

BCPS REGULATORY PRACTICE TEST (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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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. Kickbacks prohibition to influence referrals for federally funded services is established by which statute?**
 - A. False Claims Act
 - B. PDMA
 - C. Anti-Kickback Statute (AKS)
 - D. PPPA

- 2. Under the FD&C Act, which statement best defines drugs?**
 - A. Articles that are foods
 - B. Articles intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease
 - C. Devices used for diagnosis
 - D. Medications used for pest control

- 3. What does GLP stand for?**
 - A. Good Laboratory Practice
 - B. Good Laboratory Protocol
 - C. General Laboratory Procedure
 - D. Good Licensing Practice

- 4. Which statement accurately describes generic drug equivalence?**
 - A. It must be identical in dosage form, strength, route of administration, and quality with identical performance characteristics.
 - B. It must have a different active ingredient but same therapeutic effect.
 - C. It must be produced by the same manufacturer.
 - D. It must be used for a different indication.

- 5. Which act provides the FDA authority to regulate the import of drugs into the United States?**
 - A. FD&C Act
 - B. Food Labeling Act
 - C. FD&C Act
 - D. Public Health Service Act

- 6. Phase IV drug trial refers to**
- A. Post-market surveillance
 - B. Early stage nonclinical studies
 - C. Preclinical safety testing
 - D. Manufacturing validation
- 7. Which organization has a policy on IRB and investigational use of drugs that supports pharmacists in managing control and distribution of drugs used in research?**
- A. FDA
 - B. NIH
 - C. ASHP
 - D. DEA
- 8. Which form is used to authorize sharing protected health information under HIPAA in research?**
- A. HIPAA authorization form
 - B. Informed consent form
 - C. Conflict of interest disclosure
 - D. Recruitment material
- 9. Which statement reflects a limitation of tox studies in preclinical trials?**
- A. Fetal events in humans always match animal findings
 - B. Toxicology studies replace human trials
 - C. They predict all adverse events in humans
 - D. Fetal events in humans may occur that did not occur in animals
- 10. The HITECH Act is associated with which objective?**
- A. Expanding telehealth coverage
 - B. Promoting meaningful use of electronic health records
 - C. Expanding HIPAA enforcement and promoting meaningful use of electronic health records
 - D. Regulating medical devices manufacturing

Answers

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

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Explanations

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1. Kickbacks prohibition to influence referrals for federally funded services is established by which statute?

- A. False Claims Act
- B. PDMA
- C. Anti-Kickback Statute (AKS)**
- D. PPPA

The main idea is that there is a federal law that bars paying or receiving kickbacks to influence referrals for items or services paid for by federal health care programs. This is the Anti-Kickback Statute. It makes it illegal to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals for services or supplies that are reimbursed by programs like Medicare or Medicaid. The goal is to protect clinical judgment from financial incentives and protect program integrity. Penalties can be severe, including criminal fines, imprisonment, and exclusion from federal programs. There are safe harbors for certain arrangements that meet specific criteria, but outside those, such payments can lead to liability. The other statutes listed don't govern referral incentives: the False Claims Act targets submitting false claims to the government; the Prescription Drug Marketing Act addresses drug marketing and distribution; and the Poison Prevention Packaging Act deals with packaging safety.

2. Under the FD&C Act, which statement best defines drugs?

- A. Articles that are foods
- B. Articles intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease**
- C. Devices used for diagnosis
- D. Medications used for pest control

Under the FD&C Act, what makes a product a drug is its intended use to diagnose, cure, mitigate, treat, or prevent disease in humans or animals (and, more broadly, to affect the structure or function of the body). The statement describing articles intended for diagnosing, curing, mitigating, treating, or preventing disease matches that core criterion, so it best defines a drug. Foods are regulated separately as foods, not drugs. Devices are a distinct category with their own definitions, and pest-control products fall under EPA pesticide regulation, not FDA drug regulation.

3. What does GLP stand for?

- A. Good Laboratory Practice**
- B. Good Laboratory Protocol
- C. General Laboratory Procedure
- D. Good Licensing Practice

GLP stands for Good Laboratory Practice, a regulatory quality system that ensures nonclinical laboratory studies used for regulatory submissions are planned, performed, monitored, recorded, reported, and archived in a standardized, controlled way. It sets requirements for study planning, qualifications of personnel, validated methods, proper facilities and equipment, appropriate handling of test and reference substances, detailed documentation, and reliable data reporting. This framework aims to guarantee the integrity and reliability of safety data submitted to authorities. General Laboratory Procedure is too vague and non-regulatory; it refers to routine steps rather than an overarching quality system. Good Laboratory Protocol would imply just a single protocol, whereas GLP governs the entire practice framework. Good Licensing Practice isn't the recognized term in this regulatory context, and it doesn't describe the systematic quality standards for nonclinical studies.

4. Which statement accurately describes generic drug equivalence?

- A. It must be identical in dosage form, strength, route of administration, and quality with identical performance characteristics.**
- B. It must have a different active ingredient but same therapeutic effect.
- C. It must be produced by the same manufacturer.
- D. It must be used for a different indication.

Generic drug equivalence means a generic product must be therapeutically equivalent to the brand-name drug, delivering the same active ingredient in the same dosage form and strength, by the same route, and meeting the same quality standards so its pharmacokinetic profile is the same enough to produce the same safety and efficacy. The statement that describes identical dosage form, strength, route of administration, and quality with identical performance characteristics best captures these requirements, because it implies both the same active ingredient (through the same dosage form and strength) and the same bioequivalence/therapeutic effect. This is why a generic should not differ in active ingredient, should not be tied to the same manufacturer as a requirement, and should not be used for a different indication.

5. Which act provides the FDA authority to regulate the import of drugs into the United States?

- A. FD&C Act
- B. Food Labeling Act
- C. FD&C Act**
- D. Public Health Service Act

The FDA's authority to regulate the import of drugs comes from the Federal Food, Drug, and Cosmetic Act. This act grants the agency power to ensure that drugs entering the United States are safe, effective, properly labeled, and not adulterated or misbranded, and it provides authority to inspect, detain, and refuse admission of imported drugs that don't meet those standards. The Public Health Service Act covers other public health areas but not the core authority for drug import regulation. Labeling rules are part of overall FD&C Act requirements, but the key source for regulating imports is the FD&C Act. Therefore, the Federal Food, Drug, and Cosmetic Act is the correct basis for regulating drug imports.

6. Phase IV drug trial refers to

- A. Post-market surveillance**
- B. Early stage nonclinical studies
- C. Preclinical safety testing
- D. Manufacturing validation

Phase IV is post-marketing surveillance conducted after approval to monitor a drug's safety in real-world use. Once a medication is on the market, Phase IV studies collect long-term safety data, detect rare or delayed adverse events, assess effectiveness across broader and more diverse patient populations, and evaluate drug interactions or risks in specific subgroups. This stage helps refine the safety profile and labeling based on actual use outside controlled trial settings. Early-stage nonclinical studies and preclinical safety testing occur before humans and are not clinical trial phases, while manufacturing validation ensures production quality rather than evaluating patient safety after approval.

7. Which organization has a policy on IRB and investigational use of drugs that supports pharmacists in managing control and distribution of drugs used in research?

- A. FDA
- B. NIH
- C. ASHP**
- D. DEA

Pharmacists working with research drugs rely on formal guidance about how to handle investigational products within study protocols and IRB oversight. The American Society of Health-System Pharmacists provides policy statements and standards specifically about investigational drug services, including how to coordinate with IRBs, manage storage, dispensing, labeling, documentation, and accountability of investigational agents in hospital and health-system settings. This guidance directly supports pharmacists in controlling and distributing drugs used in research while complying with regulatory requirements and protecting patient safety. While the FDA sets the regulatory framework for investigational drugs (like INDs and IRB approvals), its role is regulatory, not a practice policy for pharmacists' day-to-day management. NIH offers research guidance and funding policies, not pharmacy-specific policies for investigational drug handling. DEA focuses on controlled substances and enforcement, not the broader policy framework for research drug management in clinical settings.

8. Which form is used to authorize sharing protected health information under HIPAA in research?

- A. HIPAA authorization form**
- B. Informed consent form
- C. Conflict of interest disclosure
- D. Recruitment material

Authorization to use and disclose protected health information for a research study is granted through a HIPAA authorization form. This form specifies exactly what PHI may be shared, who may receive it, the purpose of the disclosure, the expiration date, and the right to revoke authorization. It's the mechanism that gives patients control over whether their PHI can be used in the study. Informed consent, by contrast, is about agreeing to participate in the research and understanding risks and procedures—not about authorizing PHI sharing. Recruitment materials and conflict of interest disclosures don't authorize PHI disclosures. So the HIPAA authorization form is the proper instrument to permit sharing PHI under HIPAA in research.

9. Which statement reflects a limitation of tox studies in preclinical trials?

- A. Fetal events in humans always match animal findings
- B. Toxicology studies replace human trials
- C. They predict all adverse events in humans
- D. Fetal events in humans may occur that did not occur in animals**

Preclinical toxicology aims to flag safety risks before humans are exposed, but it cannot fully predict fetal risk in people. Differences in development, placental transfer, metabolism, and dosing between animals and humans mean some fetal effects may occur in humans that were not seen in animal studies. This is why fetal events in humans may arise even when animal studies did not show them. That's why statements claiming that fetal outcomes always match animal findings, that tox studies replace human trials, or that they predict all adverse events in humans aren't accurate. Animal data are essential but imperfect, and human trials with careful safety monitoring remain necessary to fully understand fetal risks.

10. The HITECH Act is associated with which objective?

- A. Expanding telehealth coverage
- B. Promoting meaningful use of electronic health records
- C. Expanding HIPAA enforcement and promoting meaningful use of electronic health records**
- D. Regulating medical devices manufacturing

The main idea behind the HITECH Act is to drive adoption and meaningful use of electronic health records while strengthening privacy and security through HIPAA enforcement. It created financial incentives for providers and hospitals to demonstrate meaningful use of EHRs and it expanded HIPAA enforcement, including tougher penalties, broader reach to business associates, and required breach Notification. Because the question asks for the objective associated with HITECH, the option that includes both promoting meaningful use of electronic health records and expanding HIPAA enforcement best reflects the Act's purpose. The other options miss one of these key elements: telehealth expansion isn't the central aim, and regulating medical devices falls under a different regulatory scope.

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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://bcpsregulatory.examzify.com>

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

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