

The Importance of Compliance

All entities covered by the 340B Drug Pricing Program are subject to audit by manufacturers or the federal government. It is important that your entity is compliant with the 340B requirements, as failing to do so can make your entity liable to manufacturers for refunds obtained through the program or removed from the 340B Program altogether.

The following tips will help you ensure that your entity is in compliance with the 340B Program requirements.

Compliance Best Practices

To ensure your entity's compliance with the 340B program:

1. Have robust, detailed written policies and procedures that document your 340B-related decisions and match your practice's policies and procedures. This is the most important thing you can do to ensure compliance with the 340B Program. Establish a regular schedule for reviewing and updating your 340B policies and procedures.
2. Check and update your 340B database entry at least quarterly to make sure that all data related to prescribing and distributions are accurate and match your practice (i.e., if you are listed as being carved-in, that you are in fact using 340B-priced drugs with your Medicaid patients). Outdated information (such as authorizing officials who no longer work at your organization) is considered a finding on an audit.
3. Conduct regular internal audits of 340B compliance of your service site(s) and any vendors that you are contracting with to do 340B work. For example, if you have contract pharmacy arrangements or a third-party vendor for a virtual inventory system, you are expected to audit that arrangement at least annually, to make sure that all data going into that system are accurate and that the vendor is maintaining 340B compliance.
4. Conduct regular (e.g., monthly or quarterly) inventory checks to monitor compliance of inventory management and tracking.
5. Conduct regular chart audits to ensure that no diversion or duplicate discount is occurring (see below for more information). Make sure your charts reflect that patients are meeting the 340B patient definition and that the billing for Medicaid matches your Medicaid Exclusion File selection.
6. Orient new staff and conduct regular training for all staff. All staff involved in the process of inventory or dispensing of 340B-priced drugs should be updated regularly.

Diversion

If an individual seeks services at your agency and does not meet the 340B patient definition, but is provided 340B-priced drugs, this is considered “diversion.”

Examples of diversion:

- » Using 340B-priced drugs for a patient who has been admitted as an inpatient
- » Using 340B-priced drugs for an individual who only wants to purchase medication, but with whom you have no established patient relationship
- » Transferring drugs from one covered entity to another covered entity (this includes transferring drugs across 340B entities within the same agency)
- » Transferring 340B drugs to a non-340B-covered entity
- » Using 340B-priced drugs for inpatient/non-eligible patients if your non-340B supplies run out (even if you later replace them)

Mixed Use Setting

If you are going to use 340B-priced drugs in a “mixed use” setting (both inpatient and outpatient), you have two options for organizing your inventory:

1. You can maintain two distinct and physically separate inventories of drugs, storing the 340B drug inventory in one place and non-340B drug inventory in another. While this option is viable, it requires ample space to accommodate both inventories.
2. You can use a virtual inventory model. This entails establishing one centralized, neutral inventory and using a split billing software system to manage it. Once all your data are logged in, the system will identify retroactively whether a patient is 340B-eligible (i.e., established and has received a family planning service at your agency) or not.

Duplicate Discount

A “duplicate discount” occurs when a state Medicaid agency collects a rebate from a manufacturer on a drug that was purchased at a 340B price. It is the responsibility of the covered entity to take the necessary steps to avoid duplicate discount.

If an entity has chosen to carve-out for Medicaid fee-for-service and is listed appropriately in the [Medicaid Exclusion File](#), the Medicaid agency is entitled to collect rebates from the manufacturer on those drugs. If, in actuality, the entity is giving 340B-priced drugs to Medicaid patients, duplicate discounts will occur.

Carve-in or Carve-out?

When registering for the 340B program as a covered entity, you have to choose to carve in or carve out for Medicaid fee-for-service. This is a decision that applies to all of your Medicaid fee-for-service patients. You must decide whether or not to use 340B-priced drugs with your Medicaid fee-for-service patients.

- » Carve-in means you will use 340B-priced drugs with Medicaid FFS patients
- » Carve-out means you are not going to use 340B-priced drugs with Medicaid FFS patients

Policies and Procedures Should Include:

- » How you define a patient. Beyond the 340B definition of a patient, covered entities need to be specific about how they define a patient, especially with respect to what services they define to be consistent with the grant. What are these services?
- » How you are making sure that drugs are not being diverted to non-eligible patients
- » How you are making sure that duplicate discount is not happening
- » What point in the process a patient goes from outpatient to inpatient (if applicable)
- » How you determine whether a patient is inpatient or outpatient when a drug is dispensed
- » How you manage inventory, how frequently you do a physical inventory, and how frequently you check your inventory management systems
- » What staff is involved in managing the inventory, and who has access to the drugs
- » Who are the responsible staff, and what positions are engaged in all the steps in managing 340B at your agency
- » If you are a Title X-funded entity and provide other primary care services, how you are keeping the 340B-priced drugs separate from the non-340B-priced drugs
- » If your entity decided to carve-in or carve-out for Medicaid fee-for-service, and how you are billing in a way that is compliant
- » A description of the oversight and management of your vendors, providers, and contract pharmacies
- » How, when, how frequently, and who is involved in your internal audits
- » What percentage/number of charts you are going to pull in an internal audit
- » What your policy is around material breach (*the term for when a compliance problem rises to the level of something that needs to be reported to the federal government*)

Additional Resources

- » [HRSA 340B Drug Pricing Program Frequently Asked Questions](#)
- » [340B Prime Vendor Program website](#) (1-888-340-2787 or apexusanswers@340bpvp.com)
- » [National Family Planning and Reproductive Health Association 340B Resources](#)
- » [The Family Planning National Training Center](#)
- » [340B Drug Pricing Program Requirements](#)
- » [340B Federal Register Notices](#)
- » [340B Drug Pricing Program Updates](#)