Federal Pharmacy Law Practice Exam (Sample)

Study Guide

Everything you need from our exam experts!

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Questions

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1. What is the form used when ordering CII drugs?

A. DEA 106

B. DEA 222

C. DEA 315

D. DEA 404

2. What action should be taken if a controlled substance is lost or stolen?

A. Report to the police only

B. Notify the DEA immediately

C. Replace the item without reporting

D. Wait and see if it is returned

3. What is a common characteristic shared by Schedule III and IV drugs?

A. They are both available over the counter

B. They may be refilled multiple times

C. They require special storage conditions

D. They have a high potential for abuse

4. What schedule is characterized by the combination of ibuprofen + hydrocodone?

A. Schedule I

B. Schedule II

C. Schedule III

D. Schedule IV

5. How often must a controlled substance inventory be conducted according to regulations?

A. Every year

B. Every six months

C. Every two years

D. Every five years

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6. Which Schedule IV drug is recognized with the brand name Klonopin?

- **A. Clorazepate**
- **B. Amphetamine**
- **C. Clonazepam**
- **D. Diazepam**

7. Which of the following substances is classified as a Schedule II drug?

- **A. Methadone**
- **B. Hydrocodone w/ acetaminophen**
- **C. Drobabinol (Marinol)**
- **D. Codeine w/ acetaminophen (Tylenol No. 3)**

8. What is the function of a commercial invoice in pharmacy operations?

- **A. To provide a product warranty**
- **B. To serve as proof of receipt for controlled substances**
- **C. To record patient payment details**
- **D. To track employee performance**

9. What information must be recorded in a pharmacy's controlled substances record keeping system?

- **A. Prescription number and pharmacy location**
- **B. Date of purchase, quantity received, name of supplier, and prescription number**
- **C. Prescriber information and patient insurance details**
- **D. Only the date of purchase and quantity received**

10. Which medication is identified as Schedule II and is a strong opioid pain reliever?

- **A. Oxycodone**
- **B. Hydrocodone**
- **C. Meperidine**
- **D. All of the above**

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Answers

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1. B
2. B
3. B
4. C
5. C
6. C
7. A
8. B
9. B
10. D

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Explanations

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1. What is the form used when ordering CII drugs?

A. DEA 106

B. DEA 222

C. DEA 315

D. DEA 404

The correct form used for ordering controlled substances classified as Schedule II drugs (CII) is the DEA 222 form. This form is specifically designed to request and transfer CII medications, ensuring proper tracking and accountability in the supply chain of narcotics. The DEA 222 form is a triplicate form that allows pharmacies, hospitals, and practitioners to order CII substances from wholesalers or manufacturers. Each copy of the form serves a distinct purpose: one for the supplier, one for the purchaser, and one for the DEA. This system helps maintain a detailed record of CII drug transactions, which is critical for regulatory compliance and preventing misuse. In contrast, the other forms listed serve different purposes. For example, DEA 106 is used to report the theft or loss of controlled substances, DEA 315 is for the application for a manufacturing registration, and DEA 404 relates to the registration needed for a non-resident manufacturer or distributor. Each of these forms addresses specific regulatory processes, but none is suitable for ordering CII drugs like the DEA 222 form.

2. What action should be taken if a controlled substance is lost or stolen?

A. Report to the police only

B. Notify the DEA immediately

C. Replace the item without reporting

D. Wait and see if it is returned

When a controlled substance is lost or stolen, it is crucial to notify the Drug Enforcement Administration (DEA) immediately. According to federal regulations, pharmacies and healthcare providers are required to report any theft or significant loss of controlled substances to the DEA as soon as possible, but no later than one business day after the discovery of the loss. This allows the DEA to investigate the incident and take necessary actions to prevent further occurrences. Reporting to law enforcement is also important and may be part of the process, but the DEA must be notified as part of the regulatory compliance requirements specific to controlled substances. Simply replacing the lost item without reporting is not permissible, as it fails to address the legal obligations and potential implications of the loss. Waiting to see if the item is returned does not fulfill the requirement to report the incident and can result in severe consequences for the pharmacy or healthcare provider. Therefore, promptly notifying the DEA is the appropriate and legally mandated action to take in the event of a loss or theft of controlled substances.

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3. What is a common characteristic shared by Schedule III and IV drugs?

A. They are both available over the counter

B. They may be refilled multiple times

C. They require special storage conditions

D. They have a high potential for abuse

Schedule III and IV drugs are indeed characterized by the allowance for multiple refills. The law permits these medications to be refilled up to five times within a six-month period from the date of the original prescription. This reflects a balance between managing the potential for abuse and ensuring access to medications that may be needed on a regular basis for legitimate medical use. In contrast to other schedules, Schedule I and II drugs have stricter regulations, including limits on refills (typically no refills allowed) due to their higher potential for abuse and dependency. Schedules III and IV drugs are considered to have a lower potential for abuse compared to I and II, allowing for this more flexible approach regarding refilling prescriptions. While other choices touch on aspects of drug regulation, they do not accurately apply to both Schedule III and IV drugs. Availability over the counter is incorrect as these schedules must be obtained through a prescription. Special storage conditions are generally not mandated for these schedules in the same way they are for more controlled substances. Finally, Schedule III and IV drugs are recognized as having a moderate to low potential for abuse, which is significantly less than that of Schedule I and II drugs.

4. What schedule is characterized by the combination of ibuprofen + hydrocodone?

A. Schedule I

B. Schedule II

C. Schedule III

D. Schedule IV

The combination of ibuprofen and hydrocodone is classified as a Schedule III controlled substance. Federal regulations categorize drugs based on their potential for abuse and accepted medical use. Schedule III drugs are substances that have a lower potential for abuse compared to Schedule I and II drugs, and they can be prescribed by a healthcare provider. Hydrocodone, when combined with non-narcotic analgesics like ibuprofen, is less likely to lead to severe psychological or physical dependence, which is one of the key factors in determining its schedule. This classification allows it to be prescribed with less stringent restrictions compared to Schedule II substances, such as ones found in opioid formulations that are more potent on their own. The combination serves to manage pain effectively while potentially reducing the risk of addiction associated with stronger opioid formulations. The other schedules involve substances with varying levels of restriction and abuse potential, where Schedule I contains drugs with no accepted medical use, Schedule II contains more potent drugs with a higher potential for abuse and stricter prescribing regulations, and Schedule IV encompasses medications with an even lower potential for abuse, allowing for more liberal prescribing. Thus, the classification of ibuprofen and hydrocodone as Schedule III reflects its status as a medically accepted and less tightly controlled option

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5. How often must a controlled substance inventory be conducted according to regulations?

A. Every year

B. Every six months

C. Every two years

D. Every five years

The correct frequency for conducting a controlled substance inventory is every two years. This requirement is in accordance with the regulations established by the Drug Enforcement Administration (DEA) under the Controlled Substances Act. Conducting an inventory every two years helps ensure that pharmacies and other registrants maintain accurate records of their controlled substance stocks, which is crucial for preventing misuse and maintaining compliance with federal law. The inventory serves as a measure to check for discrepancies, reduce the risks of loss, and increase accountability regarding the handling of controlled substances. Options indicating more frequent inventories, such as annually or every six months, do not align with the regulatory framework set by the DEA. Conversely, conducting an inventory every five years would not meet the minimum regulatory requirement set forth by the DEA either. Thus, conducting an inventory every two years strikes the right balance between oversight and operational efficiency for entities handling controlled substances.

6. Which Schedule IV drug is recognized with the brand name Klonopin?

A. Clorazepate

B. Amphetamine

C. Clonazepam

D. Diazepam

Klonopin is the brand name for clonazepam, which is classified as a Schedule IV controlled substance. Clonazepam belongs to the benzodiazepine class of medications, primarily used to treat anxiety disorders, panic disorders, and certain types of seizures. Its effectiveness in managing these conditions, alongside its sedative properties, underpins its classification as a controlled substance, reflecting its potential for abuse and dependence relative to substances in lower schedules. The recognition of Klonopin specifically as clonazepam helps unify understanding within pharmacy practice regarding the medications that patients might be prescribed. Knowing brand names and their corresponding generic substances is crucial for professionals in the field, as it aids in avoiding medication errors and facilitates effective communication among healthcare providers and patients. In this context, the other options represent different drugs with distinct uses and classifications. Clorazepate, for example, is also a benzodiazepine but is not marketed under the name Klonopin. Amphetamine is a stimulant with different applications, and diazepam is another benzodiazepine but is known by the brand name Valium. Thus, identifying clonazepam as the correct substance corresponding to the brand Klonopin is essential for both patient safety and professional practice within pharmacy.

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7. Which of the following substances is classified as a Schedule II drug?

A. Methadone

B. Hydrocodone w/ acetaminophen

C. Drobabinol (Marinol)

D. Codeine w/ acetaminophen (Tylenol No. 3)

Methadone is classified as a Schedule II drug due to its high potential for abuse, which can lead to severe psychological or physical dependence. Schedule II substances are considered to have legitimate medical uses but are tightly regulated because of the risks associated with their misuse. Methadone is primarily used in the treatment of opioid addiction and for pain management. In contrast, hydrocodone with acetaminophen is often classified as a Schedule III drug when combined with other non-narcotic analgesics, indicating a lower potential for abuse compared to Schedule II substances. Dronabinol (Marinol) is a Schedule III drug as well, primarily used for nausea and to stimulate appetite in certain patient populations. Codeine with acetaminophen, commonly known as Tylenol No. 3, is classified as a Schedule III drug, signifying it has lower abuse potential than Schedule II drugs. Understanding the classification system of controlled substances is crucial for ensuring their safe and effective use while minimizing the risk of abuse and dependency.

8. What is the function of a commercial invoice in pharmacy operations?

A. To provide a product warranty

B. To serve as proof of receipt for controlled substances

C. To record patient payment details

D. To track employee performance

In pharmacy operations, a commercial invoice serves as a key document that plays a crucial role in the supply chain, particularly in the context of controlled substances. It functions as proof of receipt when pharmaceuticals, especially regulated items like controlled substances, are shipped from wholesalers or manufacturers to pharmacies. This document contains important details about the transaction, including the type and quantity of substances being delivered. The significance of having a commercial invoice lies in its use during inspections or audits by regulatory authorities. The invoice verifies that the pharmacy has received the exact quantity of controlled substances that were shipped, thereby maintaining compliance with legal and regulatory requirements. Pharmacies must accurately maintain records of these transactions to ensure accountability and traceability of controlled substances, which is essential for preventing misuse and diversion. Understanding the purpose of a commercial invoice helps pharmacy personnel appreciate the importance of documentation in ensuring the legality and safety of the pharmaceutical distribution process.

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9. What information must be recorded in a pharmacy's controlled substances record keeping system?

A. Prescription number and pharmacy location

B. Date of purchase, quantity received, name of supplier, and prescription number

C. Prescriber information and patient insurance details

D. Only the date of purchase and quantity received

The correct choice emphasizes the necessity for specific information to be meticulously documented in a pharmacy's controlled substances record-keeping system. This includes the date of purchase, the quantity of the controlled substance received, the name of the supplier, and the prescription number associated with the order. Recording the date of purchase is vital for tracking when substances have entered the pharmacy, which aids in inventory management and regulatory compliance. The quantity received must be documented to maintain accurate inventory records, ensuring that the pharmacy does not exceed federal and state limits on stock. Additionally, noting the name of the supplier is crucial for accountability and traceability, enabling the pharmacy to confirm the legitimacy of the products received and to maintain a reliable source of controlled substances. Lastly, the prescription number is important as it ties the substance back to the specific patient or prescriber, allowing for better oversight and record management in patient care. This thorough record-keeping is essential not only for operational efficiency but also for ensuring compliance with federal laws governing controlled substances, thereby preventing misuse and facilitating monitoring of substance distribution within the pharmacy. The other options do not provide the same depth or relevancy regarding the requirements stipulated by federal regulations for controlled substances.

10. Which medication is identified as Schedule II and is a strong opioid pain reliever?

A. Oxycodone

B. Hydrocodone

C. Meperidine

D. All of the above

The correct identification of a Schedule II medication that acts as a strong opioid pain reliever includes Oxycodone, Hydrocodone, and Meperidine. Schedule II substances are classified under the Controlled Substances Act as having a high potential for abuse, which may lead to severe psychological or physical dependence. Oxycodone is widely used to manage moderate to severe pain, exhibiting high potency and effectiveness in pain relief. Hydrocodone, also a strong opioid, is utilized predominantly in combination with other medications for pain relief, particularly in a hydrocodone-acetaminophen formulation. Meperidine, although less frequently used today due to safety concerns, is another potent opioid that is classified as Schedule II. Each of these medications requires careful management and is subject to strict regulatory controls due to their potential for abuse and addiction. Therefore, the answer includes all of these medications, as they all meet the criteria for Schedule II classification.

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