West Virginia MPJE (Pharmacy Jurisprudence) Practice Exam (Sample)

Study Guide

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Questions

1. Are precursor substances placed in the controlled substance schedule in West Virginia?

A. Yes, Schedule III

B. No, they are not scheduled

C. Yes, Schedule V

D. Yes, Schedule II

2. What is the electronic equivalent of the DEA 222 form?

A. Electronic Prescription Management System (EPMS)

B. Automated Drug Order System (ADOS)

C. Controlled Substances Ordering System (CSOS)

D. Drug Enforcement Secure System (DESS)

3. What does the term "misbranding" mean?

A. Keeping expired drugs

B. Inaccurate drug labeling

C. Dispensing drugs without a prescription

D. Drug quality is below standard

4. True or False: Opened prescription drug containers must be identified as opened and be physically separated from other prescription drugs until they are destroyed or returned to the supplier.

A. False

B. True

5. Which law made a clear distinction between OTC and Rx drugs?

A. Adulteration and Misbranding Act

B. Durham-Humphrey Amendment of 1951

C. Federal False Claims Act of 1982

D. Pure Food and Drug Act of 1906

6. What must be included in the label of customized med paks that contain controlled substances?

A. Date of birth of the patient

B. Directions and required cautionary statements for each drug

C. Pharmacist's signature and license number

D. Signature of the prescriber

7. What kind of prescribing authority do EMT paramedics and midwives (not nurse midwives) have in West Virginia?

A. Full prescriptive authority

B. Limited prescribing for emergency medications only

C. No prescriptive authority, use only

D. Prescriptive authority for controlled substances only

8. A practitioner not registered with the DEA to treat narcotic addiction can administer how much treatment at one time while arranging proper referral?

A. One day's worth

B. Two day's worth

C. One week's worth

D. Three day's worth

9. Under the guidance of which law do generic drug manufacturers use the ANDA for approval?

A. Biologics Control Act of 1902

B. Drug Listing Act of 1972

C. Hatch-Waxman Act (Price Competition and Patent Act) of 1984

D. Prescription Drug Marketing Act of 1987

10. What is the BUD for a nonaqueous formulation (lotion, cream, ointment, etc.)?

A. 6 months or the time remaining until the earliest expiration date of any API, whichever is earlier

B. 14 days or the time remaining until the earliest expiration date of any API, whichever is earlier

C. 30 days or the time remaining until the earliest expiration date of any API, whichever is earlier

D. 12 months or the time remaining until the earliest expiration date of any API, whichever is earlier

Answers

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

Explanations

1. Are precursor substances placed in the controlled substance schedule in West Virginia?

A. Yes, Schedule III

B. No, they are not scheduled

C. Yes, Schedule V

D. Yes, Schedule II

In West Virginia, precursor substances are indeed subject to regulation under the controlled substances schedule, specifically Schedule III. This refers to the classification of certain chemicals which, while not classified as narcotics, may be used in the illegal synthesis of controlled substances and thus require oversight. Choosing Schedule III indicates an understanding of the nature of these substances within the legal framework of pharmaceuticals and controlled substances. Schedule III includes substances that have legitimate medical uses but can be manipulated to create illegal drugs. Regulatory measures are in place to ensure that handling and dispensing these precursors occur under strict guidelines to prevent misuse while allowing their medical applications. The other choices do not accurately reflect the scheduling of precursor substances in West Virginia. Schedule V includes substances with a lower potential for abuse than those in Schedule III, while Schedule II consists of substances that are highly regulated due to their strong potential for abuse. Saying they are not scheduled completely disregards the state's regulatory framework for managing these substances.

2. What is the electronic equivalent of the DEA 222 form?

A. Electronic Prescription Management System (EPMS)

B. Automated Drug Order System (ADOS)

C. Controlled Substances Ordering System (CSOS)

D. Drug Enforcement Secure System (DESS)

The correct answer is the Controlled Substances Ordering System (CSOS). The CSOS serves as the electronic equivalent of the DEA 222 form, which is used for the ordering of controlled substances. It provides a secure and efficient method for registrants such as pharmacies and hospitals to electronically order Schedule I and II controlled substances while ensuring compliance with federal regulations. The system promotes accountability and traceability throughout the chain of custody of controlled substances, helping to prevent diversion and misuse. In contrast, the other options do not fulfill the same purpose as the CSOS. The Electronic Prescription Management System (EPMS) primarily focuses on the e-prescribing of medications, which encompasses prescriptions for all medication categories, not solely controlled substances. The Automated Drug Order System (ADOS) is typically used for managing medication dispensing and inventory but does not specifically pertain to the ordering of controlled substances in the same rigorous manner as CSOS. The Drug Enforcement Secure System (DESS) is not a recognized system related to the ordering of controlled substances. Therefore, CSOS accurately reflects the electronic counterpart to the traditional DEA 222 form.

3. What does the term "misbranding" mean?

A. Keeping expired drugs

B. Inaccurate drug labeling

C. Dispensing drugs without a prescription

D. Drug quality is below standard

The term "misbranding" specifically refers to inaccurate drug labeling. This includes scenarios where the information on the drug's label is false or misleading, which can affect a healthcare provider's or patient's understanding of the drug's uses, dosage, side effects, or other critical information. It is essential for drug labeling to be accurate to ensure safe and effective use of medications. Accurate labeling is crucial for protecting public health, as consumers and healthcare professionals rely on this information for proper medication management. Other options, while related to pharmaceutical regulations, do not accurately define misbranding. Keeping expired drugs pertains to storage and handling standards rather than labeling. Dispensing drugs without a prescription involves issues of legal pharmacy practice but doesn't relate to labeling accuracy. Drug quality being below standard relates to manufacturing practices and product safety, which falls under different regulatory actions, not misbranding.

4. True or False: Opened prescription drug containers must be identified as opened and be physically separated from other prescription drugs until they are destroyed or returned to the supplier.

A. False

B. True

Prescription drugs must be stored separately from other drugs, but there is no requirement that opened containers be physically separated. Therefore, this statement is false.

5. Which law made a clear distinction between OTC and Rx drugs?

A. Adulteration and Misbranding Act

B. Durham-Humphrey Amendment of 1951

C. Federal False Claims Act of 1982

D. Pure Food and Drug Act of 1906

The Durham-Humphrey Amendment of 1951 is indeed the correct answer because this legislation specifically established the framework to differentiate between over-the-counter (OTC) drugs and prescription (Rx) drugs. Prior to this amendment, there was no formal classification, leading to potential confusion about whether certain medications required a prescription for safe use. The amendment defined two categories of drugs: those that could be safely used by consumers without a prescription when used according to the label, and those that required a healthcare provider's oversight due to their potential risks or side effects. This distinction was crucial for public health and safety, ensuring that patients only received prescription medications when necessary. The other options, while relevant to pharmaceutical law, do not focus on creating this distinction. The Adulteration and Misbranding Act deals primarily with the purity and labeling of drugs, the Federal False Claims Act pertains to fraud against the government, and the Pure Food and Drug Act of 1906 focused on the regulation of food and drug safety more generally, without establishing a clear boundary for OTC vs. Rx classification.

6. What must be included in the label of customized med paks that contain controlled substances?

A. Date of birth of the patient

B. Directions and required cautionary statements for each drug

C. Pharmacist's signature and license number

D. Signature of the prescriber

For customized med paks that contain controlled substances, the label must include directions and required cautionary statements for each drug. This requirement ensures that patients receive clear instructions on how to appropriately take their medications, as well as any important safety information relevant to each controlled substance included in the med pak. Proper labeling is essential not only for compliance with regulations but also for promoting safe medication practices and preventing misuse of controlled substances. In contrast, while having the patient's date of birth can be important for identification purposes, it is not a federal or state requirement for the labeling of med paks. The pharmacist's signature and license number, as well as the prescriber's signature, may be important for verification and accountability but are not specifically mandated components of the labeling for customized med paks containing controlled substances. The emphasis on directions and cautionary statements aligns with the overall goal of ensuring patient safety and effective medication management.

7. What kind of prescribing authority do EMT paramedics and midwives (not nurse midwives) have in West Virginia?

A. Full prescriptive authority

B. Limited prescribing for emergency medications only

C. No prescriptive authority, use only

D. Prescriptive authority for controlled substances only

In West Virginia, EMT paramedics and midwives (specifically, those who are not certified nurse midwives) have no prescriptive authority. This means that while they are trained to provide essential medical care and can administer medications, they cannot prescribe medications. Their role is typically focused on immediate patient care and stabilization, especially in emergency situations, rather than ongoing treatment plans that would require prescribing authority. This limitation is in place to ensure that prescribing responsibilities are held by professionals with the appropriate training and oversight, such as physicians or certified nurse practitioners, who can evaluate patients comprehensively before determining the necessary medications. Therefore, the correct answer reflects the clear regulatory framework governing the practice and authority of EMT paramedics and midwives in West Virginia.

8. A practitioner not registered with the DEA to treat narcotic addiction can administer how much treatment at one time while arranging proper referral?

A. One day's worth

B. Two day's worth

C. One week's worth

D. Three day's worth

The correct answer is that a practitioner not registered with the DEA to treat narcotic addiction can administer one day's worth of treatment while arranging for proper referral. This provision is in place to allow practitioners to provide immediate care to patients struggling with narcotic addiction while ensuring they do not exceed the limits set by regulations. The rationale behind this restriction is to prevent unauthorized extended treatment and to ensure that patients are eventually referred to a qualified provider who can offer comprehensive treatment. By limiting the amount to a single day's supply, the regulations maintain a level of oversight that encourages patients to seek further help rather than relying on temporary solutions. Different jurisdictions might have varying rules, but the principle remains the same. Ensuring that immediate care is available while facilitating appropriate referral paths is integral for patient safety and effective addiction management.

9. Under the guidance of which law do generic drug manufacturers use the ANDA for approval?

A. Biologics Control Act of 1902

B. Drug Listing Act of 1972

C. Hatch-Waxman Act (Price Competition and Patent Act) of 1984

D. Prescription Drug Marketing Act of 1987

Generic drug manufacturers use the Abbreviated New Drug Application (ANDA) for approval under the guidance of the Hatch-Waxman Act (Price Competition and Patent Act) of 1984. This law created the ANDA pathway, which allows generic drug manufacturers to demonstrate bioequivalence to the reference listed drug without having to conduct extensive clinical trials. Therefore, the correct answer is C. The other options are incorrect: A. The Biologics Control Act of 1902 primarily focuses on regulating the production and sale of biological products. B. The Drug Listing Act of 1972 is intended to provide the FDA with a list of all drugs being manufactured, prepared, propagated, compounded, or processed by a drug manufacturer. D. The Prescription Drug Marketing Act of 1987 primarily addresses the distribution and wholesale marketing of prescription drugs to ensure their safety and effectiveness.

10. What is the BUD for a nonaqueous formulation (lotion, cream, ointment, etc.)?

A. 6 months or the time remaining until the earliest expiration date of any API, whichever is earlier

B. 14 days or the time remaining until the earliest expiration date of any API, whichever is earlier

C. 30 days or the time remaining until the earliest expiration date of any API, whichever is earlier

D. 12 months or the time remaining until the earliest expiration date of any API, whichever is earlier

The beyond-use date (BUD) for a nonaqueous formulation is determined based on the stability of the ingredients within the formulation. For nonaqueous products, which can include lotions, creams, and ointments that do not contain water, the general guideline is that the BUD is set at 6 months, or until the earliest expiration date of any active pharmaceutical ingredient (API) in the formulation, whichever is sooner. This guideline is crucial for maintaining the efficacy and safety of the preparation, as nonaqueous formulations may have longer stability due to the absence of water, which can promote microbial growth and chemical degradation. The 6-month timeframe is a standard established by the United States Pharmacopeia (USP) for nonaqueous preparations, reflecting a balance of practicality and safety in pharmacy practice. In contrast, shorter BUDs such as 14 days and 30 days are applicable to other specific situations, like aqueous formulations (those containing water), which are more prone to microbial contamination and degradation due to hydrolysis. Therefore, selecting the BUD of 6 months aligns with the best practices in compounding pharmacy for nonaqueous formulations.