340B COMPLIANCE FOR THE C-SUITE

Apexus | 340B Prime Vendor PROGRAM™

The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

1 340B: WHAT EXECUTIVES NEED TO KNOW

The 340B Drug Pricing Program provides access to prices often up to 50% lower than typical market prices. In order to participate, entities must meet eligibility criteria and agree to comply with program requirements. This program is administered by the Health Resources and Services Administration (HRSA).

2 WHY IS 340B COMPLIANCE IMPORTANT?

Covered entities can face sanctions for non-compliance, including being removed from the 340B Program and/or repayment to manufacturers for the time period in which the violation occurred.

3 ENTITIES ARE RESPONSIBLE FOR ENSURING:

1. Only eligible patients receive 340B drugs; and
2. A Medicaid rebate is not requested on a 340B purchased drug; and
3. All entity eligibility requirements are met; and
4. Auditable records are maintained to illustrate compliance.

4 A PATIENT IS ELIGIBLE FOR 340B WHEN A COVERED ENTITY:

- Establishes a health care relationship with the patient; and
- Maintains records of the patient's health care; and
- Provides services by a health care professional who is employed or under contractual or other arrangements with the entity, such that the responsibility for care remains with the entity; and
- Provides health care services consistent with scope of grant (federal grantees only).

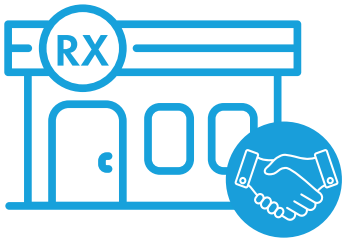
*** The 340B Prime Vendor, managed by Apexus, provides tools that can help covered entities address these components of the program at 340Bpvp.com/tools**

A BEST PRACTICE:

entities document their use of 340B savings in alignment with this intent.*

340B PROGRAM COMPLIANCE REQUIRES ONGOING ATTENTION:

- Self audits are essential for understanding program integrity.
- Software and systems used to support the program require regular monitoring and maintenance.
- Interdisciplinary oversight ensures accountability and broad institutional understanding.
  - Sites often accomplish this through the development of a council consisting of multiple disciplines such as Finance, Billing, Nursing, Medicine, Medical Records, Pharmacy, and Compliance.
- Dedicated resources with defined roles and responsibilities can help improve compliance and create additional accountability.
- Individuals responsible for the program should remain educated about the program so they will be informed of the current HRSA policy.
  - Send them to 340B University or have them complete the online version, 340B University OnDemand. Both are offered for free through the 340B Prime Vendor.



340B CONTRACT PHARMACY

Consider this before signing a contract pharmacy agreement:

1. It is the covered entity that is responsible for 340B compliance (not vendors).
2. A covered entity must have fully auditable records to demonstrate that no diversion or duplicate discounts have occurred at a contract pharmacy.
3. Contract pharmacy agreements may present financial risk to the entity. Be aware of the terms in your contract and make sure they are reasonable and consistent with any program or grant requirements you may have.
4. Use discretion when considering how many contract pharmacies are appropriate; large numbers of contract pharmacies increase the risk of a HRSA audit and often require additional oversight.
5. Fee for Service Medicaid prescriptions should not be included in contract pharmacy arrangements (unless the state has a special arrangement and the entity has notified HRSA).

HOSPITAL CORNER

A TIP FOR HOSPITAL LEADERS

Dedicated resources are critical for maintenance of complex software systems. Many hospitals have one or more FTEs dedicated to the program. Tools to address components of the 340B Program can be found on our website.

AS A HOSPITAL, HOW DO I KNOW WHICH FACILITIES ARE ELIGIBLE FOR 340B?

All clinics/departments/services of the parent hospital must be listed as reimbursable lines with associated outpatient costs and charges on the covered entity's most recently filed Medicare Cost Report. Those clinics/departments/services located outside of the four walls, regardless of whether they are in the same building [including another hospital], must be registered on OPAIS.

MY HOSPITAL IS SUBJECT TO THE GPO PROHIBITION. CAN WE EVER USE A GPO?

Hospitals registered on OPAIS as disporportionate share hospitals (DSH), freestanding cancer hospitals (CAN), or children's hospitals (PED) are subject to the GPO Prohibition. These hospitals may continue to use GPO for inpatients. Certain off-site outpatient facilities may use a GPO for covered outpatient drugs if they meet all of the following criteria:

1. Are located at a different physical address than the parent;
2. Are not registered on the OPA 340B OPAIS as participating in the 340B Program;
3. Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
4. The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B OPAIS.

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