

# 340B Drug Pricing Program Frequently Asked Questions for Title X Family Planning Agencies



## What is 340B?

The 340B Drug Pricing Program allows safety-net providers to obtain and provide outpatient drugs at a discounted or “340B” rate. The program’s purpose is to help safety-net providers take advantage of limited federal resources in order to reach more eligible patients and provide more comprehensive services. The program is administered by the Office of Pharmacy Affairs, within the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS). This office is sometimes abbreviated to OPA (but should not be confused with HHS’s Office of Population Affairs, also known as OPA).

## ACCESSING THE PROGRAM

### What kind of organizations can use 340B supplies?

Safety-net providers, including “[disproportionate share](#)” hospitals and recipients of specific federal grants from HRSA, the Centers for Disease Control and Prevention (CDC), the Office of Population Affairs, and the Indian Health Service are eligible to participate in the 340B program. Once approved and registered in the 340B database, safety-net providers are understood to be “covered entities.”

### How do we access this program?

All Title X-funded health centers are eligible to participate in the 340B program.

If you believe your agency is eligible, you can go to the [340B Office of Pharmacy Affairs Information System](#) to register during one of the four annual open enrollment periods. New registrations are accepted January 1-15, April 1-15, July 1-15, and October 1-15 annually.

After you set up your account, you may make changes, such as update addresses, change contact information, and withdraw service sites from the program at any time. New sites or contract pharmacy arrangements may only be added during one of the four open enrollment periods.

When you register for the 340B program, each site must select an authorizing official (AO) and a primary contact (PC). AOs must be able to sign for and represent your organization legally. AOs and PCs must create individual user accounts and will not be able to share access. It is required that you select different individuals to serve in the AO and PC roles to ensure access to your 340B database entry, links and information for annual recertification, and to provide continuity if one of the two is away or leaves the organization.

### Does the service site, the sub-recipient, or the grantee apply for certification?

In the past, the Title X grantee was responsible for the application. Now the sub-recipient or service site is usually the entity responsible for applying, with the grantee identified as part of the application. The grant number must be provided as part of the application, which is obtained from the grantee.

## Do we have to recertify every single year?

Yes, 340B-covered entities must recertify annually. Covered entities must prove their continued eligibility to participate in the 340B Drug Pricing Program as part of applying for recertification. Recertification also serves as an annual attestation of compliance with the requirements of the 340B program.

## How do we access discounted medications?

The primary way to access discounted medications is through the Prime Vendor Program, run by [Apexus](#). This program operates as a large group purchasing organization. Any 340B-covered entity can become a member of the Prime Vendor Program. It is free of cost to join and drugs and devices can be purchased through the program. Most pricing is set at what is referred to as a “sub-ceiling” price and may be more cost effective than other purchasing options. The Prime Vendor Program also offers other non-340B eligible items, including male and female condoms, test kits, and vaccines, at a reduced price to its members.

Alternatively, you can purchase medications through the manufacturer, a wholesaler, or a group purchasing organization (GPO) at a 340B price. Some manufacturers of long-acting reversible contraceptives (LARC) require their devices to be purchased from specified specialty distributors, which make 340B pricing available to eligible entities. There are some GPOs that cater to family planning providers, such as Afaxys.

## We receive both Title X funding and 318 STD funding. Do we need to be certified as a 340B-covered entity twice?

You are not required to register for each eligible grant you receive. Some entities choose to maintain two registrations in order to maximize the number of patients able to receive 340B-priced drugs.

## We are a federally-qualified health center (FQHC) that also receives Title X funding. Do we need to be certified as a 340B-covered entity twice?

No. Because FQHCs have an expanded scope of services that includes family planning services, many choose to register only once under their FQHC designation.

## How can we find out if we are already a covered entity?

Search the [340B Office of Pharmacy Affairs Information System \(OPAIS\)](#).

## ELIGIBLE PATIENTS

Now that we know we are a covered entity, which patients can get these drugs, and which cannot?

There are three criteria that a patient at a Title X-funded health center must meet in order to receive 340B-priced drugs:

1. The patient must have an established relationship with you (i.e., medical record). *(This individual must be your patient already and not coming to you solely for the purpose of obtaining discounted medications.)*
2. The patient must have received some clinical services from a provider that is employed by or contracted with your organization. *(This patient must not be coming to you solely for the purpose of obtaining discounted medications.)*
3. The patient has to receive a health care service that is consistent with the grant that makes you eligible for 340B pricing. In an entity certified for 340B under Title X, a patient has to receive some kind of family planning or family planning-related service, in order to be eligible to receive 340B-priced drugs. *(If you are also a 318 STD site or a FQHC, a patient can receive health care services that are consistent with those grants, if you are certified as a covered entity for those grant programs.)*

As long as the patient is an outpatient and meets these three criteria, any drug that you give at that visit can be a 340B-priced drug. If a patient receives a service consistent with the grant, but then you prescribe an additional drug that has nothing to do with family planning but is needed by the patient, both medications can be 340B-priced.

Note that there are no requirements about insurance status or income level when considering if a patient is eligible to receive 340B-priced drugs.

### Can patients get 340B-priced drugs on their first visit?

Yes. Patients can receive 340B-priced drugs during their first visit, as long as a clinical service was provided and a medical record was initiated by the covered entity. Contraceptive counseling may be considered a service consistent with the grant in this context.

### Do patients have to see a provider and have an encounter in order to get 340B-priced drugs?

Yes. Patients have to see a provider and receive a health care service for the patient to receive a 340B-priced drug. Note: They can receive 340B medications—such as regular Depo Provera, or pills, patch, and the ring—as refills without seeing a provider every visit.

## USING 340B IN SPECIFIC SCENARIOS

Can we use Title X funds to purchase 340B-priced drugs? (Can we use our 340B-priced drugs for our Title X patients who slide to zero?)

Yes.

Can we use 340B-priced drugs for expedited partner therapy (EPT)?

While there is no clear guidance, there are both Title X and 318 providers who use 340B-priced drugs for EPT and have had clean 340B audits. The argument is that EPT is actually treatment for your patient, as it is preventing reinfection.

If a patient has private insurance, can we give them a 340B-priced drug and bill their insurance at the same time?

Yes.

If we use a 340B-priced drug for a privately insured patient that costs \$20 at 340B pricing, do we bill the insurance company \$20 or \$50, the rate that is in our contract with the company?

You should bill the insurance company at whatever your agreed-upon contracted rate is, regardless of what you paid for the drug. For patients with Medicaid coverage, it depends on the state. You should check your state Medicaid policy.

Can 340B be used for immediate postpartum LARC in the hospital setting?

No. 340B only applies to covered outpatient drugs. That is a statutory requirement of the program.

What if, for instance, the hospital discharged the patient after a delivery and sent her to the clinic across the hall for a hormonal implant insertion?

That would be considered an outpatient service, and 340B can be used. It is up to the hospital to specify how it determines when a patient has transitioned from inpatient to outpatient. This should be included in its 340B policies and procedures. The use of a 340B-priced drug is acceptable as long as it is being dispensed and inserted after the patient has officially become an outpatient.

## **340B WITH MEDICAID FEE-FOR-SERVICE AND MEDICAID MANAGED CARE PATIENTS**

### **How do we use 340B-priced drugs with Medicaid fee-for-service patients?**

Using 340B-priced drugs with Medicaid patients is more complicated in terms of compliance, than with patients who have other health insurance coverage or self-pay patients. There are important differences in how you use 340B with Medicaid fee-for-service (FFS, also referred to as “straight Medicaid”) versus Medicaid managed care patients. Federal guidance is available on how to use 340B with Medicaid patients. Consult your state Medicaid agency’s policies.

### **What does “carve-in/carve-out” mean?**

When you register for the 340B program as a covered entity, one of the things you have to elect is whether to carve in or carve out for Medicaid fee-for-service. You must decide whether or not you will use 340B-priced drugs with your Medicaid fee-for-service patients. This is an all-or-nothing decision.

- » 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 your Medicaid FFS patients
- » If you carve in, then your entity will be listed in the Medicaid Exclusion File, maintained by HRSA. The State Medicaid agency will not collect a rebate from the manufacturer on these drugs, because the manufacturer has already sold the drugs at the discounted 340B price.
- » If you carve out, then the Medicaid agency is entitled to claim a rebate from the manufacturer.

You may change that selection at any point, but it doesn’t become effective until the beginning of the next calendar quarter when the Medicaid Exclusion File is updated.

### **How does using 340B-priced drugs for Medicaid fee-for-service differ from Medicaid managed care?**

Medicaid managed care patients can be eligible for 340B-priced drugs, but duplicate discounts are still prohibited, as they are in Medicaid fee-for-service. You have to be listed in the Medicaid Exclusion File for both fee-for-service and Medicaid managed care patients, and your listing has to match your practice. However, the federal government has not yet issued a recommendation (or requirement) to use any particular process to avoid duplicate discounts for Medicaid managed care patients. Therefore, the process providers must use to make sure their respective state Medicaid agencies can identify those drugs given to Medicaid managed care patients are 340B-priced ones varies from state to state. Some states just use the Medicaid Exclusion File, as they do with fee-for-service patients. Others require the use of specific modifiers or other mechanisms. It is important to note that states are not required to use the Medicaid Exclusion File

to identify 340B claims, but covered entities are required to be listed appropriately in the file regardless of whether the state uses it.

Because of this variation in processes for the use of 340B-priced drugs with Medicaid managed care patients, you must consult your state Medicaid agency's policies.

### Use of 340B-priced Drugs by Payment Source

Insurance	Can I use 340B?	How do I bill for drugs?
<b>Self-Pay</b>	Yes, can use 340B-priced drugs if patient meets eligibility criteria.	Use sliding fee scale to determine patient charges. Title X funds can be used to cover the remaining portion if less than full fee.
<b>Private</b>	Yes, can use 340B-priced drugs if patient meets eligibility criteria	Charge patient co-pay (if necessary) using Title X program requirements for income levels.  Bill private insurance at the contracted rate.
<b>Medicaid FFS</b>	<u>If you have elected to carve in</u> , then, yes, can use 340B-priced drugs if patient meets eligibility criteria.	Carve out: Bill your state Medicaid agency as specified in state policy.  Carve in: List your agency as carved in in the Medicaid Exclusion File. Bill the state Medicaid agency as specified in state policy.
<b>Medicaid Managed Care</b>	<u>If you have elected to carve in</u> , then, yes, can use 340B-priced drugs if patient meets eligibility criteria	Bill the Medicaid managed care organization according to your state Medicaid agency's policy.

## 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 Educational Resources](#)
- » [340B Eligibility & Registration](#)
- » [Title X Family Planning Clinics](#)