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The Top 10 Pitfalls of Participating in the 340B Drug Pricing Program

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Given today's declining reimbursement landscape, most health care organizations are engaging in additional cost-saving strategies. The federal 340B Drug Pricing Program is one such opportunity that is available to critical access hospitals (CAHs), disproportionate share hospitals (DSHs), and other eligible covered entities.

Congress created a program intended to reduce outpatient drug costs for certain types of health care organizations serving large numbers of uninsured indigent patients. The 340B program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The federal program requires drug manufacturers participating in the Medicaid drug rebate program to provide outpatient drugs to enrolled "covered entities" at or below the statutorily defined ceiling price.

In return, the covered entities receive significant cost savings. Typical hospitals can expect to save 30 to 40 percent of the cost of drugs used for outpatients, with higher savings on high-cost, brand-name drugs.

To participate in the program, the hospital must file an application for 340B status with the Office of Population Affairs (OPA). Once approved, a separate 340B account is established with an existing drug wholesaler. The purchasing system remains the same, and the new account includes the 340B prices.

The hospital pharmacy department then purchases eligible drugs on the newly established 340B account and all other drugs on the GPO account, except for DSHs.

Drugs from both accounts can be delivered from the same wholesaler. Drugs purchased directly from a manufacturer can also be obtained at 340B prices.

If the hospital utilizes a virtual inventory system, there is no need to keep a separate inventory for the 340B drugs. Cost savings are realized, and revenue is received by the hospital with small investments in personnel, equipment, or infrastructure.

As the 340B program has continued to grow, so has regulatory scrutiny. Some entities were ejected from the 340B program last year and with proposed Health Resources and Services Administration (HRSA) regulations, more are sure to follow.

In light of this increased scrutiny, covered entities should shore up their tracking systems, examine their audit trails, review their policies and procedures, and contract for a third-party assessment.

Whether an entity already participates in the 340B program or is considering it, it's important to understand the compliance risks and overall program challenges. Here are the top pitfalls to avoid to help ensure a well-run program.

1. **Poor tracking.**
   Good tracking systems are essential to compliance. Hospitals must be able to prove that the drugs purchased on the 340B account were administered to an outpatient in an eligible point of service. Hospital pharmacies that purchase drugs for both inpatients and outpatients have an increased responsibility to ensure that proper safeguards protect against the diversion of 340B drugs to hospital inpatients.

   Effective tracking is also imperative when dispensing 340B - discounted drugs for patients treated in mixed-use settings, such as a surgery department where both inpatients and outpatients are treated.

   When working with contract pharmacies, hospitals must have an established and well-maintained tracking system to prevent diversion of 340B drugs and duplicate discounts.

2. **Incomplete, inaccurate database.**
   Hospital databases must be updated with active provider listings. The only way pharmacies will know whether to dispense 340B drugs to eligible outpatients is through a current database.

3. **Lack of contract pharmacy oversight.**
   Using contract pharmacies to dispense 340B drugs is common, but it does not come without challenges, especially regarding compliance. Covered entities are ultimately responsible for monitoring contract pharmacies and ensuring total compliance with all 340B program requirements. If a diversion or duplicate discount is identified, the covered entity must notify the OPA of the violation.

4. **Having too many contract pharmacies.**
   The general rule of thumb is five pharmacy contracts. Having more will likely raise a red flag with regulators. It is hard to convince the OIG that covered entities are capable of effectively overseeing more than that.

5. **Poor audit trail.**
   All participating entities must maintain auditable records on all 340B purchases and be prepared to respond to pharmaceutical manufacturers' or OPA's inquiries. These records need to be maintained for a period of time that complies with all applicable federal, state, and local requirements. The data required includes purchase histories on 340B and GPO. For DSHs, the wholesale average cost purchase history is required.

   HRSA expects that most covered entities will use independent audits as part of their ongoing obligation to ensure compliance. The best recommendation to ensure compliance is to incorporate 340B into internal audit work plans.

6. **Ineligible patients receiving 340B drugs.**
Diverting drugs to those who are not 340B eligible is strictly prohibited. Yet there is often confusion over which patients do and do not qualify. For instance, many providers erroneously consider nursing home patients outpatients under 340B and assume they are thus eligible. While nursing home patients are considered outpatients in the general industry sense, they are considered *inpatient* under 340B and, therefore, do not qualify.

   According to HRSA, an eligible patient is one who meets the following criteria:

   - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
   - The individual receives health care services from a health care professional who either is employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care remains with the covered entity.
   - An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

7. **Use of a third-party administrator without deference to compliance.**
Always keep in mind that entities cannot outsource their 340B compliance responsibilities. Covered entities must have policies and procedures in place and are ultimately fully accountable regardless of any outsourcing arrangements.

8. **Failure to register all "child" sites.**
Covered entities with child sites that intend to purchase or provide 340B drugs must register each one. Even if a child site falls within the "four walls" of a facility, it's a good idea to register it anyway. That way, should the entity need to move the child site in the future, it will not have to go through the lengthy registration process—a process that can typically take six to nine months, and even up to a year, during which time revenue is lost.

9. **Poor maintenance.**
The 340B program must be mindfully managed. While the operational administration of the program can require additional resources such as staff time, with proper written policies and procedures as guidance, maintenance can be easily integrated into business processes.

10. **Overlooked 340B opportunities.**
There are several 340B savings opportunities that providers often overlook. One is direct purchases. As 340B entities, the providers are entitled to 340B pricing regardless of the vendor. Another is non-pharmacy purchases like those made through the blood bank, central supply, and radiology (e.g., albumin, factors, Suprane, Magnevist, Tisseel, etc.). All could qualify for 340B pricing. Other opportunities include take-home or indigent drugs and drugs administered in off-site provider-based settings (e.g., seasonal clinics and ambulances), to name a few.

The HRSA Horizon

HRSA is in the process of drafting new formalized regulations and will release them for public comment this summer. Among the many items expected to be addressed is the definition of eligible patient and the compliance requirements for contract pharmacy arrangements.

In light of this increased scrutiny, covered entities should shore up their tracking systems, examine their audit trails, review their policies and procedures, and consider a third-party assessment.

About the Author

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Vicki Mueller has more than 20 years of consulting experience in the health care and senior living industries. She works in a variety of health care settings including hospitals, nursing facilities, assisted living, independent living, home health agencies, and rural health clinics. Vicki provides expert advice in the areas of reimbursement, financial modeling, clinic assessments, strategic planning, Medicare enrollment, and revenue, integrity, and operations assessments.

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