

# 340B Program Operations Certificate Practice Exam (Sample)

## Study Guide



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## **Questions**

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- 1. What type of account is used for bulk drug purchasing?**
  - A. 340B account**
  - B. Purchasing account**
  - C. GPO account**
  - D. Medicare account**
- 2. What is vital when managing orphan drug status?**
  - A. Regular market analysis**
  - B. Collaboration with medical institutions**
  - C. Engagement with the drug manufacturer**
  - D. Assessment of retail pricing**
- 3. What resource provides a list of registered 340B entities?**
  - A. HRSA 340B Database**
  - B. Medicaid directory**
  - C. Federal Drug Administration database**
  - D. Healthcare provider registry**
- 4. What process involves the management of stock for different pricing categories?**
  - A. Inventory Management**
  - B. Stock Consolidation**
  - C. Physical Inventory**
  - D. Price Categorization**
- 5. Which organization is primarily responsible for overseeing the 340B program?**
  - A. CDC**
  - B. HRSA**
  - C. Medicaid**
  - D. FDA**

- 6. What is a common term for a system that requires physical counting and management of items in stock?**
- A. Digital Inventory**
  - B. Physical Inventory**
  - C. Stock Ledger**
  - D. Inventory Tracking**
- 7. Which type of entity is classified as a 340B drug pricing provider?**
- A. Medicaid service provider**
  - B. Covered entity**
  - C. Pharmacy benefit manager**
  - D. Private insurance company**
- 8. What situation describes when a medication is not available?**
- A. Supply chain issue**
  - B. Drug shortage**
  - C. Stockout**
  - D. Dispensing error**
- 9. What type of pharmacy dispenses medications under the 340B program?**
- A. Retail pharmacy**
  - B. Contract pharmacy**
  - C. Mail-order pharmacy**
  - D. Specialty pharmacy**
- 10. Which of the following best describes the role of split-billing software?**
- A. To manage drug administration records**
  - B. To facilitate drug purchases across different accounts**
  - C. To track patient health outcomes**
  - D. To handle billing disputes**

## **Answers**

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

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## **Explanations**

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## 1. What type of account is used for bulk drug purchasing?

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

The correct choice is the GPO account, which stands for Group Purchasing Organization account. GPOs facilitate bulk purchasing for healthcare providers, allowing them to leverage collective buying power to negotiate better prices on pharmaceuticals and medical supplies. This model enables participating healthcare entities to access lower costs, which is particularly beneficial for 340B entities looking to maximize their savings and ensure they can provide more affordable medications to their patients. The structure of a GPO account is tailored specifically for the purpose of facilitating bulk purchases across multiple healthcare organizations. This collaborative approach helps mitigate rising drug prices and enhances the overall efficiency in procurement processes. By utilizing a GPO account, healthcare providers can access a wide variety of drugs at negotiated discounted rates, making it a vital resource for effective inventory management and cost control. In contrast, options like the 340B account, purchasing account, and Medicare account serve different functions. A 340B account specifically pertains to the 340B Drug Pricing Program, which allows eligible healthcare organizations to purchase outpatient drugs at reduced prices but does not encompass bulk purchasing strategies. The purchasing account is a more general term and lacks the specific regulatory framework needed for bulk purchasing in a healthcare context. Meanwhile, a Medicare account relates to Medicare-funded services and does not deal directly with

## 2. What is vital when managing orphan drug status?

- A. Regular market analysis
- B. Collaboration with medical institutions
- C. Engagement with the drug manufacturer**
- D. Assessment of retail pricing

Engagement with the drug manufacturer is crucial when managing orphan drug status because it allows for direct communication about drug development, regulatory requirements, and marketing strategies specific to orphan drugs. Manufacturers of orphan drugs must navigate unique challenges, including the limited patient population, specific regulatory incentives, and potential market exclusivity. By engaging with the manufacturer, stakeholders can ensure that they are aligned in their objectives for drug accessibility, comply with the regulations surrounding orphan drugs, and address any manufacturing or distribution issues that may arise. Additionally, this engagement can lead to insights into ongoing research and development that could affect the drug's status and availability in the market. While regular market analysis, collaboration with medical institutions, and assessment of retail pricing are important components of pharmaceutical management, they do not specifically address the unique aspects and regulatory considerations related to managing orphan drug status. Understanding the specifics of the drug's development process and maintaining a strong relationship with the manufacturer is essential for navigating the complexities of the orphan drug landscape effectively.

### **3. What resource provides a list of registered 340B entities?**

- A. HRSA 340B Database**
- B. Medicaid directory**
- C. Federal Drug Administration database**
- D. Healthcare provider registry**

The HRSA 340B Database is the authoritative source for information on registered 340B entities. This resource is maintained by the Health Resources and Services Administration (HRSA) and provides comprehensive data on organizations that qualify as 340B entities, including information about their locations, types, and the services they offer. This database is crucial for eligible entities to understand their status within the program, and it allows stakeholders, including pharmaceutical manufacturers, to verify participation in the 340B Drug Pricing Program. Other resources mentioned, such as the Medicaid directory and the Federal Drug Administration database, serve different purposes and do not specifically list 340B entities. The Medicaid directory focuses on providers and services related to Medicaid, while the FDA database primarily deals with drug approvals and safety information. The healthcare provider registry may include various types of healthcare providers, but it is not tailored to the specific needs and details regarding 340B programs. Thus, the HRSA 340B Database stands out as the most relevant and accurate resource.

### **4. What process involves the management of stock for different pricing categories?**

- A. Inventory Management**
- B. Stock Consolidation**
- C. Physical Inventory**
- D. Price Categorization**

The process that involves the management of stock for different pricing categories is closely aligned with inventory management. Proper inventory management entails tracking various stock items and their respective prices while ensuring the correct implementation of multiple pricing categories. This process ensures that facilities or organizations can effectively manage and account for their inventory according to the different pricing structures that may apply based on factors such as patient eligibility under programs like 340B or other contractual obligations. In contrast, stock consolidation refers to the method of combining items for efficiency rather than focusing on their pricing structures. Physical inventory involves counting and verifying the stock on hand, which does not inherently pertain to pricing categories but rather to stock accuracy. Price categorization deals with assigning different prices to items based on set criteria but does not cover the comprehensive management of those stock items or their quantities. Thus, inventory management encompasses both the stock levels and their pricing structures effectively.

**5. Which organization is primarily responsible for overseeing the 340B program?**

- A. CDC
- B. HRSA**
- C. Medicaid
- D. FDA

The Health Resources and Services Administration (HRSA) is the organization primarily responsible for overseeing the 340B program. This program, established in 1992, is designed to allow eligible healthcare providers to purchase outpatient drugs at reduced prices, thereby enabling them to better serve vulnerable populations, including low-income and uninsured patients. HRSA administers the program and ensures compliance with its guidelines, monitoring the eligibility of participating entities and the integrity of the program as a whole. As the governing body, HRSA plays a critical role in providing guidance, technical assistance, and enforcement actions related to the program. This oversight ensures that participating organizations are using the 340B savings to expand their services and provide care to the communities that need it most, fulfilling the program's mission. In contrast, the other organizations listed have different roles: the Centers for Disease Control and Prevention (CDC) primarily focuses on public health and disease control, Medicaid is a state and federally funded program that provides health coverage to eligible low-income individuals, and the Food and Drug Administration (FDA) is responsible for approving drugs and ensuring their safety and efficacy. None of these agencies are tasked with the same level of operational oversight and administration of the 340B program that HRSA has.

**6. What is a common term for a system that requires physical counting and management of items in stock?**

- A. Digital Inventory
- B. Physical Inventory**
- C. Stock Ledger
- D. Inventory Tracking

The term "Physical Inventory" refers to the process of taking a tangible count of items in stock, which is essential for maintaining accurate records of what is available for sale or distribution. This method involves physically counting each item, often in conjunction with reconciling records to ensure accuracy in stock levels. Physical inventory provides a snapshot of inventory levels at a specific point in time and is critical for businesses in order to ensure that they do not overstock or run out of essential items. It's typically conducted periodically, such as annually or biannually, and can be contrasted with "digital inventory," which refers to inventory management systems that track stock levels electronically, often in real-time. While "Stock Ledger" and "Inventory Tracking" might seem relevant, they address different aspects of inventory management. A stock ledger is a record of transactions affecting inventory, documenting purchases, sales, and returns, but does not inherently involve a physical count. Inventory tracking can describe the ongoing management of inventory levels, typically through digital means, rather than the manual counting involved in a physical inventory. Hence, the term that most accurately describes the requirement for physically counting and managing stock items is indeed "Physical Inventory."

**7. Which type of entity is classified as a 340B drug pricing provider?**

- A. Medicaid service provider**
- B. Covered entity**
- C. Pharmacy benefit manager**
- D. Private insurance company**

A covered entity is classified as a 340B drug pricing provider because it meets specific criteria established under the 340B Program, which is designed to allow healthcare providers to purchase outpatient drugs at reduced prices. Covered entities typically include certain types of clinics, community health centers, and hospitals that serve a large number of low-income or uninsured patients. These entities are eligible to participate in the 340B Program due to their commitment to providing care to vulnerable populations, allowing them to stretch scarce resources and improve access to essential medications. This classification emphasizes the program's goal of supporting healthcare providers who serve patients in need by enabling them to offer medications at a lower cost, ultimately benefiting the patients as well. Other options, such as Medicaid service providers, pharmacy benefit managers, and private insurance companies, do not have the same eligibility or role in the 340B Program framework, as they do not directly provide the benefits associated with the 340B pricing structure focused on enhancing access to medications for those in underserved areas.

**8. What situation describes when a medication is not available?**

- A. Supply chain issue**
- B. Drug shortage**
- C. Stockout**
- D. Dispensing error**

A drug shortage refers to a situation where a medication is not available due to various factors that may impact its production or distribution. This can include manufacturing problems, raw material shortages, or increased demand that surpasses supply. In the context of pharmacy and healthcare, a drug shortage can affect patient care significantly as certain essential medications may not be accessible for treatment protocols. It is important to differentiate this from other situations. A supply chain issue relates more broadly to disruptions in the overall logistics of delivering medications, which may or may not lead directly to an absence of a specific drug. Stockout refers to a specific instance when a pharmacy runs out of a particular medication at a designated time, rather than an ongoing shortage within the market. A dispensing error, on the other hand, involves mistakes made during the preparation or distribution of medication, which does not directly correlate to the availability of the medication itself. In summary, the term drug shortage directly captures the essence of the situation where a medication is not available due to its inability to meet market demand or other logistical challenges, making it the correct answer.

**9. What type of pharmacy dispenses medications under the 340B program?**

- A. Retail pharmacy**
- B. Contract pharmacy**
- C. Mail-order pharmacy**
- D. Specialty pharmacy**

The 340B program allows eligible healthcare organizations, known as covered entities, to purchase medications at significantly reduced prices to help disadvantaged patients. Among the various types of pharmacies, contract pharmacies play a vital role in this system. Contract pharmacies are typically partnerships established between a covered entity and a pharmacy that is not owned by the entity. These relationships enable covered entities to extend their 340B benefits beyond their own in-house pharmacies, ensuring that patients have greater access to affordable medications. By utilizing contract pharmacies, covered entities can improve their reach and provide essential services in areas where they may not have a physical pharmacy presence, thus broadening their impact in community health. Other pharmacy types, such as retail, mail-order, and specialty pharmacies, can engage with the 340B program, but their roles are often less central or come with specific conditions or limitations under the program's guidelines. For example, while retail pharmacies can dispense drugs, they do so usually under standard commercial practices not specifically tailored to 340B program requirements. Therefore, contract pharmacies are essential to the operational efficiency of the 340B program, which is why this option stands out as the correct answer.

**10. Which of the following best describes the role of split-billing software?**

- A. To manage drug administration records**
- B. To facilitate drug purchases across different accounts**
- C. To track patient health outcomes**
- D. To handle billing disputes**

The role of split-billing software is primarily designed to facilitate drug purchases across different accounts, making choice B the correct option. This type of software is specifically utilized in healthcare settings, particularly by entities participating in the 340B program, to ensure that medications are billed accurately based on the appropriate pricing tiers for different groups or accounts. In practice, split-billing software allows healthcare providers to categorize and manage inventory and billing for the medications they dispense, ensuring that 340B eligible drugs are billed at the necessary reduced prices while other purchases remain at standard pricing. Notably, this capability is essential for maintaining compliance with the program's regulations and structure, as it helps organizations navigate the complexities of their purchasing and inventory management processes. The other options, while significant in healthcare operations, do not directly pertain to the specific function of split-billing software. Managing drug administration records involves tracking how medications are given to patients; tracking patient health outcomes focuses on collecting data related to treatment effectiveness; and handling billing disputes deals with resolving discrepancies in billed amounts. All these are separate functions that do not encapsulate the core role of split-billing software in the context of managing drug purchases effectively across different financial accounts.