

340B PROGRAM OPERATIONS CERTIFICATE PRACTICE EXAM (SAMPLE) STUDY GUIDE



Prepare with structure. Pass with confidence



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Table of Contents

Copyright	1
Table of Contents	2
Introduction	3
How to Use This Guide	4
Questions	5
Answers	8
Explanations	10
Next Steps	16

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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. What is the term for Medicaid services that are included in managed care plans?**
 - A. Carve-out
 - B. Carve-in
 - C. Managed Medicaid
 - D. Bundled services
- 2. Which account is utilized when a clinic aims to minimize costs through bulk purchasing?**
 - A. Medicare account
 - B. 340B account
 - C. GPO account
 - D. Insurance account
- 3. Which type of account is essential for a facility participating in the 340B program to manage its pricing strategy?**
 - A. 340B account
 - B. Medicare account
 - C. Inventory management account
 - D. Reimbursement account
- 4. Which types of drugs are not classified as covered outpatient drugs?**
 - A. Drugs from retail pharmacies
 - B. Over-the-counter drugs
 - C. Drugs cheaper on GPO
 - D. Specialty drugs
- 5. What does the term "Orphan Drug Determination" typically require?**
 - A. Consultation with patient advocacy groups
 - B. Verification from the manufacturer of orphan drug classification
 - C. A review of clinical trial data
 - D. Analysis of market data for drug sales

- 6. What report details the costs and services provided by hospitals annually?**
- A. Annual performance report
 - B. Medicare cost report
 - C. Medicaid compliance report
 - D. Hospital utilization report
- 7. What must a covered entity establish for contract pharmacy operations?**
- A. Human resources policies only
 - B. Oversight policies and procedures
 - C. Training programs for staff
 - D. Financial reports
- 8. What is the purpose of conducting a cost comparison?**
- A. To identify drug efficacy
 - B. To analyze expenses between in-house and contract pharmacies
 - C. To calculate patient savings
 - D. To evaluate employee performance
- 9. What is referred to by the acronym GPO?**
- A. General Pricing Organization
 - B. Group Purchasing Organization
 - C. Global Pharmaceutical Organization
 - D. Government Program Office
- 10. Which organization is known for managing 340B drug pricing-related programs?**
- A. HRSA
 - B. NIH
 - C. Apexus
 - D. FDA

Answers

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

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Explanations

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1. What is the term for Medicaid services that are included in managed care plans?

- A. Carve-out
- B. Carve-in**
- C. Managed Medicaid
- D. Bundled services

The term "carve-in" is used to describe Medicaid services that are included within managed care plans. This concept signifies that specific services, typically covered by Medicaid, are not separated from the managed care plan but rather integrated into it. The integration allows for a more cohesive management of care and streamlined services for beneficiaries. In the context of managed care, the focus is on the delivery of comprehensive services under one plan, which can improve care coordination and potentially lead to better health outcomes. This approach reflects a strategy to ensure that beneficiaries receive all their Medicaid services—which may include preventive, primary, and specialty care—through a single care provider or network. The term "carve-out," in contrast, refers to services that are explicitly excluded from the managed care plan and are handled separately. This would mean certain services are delivered outside the managed care structure, which can lead to fragmentation of care. Managed Medicaid generally refers to the overall structure of Medicaid services that are provided via managed care, rather than to a specific arrangement of services. Bundled services are a payment model where multiple related services are billed together, often used in various healthcare contexts, rather than specifically relating to how Medicaid services are organized under managed care plans.

2. Which account is utilized when a clinic aims to minimize costs through bulk purchasing?

- A. Medicare account
- B. 340B account
- C. GPO account**
- D. Insurance account

The correct choice is the GPO account. GPO stands for Group Purchasing Organization, which is designed to leverage the collective buying power of multiple organizations to obtain commodities and services at lower prices. When a clinic aims to minimize costs through bulk purchasing, utilizing a GPO account allows the clinic to take advantage of discounted pricing agreements that the GPO has established with suppliers based on the combined purchasing volume of its members. This approach is particularly beneficial for clinics and healthcare facilities that may not individually command enough purchasing power to negotiate favorable terms with vendors. By participating in a GPO, clinics can access lower prices on pharmaceuticals, medical supplies, and other necessary items, contributing significantly to cost reduction. In contrast, while the 340B account is related to a federal program that allows eligible healthcare organizations to purchase medications at discounted prices, it does not focus specifically on bulk purchasing arrangements like a GPO does. Medicare and insurance accounts pertain to reimbursement and claims processing, rather than direct procurement strategies aimed at minimizing costs through bulk purchasing.

3. Which type of account is essential for a facility participating in the 340B program to manage its pricing strategy?

- A. 340B account**
- B. Medicare account
- C. Inventory management account
- D. Reimbursement account

Having a 340B account is crucial for any facility participating in the 340B program as it specifically allows the entity to manage and track the benefits under the program. The 340B Drug Pricing Program enables eligible healthcare providers to purchase outpatient medications at reduced prices, which can significantly impact their pricing strategy. By utilizing a 340B account, the facility can effectively monitor and control drug inventory and expenses related to the discounted medications. This account serves as a foundation for ensuring compliance with program regulations and helps the facility leverage savings, ultimately improving its ability to provide comprehensive care to underserved populations. In contrast, a Medicare account or reimbursement account may focus more on payment processing and insurance claims rather than the strategic management of outpatient drug pricing specifically designed under the 340B program. An inventory management account, while essential for tracking stock levels and ensuring the availability of medications, does not specifically cater to the unique pricing strategies and compliance requirements associated with the 340B program.

4. Which types of drugs are not classified as covered outpatient drugs?

- A. Drugs from retail pharmacies
- B. Over-the-counter drugs
- C. Drugs cheaper on GPO**
- D. Specialty drugs

Covered outpatient drugs under the \$340B Program are defined primarily as those that are FDA-approved and prescribed for outpatient use. However, certain categories of drugs do not meet the criteria for being classified as covered outpatient drugs. Drugs that are available as over-the-counter (OTC) medications are not included as covered outpatient drugs under the program. The rationale behind this is that OTC drugs are not typically dispensed with a prescription and the program specifically pertains to prescription medications that may be purchased at reduced prices. While other choices might also seem relevant, they do not directly align with the definition of excluded drugs in the context of the \$340B Program. For instance, drugs from retail pharmacies are often included as covered outpatient drugs as long as they meet the criteria set forth by the program. Specialty drugs may also qualify, provided they are prescribed and do not fall into an excluded category. On the other hand, the mention of drugs being cheaper on a Group Purchasing Organization (GPO) does not inherently disqualify them from being considered covered outpatient drugs; it simply refers to pricing. Understanding the nuances of what constitutes a covered outpatient drug is key to navigating the complexities of the 340B Program effectively, particularly regarding compliance and ensuring eligibility for discounted pricing.

5. What does the term "Orphan Drug Determination" typically require?

- A. Consultation with patient advocacy groups
- B. Verification from the manufacturer of orphan drug classification**
- C. A review of clinical trial data
- D. Analysis of market data for drug sales

The term "Orphan Drug Determination" typically refers to the process by which a drug is classified as an orphan drug, qualifying for specific incentives and support under the Orphan Drug Act. This determination requires verification from the manufacturer of the orphan drug classification. Manufacturers must provide evidence that the drug is intended for the treatment of a rare disease or condition affecting fewer than 200,000 people in the United States. Verification is crucial because it establishes the eligibility of the drug for the benefits outlined in the Orphan Drug Act, such as tax credits for clinical trial costs, waiver of the New Drug Application (NDA) fee, and seven years of market exclusivity upon FDA approval. Therefore, confirmation from the manufacturer serves as a foundational aspect of the determination process, ensuring that the drug meets the necessary criteria for orphan designation. While considerations like consultation with patient advocacy groups, a review of clinical trial data, or analysis of market data may play roles in the overarching context of drug development and marketing, they do not specifically pertain to the core requirement of the orphan drug determination process, which hinges on the manufacturer's verification of classification.

6. What report details the costs and services provided by hospitals annually?

- A. Annual performance report
- B. Medicare cost report**
- C. Medicaid compliance report
- D. Hospital utilization report

The Medicare cost report is the document that details the costs and services provided by hospitals on an annual basis. This report is primarily used by Medicare to track the financial performance of healthcare providers and to determine the reimbursement rates for services provided to Medicare beneficiaries. Hospitals are required to submit this report annually, which includes comprehensive data on their financial operations, including expenses related to patient care, staffing, and facility costs. The information in the Medicare cost report is crucial for ensuring compliance with federal reimbursement guidelines and for facilitating transparent reporting for public and private stakeholders. This report serves as a key tool for financial planning and analysis within hospitals, allowing them to evaluate their performance and make informed decisions regarding service adjustments or financial strategies. In contrast, an annual performance report is typically more focused on meeting strategic goals and operational efficiencies rather than financial costs. A Medicaid compliance report would focus specifically on adherence to Medicaid regulations, while a hospital utilization report would primarily summarize patient service metrics without detailing the associated costs. Thus, the Medicare cost report stands as the definitive document for reporting annual costs and services provided by hospitals.

7. What must a covered entity establish for contract pharmacy operations?

- A. Human resources policies only
- B. Oversight policies and procedures**
- C. Training programs for staff
- D. Financial reports

A covered entity participating in the 340B Program must establish oversight policies and procedures for contract pharmacy operations to ensure compliance and effective management. These policies serve as a framework for how the contract pharmacies will operate, detailing their roles, responsibilities, and the operational protocols necessary to adhere to program requirements. Effective oversight is crucial for compliance with the 340B regulations, which aim to prevent issues such as diversion of 340B drugs to ineligible patients or duplicate discounts on Medicaid claims. By having established policies and procedures, covered entities can systematically monitor contract pharmacies for adherence to the 340B Program's guidelines, making sure that all operations align with federal regulations and organizational goals. The other options, while important in various contexts, do not address the primary requirement for controlling and overseeing contract pharmacy operations. Human resources policies are vital for maintaining workforce standards, training programs impart knowledge but do not ensure compliance, and financial reports monitor fiscal health but do not establish operational guidelines. Thus, oversight policies and procedures are fundamental for the smooth and lawful functioning of contract pharmacies within the 340B framework.

8. What is the purpose of conducting a cost comparison?

- A. To identify drug efficacy
- B. To analyze expenses between in-house and contract pharmacies**
- C. To calculate patient savings
- D. To evaluate employee performance

Conducting a cost comparison primarily aims to analyze expenses between in-house and contract pharmacies, which is crucial for healthcare organizations participating in the 340B Program. By comparing costs, entities can determine the financial implications of using different pharmacy models, helping them make informed decisions about how to optimize their operations and maximize savings on medications. This analysis can reveal opportunities for better financial management, ensuring that the entity remains compliant with program requirements while also leveraging the discounts offered through the 340B Program. Understanding the cost dynamics between in-house and contract pharmacies allows organizations to enhance their service delivery and allocate resources efficiently, directly impacting their ability to provide care to underserved populations. The focus of this comparison is specifically on expenses, which is fundamental for financial assessments. While drug efficacy, patient savings, and employee performance are important metrics in their own right, they do not directly pertain to the primary objectives of conducting a cost comparison in this context.

9. What is referred to by the acronym GPO?

- A. General Pricing Organization
- B. Group Purchasing Organization**
- C. Global Pharmaceutical Organization
- D. Government Program Office

The acronym GPO stands for Group Purchasing Organization. A Group Purchasing Organization primarily serves to leverage the collective purchasing power of its members to negotiate discounts and other favorable purchasing terms from suppliers. This is especially beneficial in the healthcare sector, where organizations like hospitals and clinics join GPOs to reduce costs on medical supplies, equipment, pharmaceuticals, and other goods and services. By consolidating purchases, GPOs can achieve better pricing than individual members could negotiate alone. This not only helps reduce expenses but can also improve access to necessary products for healthcare providers, ultimately benefitting patient care. Understanding the role of GPOs is critical for those involved in the 340B program operations, as they can play a crucial part in the procurement strategies of covered entities, helping them maximize their benefits under this program.

10. Which organization is known for managing 340B drug pricing-related programs?

- A. HRSA
- B. NIH
- C. Apexus**
- D. FDA

The organization known for managing 340B drug pricing-related programs is Apexus. Apexus plays a crucial role in supporting the operation and administration of the 340B Program by providing technical assistance, education, and resources to covered entities. This organization helps ensure that these entities can effectively participate in the program, maximizing the benefits they receive through discounted pricing on medications for vulnerable populations. Apexus serves as the prime vendor under the 340B Program, facilitating access to manufacturers' drugs at reduced prices and ensuring compliance with program requirements. This direct involvement with 340B stakeholders, including covered entities and pharmaceutical manufacturers, uniquely positions Apexus as the primary entity responsible for the program's operational efficiency and effectiveness. Other organizations like HRSA, NIH, and FDA play different roles in the healthcare system. For instance, HRSA, while it oversees the 340B program, is primarily responsible for enforcing compliance and providing guidance rather than direct management. Meanwhile, NIH focuses on medical research and the advancement of knowledge, and FDA is involved in the regulation of drugs and ensuring their safety and efficacy, but not specifically in the management of 340B drug pricing programs. Hence, the answer identifies the organization that directly manages operational aspects of the 340B Program, which

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://340bprogramoperations.examzify.com>

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

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