FAQ: 340B Frequently Asked Questions

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1. **What is the 340B Drug Pricing Program?**
    a. It is a federal program under the Health Resources and Services Administration (HRSA) that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to eligible healthcare organizations (called "covered entities") that serve low-income or uninsured populations.
2. **What are compliance requirements for 340B?**
        i. Keep 340B records accurate and up to date in the 340B Office of Pharmacy Affairs Information System (OPAIS)
        ii. Register all outpatient facilities and contract pharmacies
        iii. Re-certify eligibility annually
        iv. Prevent diversion of drugs to ineligible patients
        v. Prevent duplicate discounts with Medicaid
        vi. Comply with program audits
3. **Why is 340B Beneficial?**
    a. Using the 340B Drug Pricing Program is crucial to assist with hospital systems that normally would operate at a loss due to underpayment from Medicare and Medicaid. These savings can then be used to expand services, hire more staff, or offer free or reduced-cost medications to patients.
4. **What is considered a 340B "covered entity?"**
    a. A healthcare organization is eligible to participate in the 340B Drug Pricing Program by being enrolled and approved by HRSA and listed in the 340B OPAIS.
    b. Some examples include:
        i. Federally Qualified Health Centers (FQHCs)
        ii. Ryan White HIV/AIDS clinics
        iii. Critical access hospital (CAHs)
        iv. Disproportionate share hospitals (DSHs)
        v. Children's hospitals and cancer hospitals exempt from the Medicare prospective payment system
        vi. Sole community hospitals and rural referral centers
        vii. Tribal or urban Indian health programs

5. **Patient Eligibility**
    a. **What are the qualifications for a patient to receive a 340B drug?**
        i. A patient must meet all the following criteria:
            1. Be an established patient of a 340B covered entity whereby the covered entity maintains health records that document the patient's care.
            2. Receive healthcare services from a provider who is either employed by the covered entity or under a valid contractual or referral arrangement.
            3. The services the patient receives are consistent with the type of care the covered entity is qualified to provide under the 340B Drug Pricing Program.
    b. **Can eligible patients receive 340B drugs at any pharmacy?**
        i. No, eligible drugs can only be dispensed from the covered entity's in-house pharmacy or an approved 340B contract pharmacy.
6. **What is the threat to the 340B Drug Pricing Program?**
    a. Contract pharmacy restrictions
        i. Drug manufacturers have increasingly limited or denied 340B pricing for drugs dispensed through contract pharmacies, reducing access and savings for covered entities.
7. **Eligibility/Registration**
    a. **How do I know if my clinic is eligible for 340B?**
        i. Visit HRSA (https://www.hrsa.gov/opa/eligibility-and-registration) for a full list of eligibility criteria.
    b. **How does my clinic get registered for 340B?**
        i. Verify eligibility
        ii. Register through HRSA
        iii. Complete 340B enrollment form
    c. **When and how often is the registration period for enrollment?**
        i. Quarterly; during the first 15 days of January, April, July, and October.
    d. **How often do I need to recertify my 340B registration?**
        i. Annually
8. **Inventory & Drug Purchasing**
    a. **How are 340B drugs purchased?**
        i. Directly from manufacturers or wholesalers at 340B pricing

b. **May 340B drugs be used as refills?**
    i. Yes, assuming the patient meets 340B eligible criteria
c. **Can 340B pricing be transferred out to an external pharmacy?**
    i. Yes, but only if the external pharmacy is a contract pharmacy of the 340B-covered entity with a written agreement in place.
d. **Can 340B drugs be purchased at external pharmacies?**
    i. Yes, most hospitals are not able to stock all drugs and will need to source drugs from contracted external pharmacies. Of note, external pharmacies themselves do not purchase 340B drugs independently, but they can dispense on behalf of the covered entity.
e. **What is a contract pharmacy, and can they dispense 340B drugs?**
    i. A contract pharmacy is a non-hospital-based pharmacy that contracts with the hospital to dispense drugs to patients.
f. **Can vaccines be purchased at 340B pricing?**
    i. Vaccines do not qualify for 340b pricing. Group purchasing organizations (GPOs), including Apexus' 340B Prime Vendor, are often able to negotiate a discounted rate for vaccines.

9. **Clinical/Operational Implications**
    a. **How does 340B impact patient care in ambulatory care settings?**
        i. Improved medication access, affordability, and adherence through decreased drug costs
        ii. Help with managing chronic diseases like heart failure, COPD, diabetes, etc.
        iii. Greater opportunity to expand clinic services for patients due to 340B savings
    b. **What role does the pharmacist play in 340B?**
        i. Oversee medication access, support therapy optimization, ensure regulatory compliance, manage inventory systems, and help reinvest savings into patient care improvements
    c. **Can 340b drugs be used for off-labeled purposes?**
        i. Yes, 340b drugs can be used for off label purposes, provided the use is medically appropriate, legal, and the patient meets 340B eligibility.
10. **Are there 340B audits and penalties for non-compliance?**
    a. Yes, HRSA conducts audits of covered entities participating in the 340B Drug Pricing Program to assess program compliance, including eligibility criteria, record-keeping, diversion prevention, and duplicate discount avoidance. Covered

entities must maintain accurate records to ensure compliance. Non-compliance may lead to refunds to drug manufacturers, interest penalties, or removal from the 340B Drug Pricing Program.

b. HRSA allows covered entities to evaluate and correct aspects of their 340B Drug Pricing Program through self-reporting. Covered entities have a chance to proactively identify and correct compliance issues before penalties are enacted.

References

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