of the owner, Board of Pharmacy members, district managers, pharmacy supervisors, local attorneys, etc.

Final Thoughts on Diversion

- Don't drive yourself crazy trying to be perfect
- Don't take it personal
- Don't put legitimate pain patients at risk by refusing to fill prescriptions
- Patients are going to "get one by you" from time to time. Do the best you can.

Faxing Controlled Substance Prescriptions

In general, prescriptions for Schedule II drugs cannot be faxed to a pharmacy. However, there are three exceptions to this rule:

1) Pharmacists may receive faxed prescriptions for Schedule II drugs for patients in a nursing home or long-term care facility.
2) Pharmacists may receive faxed prescriptions for Schedule II narcotic drugs for patients in hospice care. The prescriber will note on the prescription that it is for a hospice patient.

Faxing Controlled Substance Prescriptions

3) Pharmacists may receive faxed prescriptions for Schedule II narcotic drugs for patients undergoing home infusion/intravenous (IV) pain therapy.

The faxed prescription received by the pharmacy is considered the original written prescription. The prescriber does not have to send the original prescription to the pharmacy. No further written prescription is required.

Faxing Controlled Substance Prescriptions

- In other instances (other than the three discussed above), a physician may want to fax a schedule II controlled substance prescription to the pharmacy so the pharmacist can "have it ready" when the patient arrives. It is important to know that the pharmacist cannot dispense the medication until the patient brings the original, hard-copy prescription from the physician, and the pharmacist should verify it against the faxed copy. The hard-copy, written prescription is considered the "original prescription" and should be filed accordingly.
- Make sure your state law allows this

Do Not Fill Until

Case: A patient has an appointment with their physician and still has a two-week supply of medication left on their prescription. The physician does not want the patient to get the prescription filled for two weeks. What can the physician do?

- First, it is illegal for physicians to post-date prescriptions. New prescriptions must be dated on the day that they are signed by the physician.

Do Not Fill Until

- Second, if a physician does not want the patient to get the prescription filled until sometime in the future, they must write "do not fill until" with the future fill date in the directions of the prescription.
- Example: The physician writes the prescription for cyclobenzaprine 10mg on 1/15/17 but does not want the patient to get the prescription filled until 1/31/17. The physician should write "do not fill until 1/31/17" in the directions on the prescription and date the prescription 1/15/17.

Do Not Fill Until

- The law is more restrictive when using "do not fill until" for schedule II prescriptions.
- Federal law allows physicians to issue multiple prescriptions for schedule II drugs. This law allows physicians to issue multiple prescriptions for a schedule II drug with "do not fill until" on them for up to a 90 day supply of medication.

Do Not Fill Until

- Case: A physician decides that he/she only needs to see a child every 90 days for his ADHD. The date of the physician visit is January 3, 2017. The physician could write three prescriptions on January 3, 2017 for Adderall XR® 5mg, #30, one daily. The first prescription would have nothing additional in the directions. The second prescription would have "Do not fill until February 2, 2017" in the directions, and the third prescription would have "Do not fill until March 4, 2017". All three of these prescriptions would have the date issued as January 3, 2017.

Do Not Fill Until

- With these dates in the directions, pharmacists are prohibited from filling them before these dates. Also, the physician is not required to write these prescriptions in 30 day increments.
- A physician may want to issue six prescriptions for a 14-day supply on each with the appropriate "do not fill until" dates on each one.
- In summary, the total days supply when multiple prescriptions are issued for a schedule II drug with "do not fill until" on it is 90 days.

Theft or Loss of Prescription Drugs

- If any prescription drug is discovered to be lost or stolen, your state board of pharmacy should be notified as soon as the theft or loss is discovered. They will instruct you in the proper procedures and documentation that your individual state requires. Many boards of pharmacy require immediate notification and formal paperwork that must be filed.
- The board should also be contacted for guidance when a "suspected" theft or loss has occurred as well.
- When in doubt, call the board of pharmacy for guidance and advice.

Theft or Loss of Controlled Substances

- 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.
- A pharmacy must notify in writing the local DEA Diversion Field Office within 1 business day of discovery of a theft or significant loss of any controlled substance.

Theft or Loss of Controlled Substances

- Although not specifically required by federal law, the pharmacy should also notify local law enforcement and your state board of pharmacy.
- If there is a question as to whether a theft has occurred or a loss is significant, the pharmacy should err on the side of caution and report it to DEA, board of pharmacy and local law enforcement authorities.

Theft or Loss of Controlled Substances

- Although the CSA regulations do not define the term "significant loss," it is the responsibility of the pharmacy to use their best judgment and take appropriate action. Whether a "significant loss" has occurred depends 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 single pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.

Theft or Loss of Controlled Substances

- The loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a pharmacy and must be reported. The burden of responsibility is on the pharmacy to identify what is a significant loss and make the required report to DEA. Again, call the DEA for guidance.
- When determining whether a loss is significant, a pharmacy should consider, among others, the following factors:

Theft or Loss of Controlled Substances

- 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

Theft or Loss of 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
- Local trends and other indicators of the diversion potential of the missing controlled substances.

Theft or Loss of 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's discretion.

Theft or Loss of Controlled Substances

- When all or part of a 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 pharmacy is responsible for reporting any loss of controlled substances after he/she has signed for or taken custody of a shipment.

Theft or Loss of Controlled Substances

- If it is discovered after that point that an in-transit loss or theft has occurred; the pharmacy must then submit DEA Form 106.
- If the pharmacy 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.
- You should also notify your State Board of Pharmacy of any prescription drugs are lost or stolen in-transit.

Spillage/Breakage of Controlled Substances

- Spillage and Breakage is not considered a “loss”
- Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any ***recoverable*** controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process.

Spillage/Breakage of Controlled Substances

- The DEA recommends that any pharmacy seeking to dispose of controlled substances first contact the nearest DEA Diversion Field Office for disposal instructions. In no case should drugs be forwarded to the DEA unless the pharmacy has received prior approval from the DEA.
- If the breakage or spillage is ***not*** recoverable, the registrant must document the circumstances of the breakage in the inventory records.

Spillage/Breakage of Controlled Substances

- Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of DEA Form 41, Registrant Record of Controlled Substances Destroyed, is not required for non-recoverable controlled substances.
- The DEA procedures established for the destruction of controlled substances shall not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

Spillage/Breakage of Controlled Substances

- When this disposal occurs, it must be reported to the DEA on a DEA Form 41.
- Your state board of pharmacy will also require copies of this documentation and/or other documentation specific to your state.

Power of Attorney for DEA 222 Forms

- Any pharmacy may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Form 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 Forms 222.

Power of Attorney for DEA 222 Forms

- 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 and should be readily retrievable. The power of attorney is not sent to DEA.

Power of Attorney for DEA 222 Forms

- The DEA has suggested language and a sample Power of Attorney Form on page 25 of the Pharmacist's Manual.
- Link: https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

Schedule II Prescriptions – Out of Stock

- Case: A patient brings the pharmacy a prescription for hydrocodone 5mg/acetaminophen 325mg, #60, one tablet every 6 hours. The pharmacy only has 30 tablets in stock. What can the pharmacy do?

Schedule II Prescriptions – Out of Stock

- A prescription for a schedule II controlled substance may be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral prescription.
- The pharmacist must note the quantity supplied on the front of the written prescription, on a written record of the emergency oral prescription, or in the electronic prescription record.

Schedule II Prescriptions – Out of Stock

- The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be dispensed within the 72 hour period, the pharmacist must notify the prescriber.
- No further quantity may be supplied beyond 72 hours without a new prescription.

Partial Refilling IIIs and IVs

- Consider this example:

A patient brings you a prescription for Tylenol #3®, one tablet QID, prn #100 with 4 refills. The patient only wants to get 50 tablets at a time. How many times can the pharmacist fill this prescription with a quantity of 50?

Partial Refilling IIIs and IVs

Discussion:

The prescription was written for a total of 500 tablets. The pharmacist can dispense the entire 500 tablets as long as they are dispensed within 6 months of the date the prescription was written.

Partial Refilling IIIs and IVs

1. These are considered partial fillings.
2. The patient is entitled to the entire quantity prescribed, even is this means the number of "partial fillings" exceeds five. The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed.

Partial Refilling IIIs and IVs

3. However, all partial fills must be dispensed within 6 months of the date the prescription was written.
4. Each partial filling is recorded in the same manner as a refill.
5. Make sure your state law allows this

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- www.streetrx.com (Accessed 12/19/16)

Exam Questions

1. Which of the following are new trends in prescription drug diversion?
    a) The new "trinity" is an opioid, sleeping pill, and muscle relaxant.
    b) Clonidine is being abused by cocaine abusers.
    c) Gabapentin is one of the most abused drugs on the street.
    d) b and c
    e) a, b, and c

2. Pharmacists and physician have equal corresponding responsibility in ensuring that a controlled substance prescription is for a legitimate medical purpose.
    a) true
    b) false

3. Which of the following are checklist items to use when looking at a PDMP Report?
    a) Number of physicians the patient is seeing.
    b) Days supply per prescription.
    c) Method of payment by the patient.
    d) a and b only
    e) a, b, and c

4. Federal law states that controlled substance prescriptions can be filled no more than 3 days early.
    a) true
    b) false

5. Which patients can you receive a fax for a schedule II controlled substance?
    a) A patient living in a condo at a retirement community.
    b) A patient who prefers to have their prescriptions delivered.
    c) A hospice patient who is taking a narcotic pain killer.*
    d) b and c only
    e) a, b and c

6. It is legal for physicians to post-date prescriptions.
    a) true
    b) false

7. For a schedule II controlled substance, a physician can provide prescriptions with "do not fill until" to the patient for up to a _____ day supply.
    a) 10
    b) 30
    c) 90
    d) 120
    e) 160

8. When a pharmacy discovers that controlled substances have been stolen, the pharmacy must notify the DEA in writing within _____.
    a) one business day
    b) three business days
    c) seven business days
    d) ten business days
    e) There is no time limit.

9. Spillage and breakage of controlled substances are not considered a loss by the DEA.
    a) true
    b) false

10. If a pharmacy is out of stock of a schedule II controlled substance, the pharmacy has _____ to dispense it.
    a) 24 hours
    b) 48 hours
    c) 72 hours
    d) 7 days
    e) 30 days