

MedTech Laws and Ethics Practice Test (Sample)

Study Guide



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SAMPLE

Questions

- 1. What does PD 657 address?**
 - A. Public Health Regulations**
 - B. Continuing Education Standards**
 - C. Professional Regulation Amendments**
 - D. Drug Regulation Policies**
- 2. What does FDA stand for?**
 - A. Food and Drug Association**
 - B. Food and Drug Administration**
 - C. Food Department of America**
 - D. Federal Drug Authority**
- 3. What is the primary goal of the Continuing Professional Development Act?**
 - A. To enhance professional skills and competencies**
 - B. To regulate drug use in society**
 - C. To establish public health policies**
 - D. To create new educational institutions**
- 4. What is RA 10912 primarily concerned with?**
 - A. Drug abuse prevention**
 - B. Continuing Professional Development**
 - C. Health care access**
 - D. Children's health issues**
- 5. What is the purpose of a Medical Device Reporting (MDR) system?**
 - A. To monitor device sales figures**
 - B. To report adverse events related to devices**
 - C. To oversee marketing strategies for devices**
 - D. To evaluate the effectiveness of marketing campaigns**

- 6. Which statement reflects the significance of patient consent in MedTech?**
- A. It is unnecessary if the device is deemed safe.**
 - B. It is critical for ensuring that patients understand the risks and benefits involved.**
 - C. It is only required for surgical procedures.**
 - D. It can be overridden by family members of the patient.**
- 7. As per PRC Resolution No. 2016-990, how frequently must medical technologists renew their qualifications?**
- A. Every year**
 - B. Every 2 years**
 - C. Every 3 years**
 - D. Every 5 years**
- 8. What are the responsibilities of healthcare professionals regarding ethical dilemmas in MedTech?**
- A. To maximize profits for their institutions**
 - B. To uphold ethical principles and advocate for patient safety and informed consent**
 - C. To follow all directives from technology companies unconditionally**
 - D. To minimize patient involvement in decision-making**
- 9. What is the main focus of RA 6425?**
- A. This Act deals with drug regulations.**
 - B. This Act pertains to educational reforms.**
 - C. This Act concerns environmental protection.**
 - D. This Act relates to health insurance provisions.**
- 10. What is the “Cadillac Tax” in healthcare?**
- A. A tax on low-cost health insurance plans**
 - B. A tax on high-cost health insurance plans intended to reduce healthcare spending**
 - C. A tax on medical device purchases**
 - D. A tax meant to incentivize preventive care**

Answers

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

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Explanations

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1. What does PD 657 address?

- A. Public Health Regulations
- B. Continuing Education Standards
- C. Professional Regulation Amendments**
- D. Drug Regulation Policies

PD 657 specifically pertains to the amendment of professional regulation standards within the healthcare and medical technology sectors. This decree introduces measures aimed at enhancing the professionalism, competency, and regulatory frameworks governing various healthcare professionals. It ensures that practitioners meet the required qualifications and adhere to defined ethical standards, thereby promoting public confidence in the health professions. The other options do not encompass the specific focus of PD 657. For instance, public health regulations generally address broader community health measures rather than specific professional standards. Continuing education standards, while important, are not the primary focus of this decree. Drug regulation policies are also distinct from PD 657's focus on the professional aspects of healthcare practitioners. Thus, the emphasis on professional regulation amendments is what makes the correct answer accurate in this context.

2. What does FDA stand for?

- A. Food and Drug Association
- B. Food and Drug Administration**
- C. Food Department of America
- D. Federal Drug Authority

The correct answer is "Food and Drug Administration." The FDA is a key regulatory agency within the U.S. Department of Health and Human Services. It is responsible for ensuring the safety, efficacy, and security of drugs, biological products, medical devices, food, and cosmetics. The agency plays a crucial role in safeguarding public health by regulating these products before they enter the market and monitoring their safety thereafter. Understanding the correct terminology is essential because it pertains to the agency's function and scope of authority. For instance, the name reflects its dual focus on both food safety and drug regulation, which are critical to public health. The incorrect options do not accurately describe the organization or its mandate, which can lead to confusion about its role and responsibilities in the healthcare system. By knowing the correct name and its implications, individuals in the medical technology field can better navigate regulatory requirements and compliance issues.

3. What is the primary goal of the Continuing Professional Development Act?

- A. To enhance professional skills and competencies**
- B. To regulate drug use in society**
- C. To establish public health policies**
- D. To create new educational institutions**

The main objective of the Continuing Professional Development Act is to enhance the professional skills and competencies of individuals in various healthcare fields. This act emphasizes the importance of lifelong learning and continually updating one's knowledge and skills to meet the evolving demands of the healthcare environment. By encouraging professionals to engage in ongoing education and training, the act aims to ensure that healthcare providers are well-equipped to deliver high-quality care and adapt to new practices and technologies. This focus on professional development recognizes that healthcare is an ever-changing field, requiring practitioners to stay current with advancements in medical knowledge, procedures, and regulations. This ongoing education ultimately leads to improved patient outcomes and higher standards of care within the healthcare system. While regulating drug use, establishing public health policies, and creating new educational institutions are all important elements of healthcare and the broader societal context, they are not the central aim of the Continuing Professional Development Act.

4. What is RA 10912 primarily concerned with?

- A. Drug abuse prevention**
- B. Continuing Professional Development**
- C. Health care access**
- D. Children's health issues**

RA 10912, also known as the Continuing Professional Development (CPD) Act of 2016, is primarily focused on enhancing the skills and knowledge of professionals in various fields, including healthcare. This law mandates that professionals must engage in continuing education and development to maintain their licenses and ensure that they are kept up-to-date with the latest practices and advancements in their respective professions. The act emphasizes the importance of lifelong learning and encourages health professionals to participate in educational programs, workshops, conferences, and other forms of training. By doing so, the law aims to improve the quality of care provided to patients and enhance the overall competency of professionals in the healthcare industry. Ensuring that practitioners remain current with evolving knowledge and practices is vital for maintaining high standards of health care delivery. While the other options listed touch upon significant aspects of health and societal issues, such as drug abuse, healthcare access, and children's health, they do not align with the specific focus of RA 10912 on professional development and competency in practice. Thus, the emphasis on continuing professional development is what makes the selected answer correct.

5. What is the purpose of a Medical Device Reporting (MDR) system?

- A. To monitor device sales figures**
- B. To report adverse events related to devices**
- C. To oversee marketing strategies for devices**
- D. To evaluate the effectiveness of marketing campaigns**

The purpose of a Medical Device Reporting (MDR) system is primarily to report adverse events related to medical devices. This system is crucial for ensuring patient safety and maintaining the integrity of medical device regulation. When healthcare professionals, manufacturers, or patients report incidents involving medical devices—such as malfunctions or injuries—regulatory authorities can collect this critical information, analyze it, and take necessary actions to prevent further occurrences. The MDR system plays a significant role in post-market surveillance, allowing the monitoring of devices after they have been approved and are in use. It helps stakeholders identify trends, potential hazards, and the overall safety and effectiveness of medical devices over time. Ultimately, the data collected through the MDR system can inform regulatory decisions, enhance device design, and improve patient outcomes by addressing potential issues proactively.

6. Which statement reflects the significance of patient consent in MedTech?

- A. It is unnecessary if the device is deemed safe.**
- B. It is critical for ensuring that patients understand the risks and benefits involved.**
- C. It is only required for surgical procedures.**
- D. It can be overridden by family members of the patient.**

The statement highlighting the critical nature of patient consent emphasizes the importance of ensuring that patients are adequately informed about the risks and benefits associated with medical technologies. Patient consent is not merely a legal requirement, but a fundamental ethical obligation that respects the autonomy of individuals. It empowers patients to make informed choices regarding their healthcare, allowing them to weigh the potential benefits of a medical device against any possible risks or side effects. Informed consent also fosters a trusting relationship between patients and healthcare providers, promoting transparency in the treatment process. It encourages discussions about alternatives and aligns medical interventions with the values and preferences of the patient. The essence of informed consent lies in providing the patient with enough information to understand their options and making a voluntary decision, which is crucial in the context of Medical Technology where innovations may involve complex risks. The other options do not correctly capture the comprehensive role of patient consent in the MedTech field: consent is required beyond just surgical procedures, it cannot be disregarded based solely on the perceived safety of a device, and it is fundamentally a decision made by the patient themselves rather than being overridden by family members.

7. As per PRC Resolution No. 2016-990, how frequently must medical technologists renew their qualifications?

- A. Every year**
- B. Every 2 years**
- C. Every 3 years**
- D. Every 5 years**

According to PRC Resolution No. 2016-990, medical technologists are required to renew their qualifications every three years. This renewal process is essential for maintaining licensure and ensuring that professionals stay current with advances in the field, as well as any changes in regulations or standards. A three-year renewal cycle helps to keep practitioners updated, reinforces the importance of continuous professional development, and ensures the ongoing competence of medical technologists in their skill set and knowledge, which is vital in the healthcare environment where technology and best practices are constantly evolving. Regular renewals serve to uphold the standards of the profession and protect patient safety by ensuring that practitioners are effectively trained and knowledgeable about the latest developments in medical technology.

8. What are the responsibilities of healthcare professionals regarding ethical dilemmas in MedTech?

- A. To maximize profits for their institutions**
- B. To uphold ethical principles and advocate for patient safety and informed consent**
- C. To follow all directives from technology companies unconditionally**
- D. To minimize patient involvement in decision-making**

Healthcare professionals have the essential responsibility to uphold ethical principles, which include advocating for patient safety and ensuring informed consent. This responsibility is central to fostering trust and respect in the patient-provider relationship, and it aligns with the overall goals of healthcare, which prioritize patient welfare and autonomy. In the context of MedTech, this means that healthcare professionals must engage with the technologies being employed, evaluate their implications, and strive to ensure that these tools enhance, rather than compromise, patient care. Advocating for informed consent involves clearly communicating the benefits, risks, and alternatives related to MedTech interventions so that patients can make educated choices about their healthcare. This commitment to ethical principles also encompasses respecting patients' rights and ensuring that their values and preferences are considered in clinical decisions. Therefore, by advocating for patient safety and informed consent, healthcare professionals can navigate ethical dilemmas effectively and serve the best interests of their patients.

9. What is the main focus of RA 6425?

- A. This Act deals with drug regulations.**
- B. This Act pertains to educational reforms.**
- C. This Act concerns environmental protection.**
- D. This Act relates to health insurance provisions.**

The main focus of RA 6425, also known as the Dangerous Drugs Act of 1972, is indeed on drug regulations. This legislation was enacted to address the growing concern of drug abuse and trafficking within the Philippines. It established legal frameworks for the control and regulation of dangerous drugs, including the penalties for drug-related offenses, the role of law enforcement in combating drug trafficking, and the establishment of rehabilitation programs for individuals affected by drug addiction. By focusing on drug regulations, the Act aims to manage and reduce the impact of illegal drugs on society, public health, and safety. This encompasses various aspects, such as defining illegal drugs, setting penalties for offenses, and detailing the responsibilities of government agencies in enforcing these laws. The emphasis on drug regulation is crucial in efforts to mitigate substance abuse and its related social problems. The other options relate to different areas: educational reforms would address the education system, environmental protection would focus on laws safeguarding the environment, and health insurance provisions would deal with healthcare financing—none of which are the primary concern of RA 6425.

10. What is the “Cadillac Tax” in healthcare?

- A. A tax on low-cost health insurance plans**
- B. A tax on high-cost health insurance plans intended to reduce healthcare spending**
- C. A tax on medical device purchases**
- D. A tax meant to incentivize preventive care**

The "Cadillac Tax" refers to a specific provision in the Affordable Care Act aimed at imposing a tax on high-cost health insurance plans. This tax is designed to target plans that provide extravagant benefits, encouraging employers and employees to become more cost-conscious about their healthcare choices. By setting a threshold above which the tax applies, it aims to reduce healthcare spending overall by incentivizing companies to offer more cost-effective insurance options rather than very generous plans that might not consider the associated costs. The rationale behind the Cadillac Tax is rooted in concerns that such high-cost plans contribute to an overall increase in healthcare expenditures, as they may encourage overutilization of services and lead to inefficiencies in the healthcare system. Thus, implementing this tax serves as a mechanism for promoting more sustainable health spending while still allowing for flexibility in how insurance coverage is structured.