

# Rhode Island Multistate Pharmacy Jurisprudence (MPJE) Practice Exam (Sample)

## Study Guide



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**SAMPLE**

## **Questions**

- 1. Who is recognized as a practitioner able to prescribe controlled substances?**
  - A. Nurse practitioners only**
  - B. APRN, PA, physician, and dentist**
  - C. Physical therapists and pharmacists**
  - D. Only scientists in research**
- 2. For Schedule III-V prescriptions, what is the maximum supply duration allowed?**
  - A. 30 days**
  - B. 60 days**
  - C. 90 days**
  - D. 120 days**
- 3. What must a prescriber note on a CII prescription for a patient in a hospice facility?**
  - A. Emergency prescription**
  - B. Hospice**
  - C. Severe illness**
  - D. Chronic medication**
- 4. What is the minimum dosage of sodium in an OTC drug that requires it to be labeled?**
  - A. 1 mg**
  - B. 5 mg**
  - C. 10 mg**
  - D. 15 mg**
- 5. What is required for dietary supplements to promote health claims under DSHEA?**
  - A. The FDA approves the claim by regulation or scientific agreement**
  - B. Claims must be based solely on anecdotal evidence**
  - C. Claims require no regulation or approval**
  - D. Health claims must include a warning label only**

- 6. For controlled substances classified as schedule III-V, which prescription details can be changed?**
- A. Dosage form and doctor's name**
  - B. Drug strength and patient's insurance**
  - C. Directions for use and issue date**
  - D. Multiple factors including dosage form and strength**
- 7. What type of drug application is an ANDA, and what does it specifically require?**
- A. New Drug Application; must demonstrate safety**
  - B. Abbreviated New Drug Application; must be bioequivalent**
  - C. Full New Drug Application; must provide clinical data**
  - D. Supplemental New Drug Application; must include manufacturing changes**
- 8. In what context is diphenoxylate significant within Schedule V classification?**
- A. It is prohibited.**
  - B. It requires co-administration with atropine sulfate.**
  - C. It is only available in compounding.**
  - D. It has no maximum dosage limitation.**
- 9. What must be included on the label of herbal supplements to ensure truthful and non-misleading claims?**
- A. A warning label**
  - B. A disclaimer**
  - C. An expiration date**
  - D. A manufacturing date**
- 10. What leads to a drug being labeled as misbranded if determined to deteriorate?**
- A. Lack of proper packaging**
  - B. Expiration date not indicated**
  - C. Over-the-counter availability**
  - D. FDA approval missing**

## **Answers**

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

SAMPLE

## **Explanations**

SAMPLE



**1. Who is recognized as a practitioner able to prescribe controlled substances?**

- A. Nurse practitioners only
- B. APRN, PA, physician, and dentist**
- C. Physical therapists and pharmacists
- D. Only scientists in research

The recognition of who can prescribe controlled substances is crucial in ensuring that medications are dispensed safely and responsibly. The correct answer identifies a range of healthcare professionals, which encompasses Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), physicians, and dentists. These practitioners have the necessary training and clinical expertise to evaluate patients, diagnose conditions, and prescribe medications, including controlled substances when it is appropriate for patient care. Their ability to prescribe is usually contingent on state regulations and the scope of practice defined by their licensing boards. In contrast, options such as nurse practitioners only or other combinations that do not include the full scope of recognized prescribers limit the range of professionals who can effectively contribute to patient care. Similarly, physical therapists and pharmacists, while essential members of the healthcare team, typically do not have prescribing authority over controlled substances in general practice; rather, their roles involve education and administration within defined parameters. Lastly, scientists in research primarily participate in experimental or academic settings, where they may not have direct patient care responsibilities or the authority to prescribe medications in a clinical context. This broad acknowledgment of multiple healthcare practitioners is designed to enhance patient access to medical care while ensuring that control measures are in place to prevent misuse of controlled substances.

**2. For Schedule III-V prescriptions, what is the maximum supply duration allowed?**

- A. 30 days
- B. 60 days
- C. 90 days**
- D. 120 days

The correct response highlights that for prescriptions categorized under Schedule III to V, the maximum allowable supply duration is indeed 90 days. This regulation aligns with federal law, which stipulates that a prescription for controlled substances in these schedules can be refilled within a timeframe that does not exceed 90 days from the date of the original prescription. This provision ensures that patients receive adequate therapy while allowing for a reasonable amount of medication to be dispensed at one time. In contrast, the other options reflect shorter durations that do not meet the established federal guidelines, limiting the ability of patients to access their required medications for longer-term treatments or for chronic conditions that necessitate consistent management with controlled substances. Recognizing the 90-day limit helps pharmacists properly manage prescriptions and ensures compliance with legal requirements regarding controlled substances. This understanding is essential in pharmacy practice to safeguard patient care while adhering to statutory regulations.

**3. What must a prescriber note on a CII prescription for a patient in a hospice facility?**

- A. Emergency prescription**
- B. Hospice**
- C. Severe illness**
- D. Chronic medication**

When a prescriber issues a prescription for a schedule II controlled substance (CII) for a patient in a hospice facility, it is essential for them to indicate "hospice" on that prescription. This notation communicates to pharmacists and regulatory bodies that the patient is receiving end-of-life care in a hospice setting. Such a designation helps to streamline the dispensing process and is particularly important for ensuring that the medication prescribed is being used to manage pain or symptoms in patients who are typically experiencing significant health challenges. In the context of hospice care, patients often require control of pain and other distressing symptoms, which may necessitate the use of CII medications. Noting "hospice" on the prescription signifies to the pharmacist that these medications are intended for patients in this specific care setting, which may influence the interpretation of regulations surrounding controlled substances and facilitate the lawful and appropriate dispensing of medications. The other options do not provide the same level of clarity or relevance regarding the setting of care and prescribing requirements for CII medications within hospice. Options like "emergency prescription," "severe illness," and "chronic medication" lack the specific identification that the "hospice" designation supplies, and could lead to misunderstandings about the intent and context of the

**4. What is the minimum dosage of sodium in an OTC drug that requires it to be labeled?**

- A. 1 mg**
- B. 5 mg**
- C. 10 mg**
- D. 15 mg**

The requirement for labeling sodium content in over-the-counter (OTC) drugs is based on safety regulations aimed at consumers who may be on sodium-restricted diets or who need to monitor their sodium intake for health reasons. According to the regulations, products containing sodium must include labeling when the sodium content is 5 milligrams or more per dosage unit. This threshold is established to inform consumers adequately without overwhelming them with information about very low sodium levels, which are typically not a health concern. Therefore, 5 mg is the minimum dosage that necessitates sodium labeling in OTC medications, ensuring consumer safety and compliance with health guidelines.

**5. What is required for dietary supplements to promote health claims under DSHEA?**

- A. The FDA approves the claim by regulation or scientific agreement**
- B. Claims must be based solely on anecdotal evidence**
- C. Claims require no regulation or approval**
- D. Health claims must include a warning label only**

The correct response is that health claims related to dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) must be scientifically substantiated and, in some cases, approved by the FDA. Specifically, any health claims that a dietary supplement is intended to prevent or treat a disease must be supported by significant scientific evidence and ideally, go through a regulatory process with the FDA. This ensures that the claims are accurate and not misleading to consumers. The other choices do not align with the requirements outlined in DSHEA. Claims based solely on anecdotal evidence do not meet the standard of scientific substantiation necessary for health claims. Claims requiring no regulation or approval do not reflect the FDA's oversight for dietary supplements making certain health claims. Lastly, while warning labels can be necessary depending on the ingredients and claims made, they do not suffice as a standalone requirement for health claims to be valid under DSHEA regulations.

**6. For controlled substances classified as schedule III-V, which prescription details can be changed?**

- A. Dosage form and doctor's name**
- B. Drug strength and patient's insurance**
- C. Directions for use and issue date**
- D. Multiple factors including dosage form and strength**

In the context of controlled substances classified as Schedule III to V, certain prescription details may be modified after consultation with the prescriber to ensure patient safety and compliance with legal regulations. Among these details, dosage form and strength are permissible changes. This flexibility allows pharmacists to accommodate specific patient needs, such as switching from a tablet to a liquid formulation or adjusting to a different strength based on the patient's condition. The importance of involving the prescriber in these modifications is critical, as it maintains the integrity of the original therapeutic intentions while allowing for necessary adjustments. The ability to change these factors aligns with the regulatory framework governing pharmacy practice, aiming for optimal patient care while adhering to legal guidelines. Other options suggest changes that may not be as widely accepted or may impose restrictions based on pharmacy regulations. For instance, the doctor's name typically can't be altered as it needs to represent the individual who authorized the prescription. Similarly, changes to the patient's insurance details do not directly pertain to the therapeutic content of the medication itself and thus fall outside the scope of acceptable modifications for the substance classification.

**7. What type of drug application is an ANDA, and what does it specifically require?**

- A. New Drug Application; must demonstrate safety**
- B. Abbreviated New Drug Application; must be bioequivalent**
- C. Full New Drug Application; must provide clinical data**
- D. Supplemental New Drug Application; must include manufacturing changes**

An Abbreviated New Drug Application (ANDA) is specifically designed for generic drugs, allowing manufacturers to seek approval without having to conduct the expensive and time-consuming clinical trials typically required for new drugs. What distinguishes an ANDA is its requirement for the applicant to demonstrate that the generic product is bioequivalent to the original branded drug. Bioequivalence means that the generic product delivers the same amount of active ingredient into a patient's bloodstream in the same amount of time as the original drug, ensuring that it is therapeutically equivalent and will have the same safety and efficacy profile as the brand-name medication. This streamlined process helps to facilitate the entry of generic drugs into the market, promoting competition and affordability. The other options listed reflect misunderstandings of the requirements for different types of drug applications. A New Drug Application entails comprehensive data on safety and efficacy, while a Full New Drug Application requires extensive clinical data. A Supplemental New Drug Application involves modifications to an existing approved drug, typically detailing manufacturing changes.

**8. In what context is diphenoxylate significant within Schedule V classification?**

- A. It is prohibited.**
- B. It requires co-administration with atropine sulfate.**
- C. It is only available in compounding.**
- D. It has no maximum dosage limitation.**

Diphenoxylate is significant within Schedule V classification primarily because it is often combined with atropine sulfate to deter potential abuse. This combination works to minimize the addictive potential of diphenoxylate, which is an opioid used primarily as an antidiarrheal agent. The inclusion of atropine serves to produce unpleasant side effects if the medication is misused, thereby discouraging individuals from taking it in higher than prescribed doses for the euphoric effects that opioids can produce. This combined formulation is pivotal because it aligns with federal regulations that aim to mitigate the risks associated with opioid misuse while still allowing for therapeutic use in patients who require it for legitimate medical reasons. The Schedule V classification itself indicates that while diphenoxylate is available for medical use, it is recognized for its potential for dependence, hence the necessity of the addition of atropine as a safeguard. In contrast, being prohibited or having no maximum dosage limitation does not accurately reflect the guidelines set forth for this substance, as there are regulations regarding its use. Similarly, its inclusion in compounding does not capture its primary significance in the context of Schedule V classification.

**9. What must be included on the label of herbal supplements to ensure truthful and non-misleading claims?**

- A. A warning label**
- B. A disclaimer**
- C. An expiration date**
- D. A manufacturing date**

The correct answer is that a disclaimer must be included on the label of herbal supplements to ensure truthful and non-misleading claims. Disclaimers serve to clarify that the product is not intended to diagnose, treat, cure, or prevent any disease, which is crucial in demarcating the differences between dietary supplements and pharmaceuticals. This is particularly important for herbal supplements, as they often make health-related claims that may not be substantiated by scientific evidence. By including a disclaimer, manufacturers can provide consumers with critical information about the intended use of the product, helping to manage expectations and promote informed decisions. Including a warning label, an expiration date, or a manufacturing date may be important for safety and compliance but do not specifically address the need for truthful claims about the product's efficacy or purpose. Thus, while those elements play a role in consumer safety and quality assurance, it is the disclaimer that directly supports the truthfulness and clarity of the product's claims.

**10. What leads to a drug being labeled as misbranded if determined to deteriorate?**

- A. Lack of proper packaging**
- B. Expiration date not indicated**
- C. Over-the-counter availability**
- D. FDA approval missing**

A drug is labeled as misbranded if it is deemed to deteriorate primarily due to lack of proper packaging. Proper packaging is essential to protect the drug from environmental factors that could cause it to degrade or lose potency. If a drug is not properly packaged, and this inadequacy leads to deterioration, it fails to meet the standards set by regulatory agencies regarding safety and efficacy. In this context, the other options do not directly correlate to misbranding due to deterioration. An expiration date not indicated is related to labeling requirements but does not inherently cause a drug to deteriorate. Over-the-counter availability is more about the drug's classification than its condition. Missing FDA approval pertains to the legal status of a drug's marketing rather than its physical quality or packaging. Proper packaging is crucial to ensure that the product remains safe and effective until its expiration, thereby playing a pivotal role in preventing misbranding due to deterioration.