

MedTech Laws and Ethics Practice Test (Sample)

Study Guide



Everything you need from our exam experts!

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Introduction

Preparing for a certification exam can feel overwhelming, but with the right tools, it becomes an opportunity to build confidence, sharpen your skills, and move one step closer to your goals. At Examzify, we believe that effective exam preparation isn't just about memorization, it's about understanding the material, identifying knowledge gaps, and building the test-taking strategies that lead to success.

This guide was designed to help you do exactly that.

Whether you're preparing for a licensing exam, professional certification, or entry-level qualification, this book offers structured practice to reinforce key concepts. You'll find a wide range of multiple-choice questions, each followed by clear explanations to help you understand not just the right answer, but why it's correct.

The content in this guide is based on real-world exam objectives and aligned with the types of questions and topics commonly found on official tests. It's ideal for learners who want to:

- Practice answering questions under realistic conditions,
- Improve accuracy and speed,
- Review explanations to strengthen weak areas, and
- Approach the exam with greater confidence.

We recommend using this book not as a stand-alone study tool, but alongside other resources like flashcards, textbooks, or hands-on training. For best results, we recommend working through each question, reflecting on the explanation provided, and revisiting the topics that challenge you most.

Remember: successful test preparation isn't about getting every question right the first time, it's about learning from your mistakes and improving over time. Stay focused, trust the process, and know that every page you turn brings you closer to success.

Let's begin.

How to Use This Guide

This guide is designed to help you study more effectively and approach your exam with confidence. Whether you're reviewing for the first time or doing a final refresh, here's how to get the most out of your Examzify study guide:

1. Start with a Diagnostic Review

Skim through the questions to get a sense of what you know and what you need to focus on. Your goal is to identify knowledge gaps early.

2. Study in Short, Focused Sessions

Break your study time into manageable blocks (e.g. 30 - 45 minutes). Review a handful of questions, reflect on the explanations.

3. Learn from the Explanations

After answering a question, always read the explanation, even if you got it right. It reinforces key points, corrects misunderstandings, and teaches subtle distinctions between similar answers.

4. Track Your Progress

Use bookmarks or notes (if reading digitally) to mark difficult questions. Revisit these regularly and track improvements over time.

5. Simulate the Real Exam

Once you're comfortable, try taking a full set of questions without pausing. Set a timer and simulate test-day conditions to build confidence and time management skills.

6. Repeat and Review

Don't just study once, repetition builds retention. Re-attempt questions after a few days and revisit explanations to reinforce learning. Pair this guide with other Examzify tools like flashcards, and digital practice tests to strengthen your preparation across formats.

There's no single right way to study, but consistent, thoughtful effort always wins. Use this guide flexibly, adapt the tips above to fit your pace and learning style. You've got this!

Questions

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- 1. How long is the term for the Medical Technology Board according to RA 5527?**
 - A. 2 years**
 - B. 3 years**
 - C. 4 years**
 - D. 5 years**

- 2. 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**

- 3. Which is a key component of clinical trial ethics?**
 - A. Administering tests without patient consent**
 - B. Necessity for informed consent from all participants**
 - C. Conducting trials without regulatory oversight**
 - D. Marketing results prior to completion of trials**

- 4. Which class of medical devices typically requires the most stringent regulatory controls?**
 - A. Class I**
 - B. Class II**
 - C. Class III**
 - D. Class IV**

- 5. Which of the following is a major consequence of violating HIPAA regulations?**
 - A. Loss of patient trust and credibility**
 - B. Increased funding for healthcare institutions**
 - C. Enhanced patient satisfaction**
 - D. No legal ramifications**

- 6. What is a major ethical concern surrounding financial conflicts of interest in clinical trials?**
- A. They can enhance the quality of research**
 - B. They may affect the integrity of research and patient safety**
 - C. They often lead to longer trial durations**
 - D. They increase the costs of research**
- 7. What was established by PD 223?**
- A. The Professional Regulation Commission (PRC)**
 - B. The National Health Insurance Program**
 - C. The Medical Education Council**
 - D. The Office of Drug Regulation**
- 8. Which of the following are main ethical principles in MedTech?**
- A. Autonomy, beneficence, non-maleficence, and justice**
 - B. Profit, efficiency, transparency, and accountability**
 - C. Informed consent, safety, effectiveness, and cost**
 - D. Risk assessment, quality control, patient satisfaction, and accessibility**
- 9. What is the significance of the Good Manufacturing Practices (GMP)?**
- A. Guidelines ensuring low-cost production**
 - B. Guidelines focused on innovative product development**
 - C. Guidelines ensuring consistent product quality**
 - D. Guidelines to determine product pricing**
- 10. What does "surrogate decision-making" refer to in healthcare?**
- A. A legal framework for patient transactions**
 - B. A method of emergency procedures**
 - C. A process in which someone makes decisions for an incapacitated patient**
 - D. A system for allocating medical resources**

Answers

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

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Explanations

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1. How long is the term for the Medical Technology Board according to RA 5527?

- A. 2 years
- B. 3 years**
- C. 4 years
- D. 5 years

The term for the Medical Technology Board, as stipulated in Republic Act No. 5527, is indeed three years. This duration is significant because it allows members of the board to effectively implement their responsibilities, which include overseeing the practice of medical technology, ensuring adherence to ethical standards, and upholding the quality of education and practice in the field. The three-year term strikes a balance, providing enough time for members to gain experience and contribute to the board's objectives while allowing for periodic renewal and introduction of new members, which can bring fresh perspectives and ideas to the practice of medical technology.

2. 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.

3. Which is a key component of clinical trial ethics?

- A. Administering tests without patient consent
- B. Necessity for informed consent from all participants**
- C. Conducting trials without regulatory oversight
- D. Marketing results prior to completion of trials

A key component of clinical trial ethics is the necessity for informed consent from all participants. This principle is foundational to ensuring that individuals are fully aware of the nature of the trial, the procedures involved, potential risks and benefits, and their right to withdraw at any time without penalty. Informed consent respects the autonomy of participants, allowing them to make educated decisions about their involvement based on their understanding of the trial. This ethical requirement promotes transparency and trust between researchers and participants, which is crucial for upholding ethical standards in medical research. It also helps to protect vulnerable populations by ensuring they are not subjected to trials without fully understanding what they entail. In contrast, the other options represent unethical practices that contradict clinical trial integrity. Administering tests without consent undermines the autonomy of participants. Conducting trials without regulatory oversight can lead to harmful practices and a lack of accountability. Marketing results prior to the completion of trials can mislead the public, skewing perceptions of the trial's effectiveness or safety before it has reached a valid conclusion.

4. Which class of medical devices typically requires the most stringent regulatory controls?

- A. Class I
- B. Class II
- C. Class III**
- D. Class IV

Class III medical devices represent the category with the most stringent regulatory controls primarily due to the significant potential risks associated with their use. These devices are generally intended for high-risk applications, such as life-supporting functions or those that sustain human life. For example, heart pacemakers and implantable defibrillators fall into this category. The regulatory process for Class III devices typically includes extensive premarket approval (PMA) requirements, which mandate that manufacturers provide scientific evidence demonstrating the device's safety and effectiveness. This involves rigorous clinical trials and comprehensive documentation to ensure that the device meets the necessary safety standards before it can reach the market. In contrast, Class I devices have the least risk and are subject to the fewest regulations; many are exempt from premarket notification. Class II devices have more stringent controls than Class I, including specific regulatory requirements that often involve a premarket notification known as 510(k), but they do not reach the level of scrutiny applied to Class III devices. By focusing on their design, potential impact on patients, and the level of risk involved, it is clear that Class III devices demand the most rigorous regulations to safeguard public health.

5. Which of the following is a major consequence of violating HIPAA regulations?

- A. Loss of patient trust and credibility**
- B. Increased funding for healthcare institutions**
- C. Enhanced patient satisfaction**
- D. No legal ramifications**

Loss of patient trust and credibility is a significant consequence of violating HIPAA regulations. When healthcare providers fail to protect patient information, it undermines patients' confidence in the healthcare system. Trust is essential in the provider-patient relationship, as patients need to feel secure that their sensitive information is being handled appropriately. In addition to loss of trust, breaches can lead to negative publicity and reputational damage for healthcare institutions, which can affect their ability to attract and retain patients. Patients who feel their privacy has been compromised may choose to seek care elsewhere, further impacting the institution's credibility and financial stability. Remaining compliant with HIPAA not only helps protect patient data but also safeguards the integrity and reliability of healthcare practices, contributing to a culture of accountability and professionalism.

6. What is a major ethical concern surrounding financial conflicts of interest in clinical trials?

- A. They can enhance the quality of research**
- B. They may affect the integrity of research and patient safety**
- C. They often lead to longer trial durations**
- D. They increase the costs of research**

Financial conflicts of interest in clinical trials pose a significant ethical concern primarily because they can compromise both the integrity of the research and patient safety. When researchers or institutions have financial ties to a drug or device manufacturer, there may be an unconscious bias introduced into the design, execution, or reporting of the trial results. This could lead to the manipulation of data or reporting favorable outcomes that do not accurately represent the findings. Such actions undermine the trustworthiness of the research findings, as they might prioritize financial gain over the well-being of participants and the validity of the scientific evidence. Additionally, if safety concerns are downplayed or overlooked due to these conflicts, it can endanger patient health and safety, further emphasizing the need for unbiased, transparent clinical trials to ensure ethical compliance and protect participants. Though enhancing the quality of research might seem plausible under certain conditions, this is not the typical outcome of financial conflicts of interest. Similarly, while longer trial durations and increased research costs can be side effects of various factors in the research environment, they are not primarily ethical concerns, nor do they directly relate to the core issue of compromising research integrity and patient safety.

7. What was established by PD 223?

- A. The Professional Regulation Commission (PRC)**
- B. The National Health Insurance Program**
- C. The Medical Education Council**
- D. The Office of Drug Regulation**

The establishment of the Professional Regulation Commission (PRC) is a significant development in the professional landscape of the Philippines. PD 223, or Presidential Decree No. 223, enacted in 1973, established the PRC as a government agency responsible for the regulation and supervision of various professions in the country, particularly in ensuring that professionals meet specific standards of competence and ethical practice. The PRC's functions include the licensing and registration of professionals, administration of professional examinations, and providing oversight to uphold professional integrity. By creating this institution, PD 223 aimed to enhance the quality of services provided by professionals and safeguard the interests of the public. The other options mention various entities and programs pertinent to health and regulation, but they do not relate directly to the establishment made by PD 223. For example, the National Health Insurance Program focuses on healthcare access and insurance, while the Medical Education Council would deal with educational frameworks for health-related studies, and the Office of Drug Regulation would oversee the regulation of pharmaceuticals. None of these were established by PD 223, making the PRC the correct answer.

8. Which of the following are main ethical principles in MedTech?

- A. Autonomy, beneficence, non-maleficence, and justice**
- B. Profit, efficiency, transparency, and accountability**
- C. Informed consent, safety, effectiveness, and cost**
- D. Risk assessment, quality control, patient satisfaction, and accessibility**

The main ethical principles in MedTech are grounded in fundamental values that guide healthcare professionals in their decision-making processes, ensuring that patient care is prioritized while upholding moral standards. The principles of autonomy, beneficence, non-maleficence, and justice represent a comprehensive framework for evaluating ethical dilemmas in medical technology. Autonomy emphasizes the right of patients to make informed decisions about their own healthcare, recognizing their capacity to determine what is best for themselves. Beneficence refers to the obligation of healthcare providers to act in the best interest of patients, promoting their well-being and taking positive actions to help them. Non-maleficence is the principle that compels healthcare professionals to refrain from causing harm to patients, a core tenet in medical ethics that safeguards patients from potential risks and adverse effects. Lastly, justice pertains to fairness and equity in the distribution of healthcare resources, ensuring that all individuals have access to necessary medical services without discrimination. These principles collectively guide ethical conduct in the rapidly evolving field of medical technology, ensuring that technological advancements serve to enhance patient welfare while respecting individual rights. Other options, while relevant to various aspects of healthcare or business practice, do not capture the foundational ethical framework that governs medical practice and technology use.

9. What is the significance of the Good Manufacturing Practices (GMP)?

- A. Guidelines ensuring low-cost production
- B. Guidelines focused on innovative product development
- C. Guidelines ensuring consistent product quality**
- D. Guidelines to determine product pricing

The significance of Good Manufacturing Practices (GMP) is centered around ensuring consistent product quality. GMP encompasses a comprehensive set of guidelines and regulations that manufacturers must adhere to in order to maintain the quality of their products throughout the production process. This includes everything from the cleanliness of the production environment to the qualifications of the workforce, the equipment, and the processes used. Adhering to GMP not only helps in producing safe and effective medical products but also ensures that each batch of product is produced to the same quality standards as previous batches, which is crucial in the medical technology field where the reliability of products can directly impact patient safety. The other alternatives do not accurately reflect the core focus of GMP. While low-cost production and product pricing are important to a business's financial viability, they do not necessarily correlate with maintaining the quality and safety of the produced goods. Additionally, while innovation in product development is valuable, GMP specifically emphasizes the necessity of established and rigorous procedures that safeguard product quality and consistency, rather than fostering innovation directly.

10. What does "surrogate decision-making" refer to in healthcare?

- A. A legal framework for patient transactions
- B. A method of emergency procedures
- C. A process in which someone makes decisions for an incapacitated patient**
- D. A system for allocating medical resources

Surrogate decision-making refers to the process where someone, often a family member or designated individual, makes healthcare decisions on behalf of a patient who is unable to make those decisions themselves due to incapacitation. This could be due to various reasons, such as severe illness, cognitive impairment, or other conditions that affect the patient's ability to communicate their wishes regarding medical treatment. The surrogate is expected to act in the best interests of the patient and, when known, adhere to the patient's previously expressed wishes about their healthcare. This process is crucial in ensuring that patients receive care that aligns with their values and preferences, even when they cannot articulate them. It's grounded in legal principles and ethical considerations that prioritize the rights of patients to have their autonomy respected, even if they cannot exercise it directly at that moment. In contrast, the other options refer to concepts that are unrelated to the idea of surrogate decision-making. The legal framework for patient transactions and the allocation of medical resources deal with structural and administrative aspects of healthcare rather than individual decision-making. Emergency procedures involve immediate medical interventions and are not about ongoing care decisions for incapacitated individuals.

Next Steps

Congratulations on reaching the final section of this guide. You've taken a meaningful step toward passing your certification exam and advancing your career.

As you continue preparing, remember that consistent practice, review, and self-reflection are key to success. Make time to revisit difficult topics, simulate exam conditions, and track your progress along the way.

If you need help, have suggestions, or want to share feedback, we'd love to hear from you. Reach out to our team at hello@examzify.com.

Or visit your dedicated course page for more study tools and resources:

<https://medtechlawsandethics.examzify.com>

We wish you the very best on your exam journey. You've got this!

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