

340B Compliance for the C-Suite



A Patient is Eligible for 340B When a Covered Entity:

- Establishes a health care relationship with the patient.
- Maintains records of the patient's health care.
- 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.
- Provides health care services consistent with grant funding (federal grantees only).

Did you know? These situations may not be adequate to meet patient definition:

- Having only financial responsibility for an employee's health, but not meeting other patient definition criteria.
- Using 340B for prescriptions written by referral providers, without adequate documentation/auditable records.
- Relying only on "admitting privileges" as a healthcare professional's relationship with a 340B entity.
- Administering a 340B drug to a patient as the only service received by that patient from the 340B entity.

340B: What Executives Need to Know

The [340B Drug Pricing Program](#) provides access to the 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).

Program Intent: The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Apexus recommends entities document their use of 340B savings in alignment with this intent.

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 for which the violation occurred.
- The findings from 340B audits may be used to refer matters to the Office of Inspector General (OIG) or Department of Justice (DOJ).

Entities are Responsible for Ensuring:

1. Only eligible patients receive 340B drugs.
2. A Medicaid rebate is not paid on a 340B purchased drug.
3. All entity eligibility requirements are met.

Best Practices for Self Audits



- Develop a clear way to **validate patient eligibility.**
- Review a report of health care professionals' NPIs to determine only professionals meeting all aspects outlined in the patient definition write for 340B drugs.
- Regularly **verify referrals** for care provided outside the entity.
- Review billing practices for Medicaid and Medicaid managed care to ensure consistency with state policy and the entity's 340B database information.
- Maintain updated Policies & Procedures on all aspects of 340B purchasing and operations.
- Ensure all information in the 340B database is current.

For detailed information on preparing for an audit by HRSA or manufacturer see: Compliance Self-Assessment Data and Transactions (<https://www.340bpvp.com/resource-center/other-resources/compliance-self-assessment/>)



Hospital Corner

Two Tips for Hospital Leaders

1. Dedicate resources to adequately manage the 340B program. Many hospitals have 1 or more FTEs dedicated to the program, and most hospitals establish a multi-disciplinary committee to guide the 340B self-audit process, including such disciplines as:
 - Finance, Billing, Nursing, Medicine, Medical records, Pharmacy, Compliance
2. Regularly educate your resources so they will be informed of the current HRSA policy; send them to 340B University or have them complete our brief, free online tutorial. Education is an ongoing activity, as policy updates or clarifications occur frequently.

340B Contract Pharmacy

What are the most important things to know about establishing a contract pharmacy?

1. Regardless of what a vendor may tell you – it is the covered entity that is responsible for 340B compliance.
2. A covered entity must have fully auditable records to demonstrate that no diversion or duplicate discounts have occurred.
3. Savings derived from utilizing the program belongs to the entity; not a vendor or payer.
4. An entity can lose money on a contract pharmacy relationship. Be aware of the terms in your contract and make sure they are reasonable and consistent with any program or grant requirements the entity may have.
5. Use discretion when considering how many contract pharmacies are appropriate; large numbers of contract pharmacies may increase compliance concerns and possibly trigger an audit.
6. Medicaid prescriptions should not be included in contract pharmacy arrangements (unless the state has a special arrangement and has notified HRSA).

340B In-House Pharmacy

For many entities, operating their own in-house pharmacy allows the entity to enjoy benefits such as:

- Allowing all 340B savings to stay with the entity.
- Facilitating the combination of access to 340B with other drug procurement programs that are only available to in-house pharmacies.
- Gaining a knowledgeable pharmacist as an addition to the clinical team.

As a Hospital, How Do I Know Which Facilities are Eligible for 340B?

HRSA requires each hospital to register all of its off-site outpatient facilities where 340B drugs are purchased and/or eligible prescriptions for 340B are provided to patients. In order for facilities outside the four walls of the main hospital to use 340B drugs for their patients, the facility must be listed as an integral part of the hospital and included as reimbursable on the covered entity's most recently filed Medicare cost report.

My Hospital is Subject to the GPO Prohibition. Can We Ever Use a GPO?

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 340B database;
- 3) Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent;
- 4) The hospital maintains records demonstrating that drugs purchased through the GPO are not utilized or otherwise transferred to the parent hospital or registered outpatient facilities.

