

PTCB Pharmacy Law Practice Exam (Sample)

Study Guide



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SAMPLE

Questions

- 1. According to federal law, what DEA form is needed for your pharmacy to transfer a bottle of percocet to another pharmacy?**
 - A. 104**
 - B. 106**
 - C. 222**
 - D. 224**
- 2. What must be reviewed in a pharmacy before a prescription can be dispensed?**
 - A. Patient's blood type**
 - B. The prescriber's office hours**
 - C. Insurance provider restrictions**
 - D. Patient's medication profile**
- 3. Which federal agency is responsible for the regulation of labeling on prescription and OTC medications?**
 - A. DEA**
 - B. CDC**
 - C. FDA**
 - D. FEMA**
- 4. What is the primary goal of the TIRF program concerning opioids?**
 - A. Reduce drug manufacturing**
 - B. Prevent misuse**
 - C. Support health insurance**
 - D. Control price fluctuations**
- 5. The iPLEDGE program requires patients to register if they are prescribed:**
 - A. Accutane**
 - B. Isotretinoin**
 - C. Finasteride**
 - D. Adapalene**

- 6. What section of the NDC identifies the manufacturer?**
- A. Third**
 - B. First**
 - C. Second**
 - D. Fourth**
- 7. After which phase of the drug approval process does a company file a New Drug Application (NDA) to sell the drug on the market?**
- A. Phase 1 testing**
 - B. Phase 2 testing**
 - C. Phase 3 testing**
 - D. Post-marketing surveillance**
- 8. What is the "do not dispense after" date on isotretinoin prescriptions for female patients of child-bearing age?**
- A. 4 days after the last negative pregnancy test**
 - B. 7 days after the last negative pregnancy test**
 - C. 14 days after the prescription date**
 - D. 30 days after the last negative pregnancy test**
- 9. Who enforces the Controlled Substance Act?**
- A. FDA**
 - B. DEA**
 - C. NIAAA**
 - D. CDC**
- 10. Which section of the NDC identifies the strength, name, and dosage form of a medication?**
- A. First**
 - B. Second**
 - C. Third**
 - D. Fourth**

Answers

SAMPLE

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

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Explanations

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1. According to federal law, what DEA form is needed for your pharmacy to transfer a bottle of percocet to another pharmacy?

- A. 104**
- B. 106**
- C. 222**
- D. 224**

A pharmacy is required to use DEA Form 222 for the transfer of controlled substances, such as percocet, to another pharmacy. This form is specifically designated for the ordering and transferring of Schedule I and II controlled substances, ensuring that such transactions are meticulously documented and compliant with federal regulations. The completion of DEA Form 222 involves providing details such as the quantity and type of the controlled substance being transferred, along with identification information for both the transferring and receiving pharmacies. This helps maintain an accurate inventory and enhances accountability in the handling of controlled substances, which is crucial for preventing misuse and ensuring regulatory compliance. In contrast, other forms mentioned, such as 104 and 106, serve different purposes. Form 104 is used for the voluntary surrender of a registration, and Form 106 is utilized for reporting the theft or loss of controlled substances. Form 224 is applied for the registration of a pharmacy to handle controlled substances, not specifically for transferring them. Hence, while all these forms play a role in the regulatory framework for controlled substances, only DEA Form 222 is applicable for transferring a bottle of percocet from one pharmacy to another.

2. What must be reviewed in a pharmacy before a prescription can be dispensed?

- A. Patient's blood type**
- B. The prescriber's office hours**
- C. Insurance provider restrictions**
- D. Patient's medication profile**

Before a prescription can be dispensed, it is essential to review the patient's medication profile. This profile contains a comprehensive record of the patient's prescribed medications, over-the-counter drugs, and any relevant health information. By assessing this profile, pharmacists can identify potential drug interactions, allergies, duplicative therapies, or contraindications that could adversely affect the patient's health. The medication profile plays a critical role in ensuring patient safety and providing effective pharmaceutical care. It allows pharmacists to make informed decisions regarding the appropriateness of the prescribed medication based on the patient's overall therapeutic regimen. This review is vital not only for safe dispensing but also for optimizing the medication therapy management process. Other options, while relevant in certain contexts, do not hold the same level of necessity in the immediate review before dispensing a prescription. For instance, knowing a patient's blood type is typically more pertinent to specific medical procedures or blood transfusions rather than routine medication dispensing. The prescriber's office hours are useful logistics, but they do not directly impact the medication's appropriateness. Similarly, understanding insurance provider restrictions is important for coverage and reimbursement but does not inform the clinical decision-making process associated with the safety and efficacy of the prescription itself.

3. Which federal agency is responsible for the regulation of labeling on prescription and OTC medications?

- A. DEA**
- B. CDC**
- C. FDA**
- D. FEMA**

The Food and Drug Administration (FDA) is the federal agency responsible for regulating the labeling of both prescription and over-the-counter (OTC) medications. This regulation includes ensuring that labels provide adequate directions for use, appropriate warnings, and other necessary information to help consumers and healthcare providers make informed decisions regarding the safe and effective use of medications. The FDA's role is crucial in maintaining public health by overseeing that all information on medication labels is accurate, truthful, and not misleading. Regulation of medication labeling is part of the FDA's broader mandate to ensure the safety and efficacy of drugs available to the public. This includes reviewing labels during the drug approval process and enforcing regulations once the drugs are on the market. Through these measures, the FDA helps ensure that patients receive vital information regarding their medications, which can help avoid misuse and enhance treatment outcomes.

4. What is the primary goal of the TIRF program concerning opioids?

- A. Reduce drug manufacturing**
- B. Prevent misuse**
- C. Support health insurance**
- D. Control price fluctuations**

The primary goal of the TIRF (Transmucosal Immediate-Release Fentanyl) program is to prevent misuse of potent opioid medications. The TIRF program was established to ensure that these medications are prescribed and used appropriately, particularly because of their high risk for abuse and potential for overdose. TIRF medications are specific formulations of fentanyl that are effective for treating breakthrough pain in patients who are already on a stable dose of around-the-clock opioid therapy. Given the risks associated with these strong opioids, the program emphasizes the importance of educating healthcare providers and patients on safe use and proper storage to reduce the likelihood of misuse, accidental exposure, and diversion. By focusing on misuse prevention, the program aims to promote safe prescribing practices and improve patient outcomes while minimizing the risks associated with opioid therapy. This is crucial in the context of the ongoing opioid crisis, where misuse and addiction have become critical public health issues.

5. The iPLEDGE program requires patients to register if they are prescribed:

A. Accutane

B. Isotretinoin

C. Finasteride

D. Adapalene

The iPLEDGE program specifically mandates that patients prescribed isotretinoin must register due to the potential risks associated with its use, particularly the severe teratogenic effects it can have on a developing fetus. Isotretinoin is a powerful medication often used for the treatment of severe acne, and its use comes with strict requirements to prevent pregnancy during treatment. The program was instituted to ensure that patients are aware of the risks, understand the necessary precautions, and comply with the birth control measures that are part of the safety protocol to avoid birth defects. This registration process helps monitor the use of the medication and reinforces the importance of safe practices while being treated with isotretinoin. In contrast, while Accutane is a brand name for isotretinoin and would also require registration, the iPLEDGE program specifically identifies the generic name. Finasteride and adapalene have different indications and safety profiles, and are not subject to the strict regulations of the iPLEDGE program.

6. What section of the NDC identifies the manufacturer?

A. Third

B. First

C. Second

D. Fourth

The first section of the National Drug Code (NDC) is specifically designated to identify the labeler, which typically refers to the manufacturer or distributor of the medication. The NDC is composed of a three-segment number usually formatted as 5-4-2 digits. The first segment, containing 5 digits, reveals the identity of the company that manufactures or distributes the drug product, making it essential for recognizing the responsible party for that medication. This information is critical in pharmacy practice as it helps pharmacists verify the source of the medication and ensures patient safety by allowing for recalls and tracking purposes when necessary. Understanding this structure is crucial for anyone involved in pharmacy operations or education.

7. After which phase of the drug approval process does a company file a New Drug Application (NDA) to sell the drug on the market?

- A. Phase 1 testing**
- B. Phase 2 testing**
- C. Phase 3 testing**
- D. Post-marketing surveillance**

The correct answer is linked to the importance of Phase 3 testing in the drug approval process. Before a pharmaceutical company can market a new drug, it must conduct rigorous clinical trials to ensure safety and efficacy. Phase 3 testing is the final stage of clinical trials where the drug is tested on a large population to confirm its effectiveness and monitor side effects. Successful completion of Phase 3 provides substantial evidence that the drug is both safe and effective for the intended use. Once this phase is concluded, the data collected is compiled into a New Drug Application (NDA), which is then submitted to the Food and Drug Administration (FDA) for review. This step is critical as the NDA serves as a formal proposal to the FDA for approval to market the drug. If the NDA is approved, the company is granted the ability to sell the drug commercially. Understanding this sequence highlights the regulatory pathway that ensures drugs meet necessary safety and efficacy standards before reaching the public.

8. What is the "do not dispense after" date on isotretinoin prescriptions for female patients of child-bearing age?

- A. 4 days after the last negative pregnancy test**
- B. 7 days after the last negative pregnancy test**
- C. 14 days after the prescription date**
- D. 30 days after the last negative pregnancy test**

The "do not dispense after" date on isotretinoin prescriptions for female patients of child-bearing age is set at 7 days after the last negative pregnancy test. This is established to ensure patient safety, as isotretinoin is a powerful teratogenic drug that can cause severe birth defects if taken during pregnancy. The 7-day window allows sufficient time to ensure that the medication is dispensed while providing a safeguard against the risk of pregnancy. This requirement is part of the iPLEDGE program, which was implemented to minimize the risks associated with isotretinoin use in women of reproductive potential. The program mandates that women must undergo monthly pregnancy testing and that prescriptions should be filled within a certain timeframe after these tests to ensure their ongoing negative status.

9. Who enforces the Controlled Substance Act?

- A. FDA
- B. DEA**
- C. NIAAA
- D. CDC

The enforcement of the Controlled Substance Act falls primarily to the Drug Enforcement Administration (DEA). The DEA is a federal agency under the Department of Justice that is specifically responsible for enforcing the provisions of the Controlled Substances Act. This act regulates the manufacture, distribution, and dispensing of controlled substances, aiming to prevent illegal drug trafficking and misuse while ensuring that those who require these substances for legitimate medical purposes have access to them. The DEA conducts investigations, initiates enforcement actions, and collaborates with other agencies and law enforcement to monitor compliance. Their role is central to ensuring that controlled substances are handled properly according to the law, making them the primary authority in this area. Other agencies mentioned, such as the FDA, NIAAA, and CDC, have distinct functions related to drug regulation, public health, or alcohol use, but they do not have the primary responsibility for enforcing the Controlled Substance Act.

10. Which section of the NDC identifies the strength, name, and dosage form of a medication?

- A. First
- B. Second**
- C. Third
- D. Fourth

The correct answer highlights the role of the second section of the National Drug Code (NDC). In the NDC format, which consists of three segments, the second segment specifically provides critical information about the medication's strength, name, and dosage form. The NDC is structured as a unique identifier that connects the drug to its manufacturer and related characteristics. The first section identifies the labeler or manufacturer, while the third segment typically indicates the package size and types. By focusing on the second section, it becomes clear that this part provides essential details such as how strong the medication is, the official name of the drug, and the form it comes in (e.g., tablet, liquid, etc.). This information is vital for pharmacists and healthcare providers to ensure they dispense the correct medication and dosage to patients accurately. Understanding this structure helps reinforce the importance of correct medication identification in pharmacy practice.