

BCPS Regulatory 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. IND is submitted at what point in development?**
 - A. Submitted at the end of preclinical trials**
 - B. Submitted after Phase 1 to begin Phase 2**
 - C. Submitted after Phase 3**
 - D. Submitted during the first year of development**

- 2. What is the main purpose of the HIPAA Privacy Rule in pharmacy practice?**
 - A. To standardize electronic health record formats**
 - B. To protect the privacy of PHI and regulate how it may be used/disclosed**
 - C. To require all disclosures be approved by a patient's family**
 - D. To provide ongoing privacy training to staff**

- 3. Which term describes a drug produced by the brand manufacturer's company and marketed at generic prices during and after the 180-day exclusivity period that is identical to the brand product in active and inactive ingredients?**
 - A. Authorized Generic**
 - B. Therapeutic Generic**
 - C. Biosimilar**
 - D. Pharmaco-equivalent**

- 4. What program mitigates known serious safety risks for certain drugs and requires prescriber/patient enrollment, such as isotretinoin?**
 - A. REMS (Risk Evaluation and Mitigation Strategy)**
 - B. Risk Management Plan (EU)**
 - C. PDR System**
 - D. NDA**

- 5. Which of the following is a JC accountability measure for children with asthma inpatients?**
 - A. Systemic steroids for inpatients**
 - B. Daily inhaled beta-agonist before discharge**
 - C. Immunization status only**
 - D. Home management/Care plan**

- 6. Under which act was a regulatory pathway for biosimilars or follow-on biologicals established?**
- A. Family Smoking Prevention and Tobacco Control Act of 2009**
 - B. FDA Modernization Act of 1997**
 - C. FDA Amendments Act of 2007**
 - D. Patient Protection and Affordable Care Act of 2010**
- 7. Which element is typically included in an informed consent document?**
- A. details about purpose, duration, procedures, risks, benefits and key contacts**
 - B. the sponsor's private financial disclosures**
 - C. a marketing summary**
 - D. results of the trial**
- 8. Which entry would be found under procurement details in the study notebook?**
- A. Receipt and disposition**
 - B. Vendor qualification records**
 - C. Inventory cost sheets**
 - D. Procurement details**
- 9. Which agency enforces the two-year retention requirement for controlled substances?**
- A. FDA**
 - B. CMS**
 - C. FTC**
 - D. DEA**
- 10. Under IRB exemptions, which activity qualifies for exemption when it involves educational tests, surveys, interviews, or observation?**
- A. Clinical trial of a drug**
 - B. Interviewing teachers about classroom strategies**
 - C. Research involving the use of educational tests, surveys, interviews or observation**
 - D. Analysis of organizational policies**

Answers

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

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Explanations

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1. IND is submitted at what point in development?

- A. Submitted at the end of preclinical trials**
- B. Submitted after Phase 1 to begin Phase 2**
- C. Submitted after Phase 3**
- D. Submitted during the first year of development**

An IND is filed after preclinical work has shown enough safety and pharmacology/toxicology data to justify testing in humans. This means animal and in vitro studies have demonstrated a reasonable expectation of safety, and manufacturing information is in place so the FDA can review the proposed clinical plan. With the IND approved, first-in-human trials can proceed. Therefore, the appropriate point in development to submit is at the end of preclinical development, before any human trials begin. Submitting after Phase 1 to start Phase 2 isn't allowed because human trials can't start without regulatory approval, and submitting only during the first year or after Phase 3 would be too late.

2. What is the main purpose of the HIPAA Privacy Rule in pharmacy practice?

- A. To standardize electronic health record formats**
- B. To protect the privacy of PHI and regulate how it may be used/disclosed**
- C. To require all disclosures be approved by a patient's family**
- D. To provide ongoing privacy training to staff**

The main aim is to protect patients' health information and control how that information is used and shared. In pharmacy practice, PHI includes any data that can identify a patient and relate to their care—such as names, diagnoses, medications, and dispensing details. The HIPAA Privacy Rule sets clear boundaries about who can see this information and for what purposes, allowing disclosures without patient authorization only for specific, permitted reasons like treatment, payment, or health care operations, and otherwise requiring an authorization. A key concept is the minimum necessary standard: only the smallest amount of PHI needed to accomplish a task should be shared. The rule also gives patients rights—access to their records, the ability to request corrections, and a right to receive a notice about how their information will be used. In practice, this means pharmacists must safeguard PHI, obtain proper authorizations when needed, and be transparent about privacy practices. The other options aren't the primary aim: the rule isn't about standardizing electronic records formats, it doesn't require family members to approve all disclosures, and while privacy training is important, the main purpose is not to mandate ongoing staff training.

3. Which term describes a drug produced by the brand manufacturer's company and marketed at generic prices during and after the 180-day exclusivity period that is identical to the brand product in active and inactive ingredients?

- A. Authorized Generic**
- B. Therapeutic Generic**
- C. Biosimilar**
- D. Pharmaco-equivalent**

Authorized generic describes a version of a brand-name drug that is produced by the brand's own company (or under its control) and marketed at generic prices. It is intended to be identical to the brand product in both active and inactive ingredients, and it can be sold during and after the 180-day generic exclusivity period. This arrangement allows the brand to compete like a generic while leveraging their own formulation. This differs from a therapeutic generic, which focuses on achieving the same therapeutic effect but not necessarily identical inactive ingredients or production source. A biosimilar applies to biologic products rather than small-molecule drugs. Pharmaco-equivalent is a broader term for products that are equivalent in active ingredient and strength but doesn't specify that the drug is produced by the brand and marketed as a generic.

4. What program mitigates known serious safety risks for certain drugs and requires prescriber/patient enrollment, such as isotretinoin?

- A. REMS (Risk Evaluation and Mitigation Strategy)**
- B. Risk Management Plan (EU)**
- C. PDR System**
- D. NDA**

REMS, or Risk Evaluation and Mitigation Strategy, is a program required by the FDA for certain drugs with known serious safety risks. It ensures that the benefits of the drug outweigh its risks by implementing specific risk-minimization measures and requiring enrollment or certification of prescribers and patients, plus ongoing monitoring as needed. Isotretinoin is a classic example, regulated under the iPLEDGE REMS program, which mandates enrollment of prescribers, patients, and pharmacists, along with mandatory pregnancy testing and contraception to prevent fetal exposure. Other regulatory tools exist in different regions (for example, the EU uses a Risk Management Plan), but this U.S. program specifically targets safe use and access through structured enrollment and monitoring. NDA refers to the drug approval process, not a safety-mitigation program.

5. Which of the following is a JC accountability measure for children with asthma inpatients?

- A. Systemic steroids for inpatients
- B. Daily inhaled beta-agonist before discharge**
- C. Immunization status only
- D. Home management/Care plan

Joint Commission accountability measures for pediatric asthma focus on concrete, verifiable actions during a hospital stay that demonstrate quality care. For children admitted with asthma, one key measure is ensuring that a daily inhaled beta-agonist is used before discharge. This reflects that the child has been stabilized with bronchodilation during the hospitalization and is leaving the hospital with evidence of ongoing symptom relief and a plan for continued rescue therapy if needed. It also supports safe discharge by showing the care team has actively managed the acute episode and prepared the family to continue appropriate inhaled-therapy use at home. Inhaled beta-agonists are central to acute asthma management, and documenting daily use before discharge helps confirm an adequate response to treatment and readiness to transition care. Systemic steroids are important during exacerbations but are not, by themselves, a discharge-quality metric in this context. Immunization status is important preventive care but does not specifically capture inpatient asthma management quality. A home management/care plan is valuable, but the measure highlighted here specifically targets the immediate inpatient process of ensuring bronchodilator therapy is appropriately addressed before discharge.

6. Under which act was a regulatory pathway for biosimilars or follow-on biologicals established?

- A. Family Smoking Prevention and Tobacco Control Act of 2009
- B. FDA Modernization Act of 1997
- C. FDA Amendments Act of 2007
- D. Patient Protection and Affordable Care Act of 2010**

The regulatory pathway for biosimilars was established by the Patient Protection and Affordable Care Act, which incorporated the Biologics Price Competition and Innovation Act to create an abbreviated licensure pathway for biosimilars under FDA oversight. This framework allows follow-on biologics to be approved based on similarity to a reference biologic, promoting competition and potential cost savings. The other acts address different areas (tobacco control, general FDA modernization, or broad health care reform) and do not establish the biosimilar pathway.

7. Which element is typically included in an informed consent document?

- A. details about purpose, duration, procedures, risks, benefits and key contacts**
- B. the sponsor's private financial disclosures**
- C. a marketing summary**
- D. results of the trial**

The key idea being tested is what information must be provided to someone when they are asked to participate in a study. An informed consent document should clearly spell out the study's purpose, what will be done (the procedures), how long the study will take (duration), the potential risks and benefits, and who to contact with questions or concerns. This combination gives the participant enough factual detail to decide whether joining the study aligns with their values and needs, and it also provides a clear route for support or reporting issues. Details about the sponsor's private financial disclosures aren't part of what participants need to decide about joining a study; those are conflict-of-interest disclosures intended for oversight bodies, not for informing a participant's decision. A marketing summary isn't appropriate because it could be biased or promotional, whereas the consent form should present balanced, neutral information. The results of the trial aren't included in the consent document because participants are not being asked to decide based on trial outcomes that may not be known yet, and results are typically communicated after the study through separate channels. So, the element that belongs in an informed consent document is the description of the purpose, duration, procedures, risks, benefits, and who to contact for questions.

8. Which entry would be found under procurement details in the study notebook?

- A. Receipt and disposition**
- B. Vendor qualification records**
- C. Inventory cost sheets**
- D. Procurement details**

The key idea is that the study notebook is organized by function, with each section holding items directly related to that area. For procurement details, the entry should clearly describe procurement-related information, so the best fit is the entry labeled Procurement details itself. It directly belongs to that section, serving as the header or descriptor for items about acquiring goods or services. The other entries belong to different sections: receipt and disposition covers receiving and handling items, vendor qualification records relate to supplier vetting, and inventory cost sheets pertain to cost accounting and inventory valuation.

9. Which agency enforces the two-year retention requirement for controlled substances?

- A. FDA
- B. CMS
- C. FTC
- D. DEA**

The Drug Enforcement Administration enforces the two-year retention requirement for controlled substances. This stems from the Controlled Substances Act, with DEA regulations requiring registrants to keep records and inventories related to controlled substances for two years. Maintaining these records ensures accountability and provides material for inspections or audits. The other agencies—FDA, CMS, and FTC—have different roles (drug safety and labeling, payer administration, and consumer protection, respectively) and do not enforce this specific recordkeeping rule.

10. Under IRB exemptions, which activity qualifies for exemption when it involves educational tests, surveys, interviews, or observation?

- A. Clinical trial of a drug
- B. Interviewing teachers about classroom strategies
- C. Research involving the use of educational tests, surveys, interviews or observation**
- D. Analysis of organizational policies

IRB exemptions include research that uses educational tests, surveys, interviews, or observation because these methods typically involve minimal risk and are common in educational and behavioral research. When the study uses these procedures, and the data collection does not expose participants to more than minimal risk (and privacy is protected), that work can be exempt from full IRB review. The described activity—research involving the use of educational tests, surveys, interviews, or observation—fits this exemption category, so it is the best answer. A drug clinical trial involves medical intervention and potential risks, so it does not qualify for this exemption. Analyzing organizational policies could be exempt under different circumstances, but it does not specifically center on educational tests, surveys, interviews, or observation.

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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