340B Drug Pricing Program

Frequently Asked Questions for Title X Family Planning Agencies

RHNTC REPRODUCTIVE HEALTH NATIONAL TRAINING CENTER

National Family Planning & Reproductive Health Association

WHAT IS 340B?

The 340B Drug Pricing Program allows safety net providers to purchase covered outpatient drugs at a discounted or "340B" rate and provide these drugs to their patients. The program's purpose is to help safety net providers maximize 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 recipients of specific federal grants (listed below) and specific types of hospitals 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."

Grant programs that confer 340B eligibility:

- Title X Program
- Centers for Disease Control and Prevention (CDC) 318 sexually transmitted diseases (STD) prevention and control grants
- Federally qualified health centers (FQHCs) and FQHC look-alikes (a specific federal designation)
- Native Hawaiian health centers
- Tribal and urban Indian health centers
- Ryan White HIV/AIDs Program
- Tuberculosis (TB) clinics
- Black lung clinics
- Hemophilia treatment centers

How does a Title X-funded health center 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 (OPAIS) during one of the four annual registration periods to enroll. New registrations are accepted January 1–15, April 1–15, July 1–15, and October 1–15 annually. New sites or contract pharmacy arrangements may only be added during one of the four annual registration 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 these two individuals is away or leaves the organization. During registration, sites will also be asked to supply the grant number conferring eligibility (subrecipients and service sites might need to obtain this number from their grantee) and to make a Medicaid carve-in/carve-out selection (more on specific requirements around 340B-priced drugs and Medicaid beneficiaries below).

If approved, new 340B-covered entities become active on the first day of the next calendar quarter after the registration period (e.g., an entity that registers during the January 1–15 period will become active on April 1). Entities may begin to purchase or dispense 340B-priced drugs and engage in contract pharmacy arrangements after becoming active in OPAIS.

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. Changes to the Medicaid carve-in/carve-out selection can also be made at any time, but they will only become active on the first day of the next calendar quarter after the change is made.

Does the service site, the subrecipient, or the grantee register as a covered entity?

In the past, the Title X grantee often took responsibility for registration and was the covered entity. The current recommendation is for registration to be done at the subrecipient/service site level. This change is to ensure that the AO, who is legally responsible for attesting to the site's compliance, is as close to the site's daily activities as possible.

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. Each 340B entity type will have a designated recertification period every year. AOs and PCs will be notified by email about all recertification matters, including the link to complete recertification. Usually Title X shares a recertification period with STD and TB entities. If an entity has more than one funding stream/340B ID, it must complete recertification for each ID separately.

How do we access 340B-priced medications?

The primary way to access 340B-priced 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 charge 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, a distributor, 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.

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., as documented in a medical record). (This individual must be your patient 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 who 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 and are certified as a covered entity for those grant programs, a patient can receive health care services that are consistent with those grants.)

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 (see more about specific rules for Medicaid beneficiaries below). 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 for insurance status or income level when considering if a patient is eligible to receive 340B-priced drugs.

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 because of the third prong of the patient definition above. Registering under more than one qualifying funding stream poses an additional compliance burden, but doing so will also allow you 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?

It is permissible, but not required. Because FQHCs have a broad 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).

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(s) was provided and documentation of that visit was initiated by the covered entity, usually in a medical record. Contraceptive counseling may be considered a service consistent with the Title X 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, either in person or via telehealth, and receive a health care service consistent with the grant in order for the patient to receive a 340B-priced drug. Note: Patients can receive 340B medications—such as regular Depo Provera, or pills, patch, and the ring—as refills without seeing a provider every visit as long as the refill is originating from a prescription connected to a qualifying visit.

What should a health center do if they leave the Title X Program or lose Title X funds from their grantee?

If a health center leaves the Title X Program (voluntarily or otherwise), that health center has lost their eligibility for the 340B program as a family planning entity. Upon losing eligibility, the health center must immediately act to terminate their 340B registration through OPAIS; it also must immediately cease to purchase and dispense 340B-priced medications, and those medications must be returned or destroyed. If the loss of eligibility is unplanned or unexpected and the entity has 340B eligibility through another funding stream, a one-time transfer of inventory may be an option, but it must be approved by HRSA.

USING 340B IN SPECIFIC SCENARIOS

Can we use Title X funds to purchase 340B-priced drugs?

Yes, but it is not required to do so. If you have other non-Title X dollars that could include funds from provider reimbursements from third-party payers, you may also choose to use those funds to purchase 340B drugs.

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

Yes. As long as the patient meets the three criteria (above), that individual will be eligible to receive 340B-priced medications. If you are dispensing drugs on-site, medications should also be slid along with other charges from the visit. One of the benefits of participating in the 340B program for a Title X-funded health center is paying less for products that the patient must receive at no cost.

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

While there is no clear guidance, there are both Title X and CDC 318 STD providers who use 340B-priced drugs for EPT and have had clean 340B audits. The argument is that EPT is actual treatment for your patient, as it is preventing reinfection. If you choose to use 340B-priced medications for EPT, you should have your process for doing so thoroughly documented in your 340B policies and procedures.

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

Yes. As long as the patient meets the three criteria listed above, they will be eligible to receive 340B-priced medications.

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. There are additional rules for patients with Medicaid coverage. See below for more information specific to Medicaid.

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

No, not if the patient is still classified as an inpatient when the LARC is inserted. 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 them 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.

My entity owns and operates multiple health centers that share an electronic health record system. Can a patient receive a qualifying service at one of our sites, but pick up the 340B-priced medication at another one of our sites?

No. If each site is registered as its own 340B covered entity, then a patient has to receive a qualifying service at the same site where their medication is dispensed, unless you are a FQHC or hospital with parent-child registration.

340B WITH MEDICAID FEE-FOR-SERVICE (FFS) AND MEDICAID MANAGED CARE PATIENTS

How do we use 340B-priced drugs with Medicaid FFS 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. This is because Medicaid agencies are generally eligible to collect a rebate from a drug manufacturer when they reimburse a provider for a drug, to ensure that Medicaid is paying the lowest price available. However, if that drug was already sold at a discount through the 340B program, then Medicaid cannot collect that rebate. If a Medicaid agency collects a rebate on a drug already sold at a 340B price, that is referred to as a duplicate discount and is prohibited. For this reason, there are additional rules to ensure that duplicate discounts do not occur.

There are federal rules that govern the use of 340B-priced drugs with Medicaid FFS patients. For these patients, each entity must make an "all-or-nothing" decision upon registration, often referred to as carving-in or carving-out (see below for definitions). Entities should make sure that their current practices match what their 340B OPAIS record says regarding Medicaid billing. There are important differences in how you use 340B with Medicaid FFS versus Medicaid managed care patients. Federal guidance only addresses FFS patients.

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 FFS. You must decide whether or not you will use 340B-priced drugs with your Medicaid FFS patients. This is an all-or-nothing decision.

- Carve-in means you will always use 340B-priced drugs with Medicaid FFS patients
- Carve-out means you are never 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 FFS 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 FFS. Your covered entity has to be listed in the Medicaid Exclusion File for both FFS and Medicaid managed care patients, and the entity listing has to match the covered entity 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. Instead, the federal government has instructed state Medicaid agencies to develop their own policies to ensure that duplicate discounts are not happening with Medicaid managed care patients.

Therefore, the identification process providers use to ensure that their respective state Medicaid agencies are giving 340B-priced drugs to their Medicaid managed care patients varies from state to state. Some states just use the Medicaid Exclusion File, as they do with FFS 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. If you are unsure of your state's policies in this regard, a good resource to start with is Apexus's 340B Medicaid Profiles by State/Territory.

Use of 340B-Priced Drugs by Payment Source

Insurance	Can I use 340B?	How do I bill for drugs?
Self-Pay	Yes, can use 340B-priced drugs if the patient meets the patient definition.	Use a sliding fee scale to determine the patient charges. Title X funds can be used to cover the remaining portion if less than full fee.
Private	Yes, can use 340B-priced drugs if the patient meets the patient definition.	Charge patient co-pay (if necessary) using Title X Program requirements for income levels. Bill private insurance at the contracted rate.
Medicaid FFS	If you have elected to carve-in, then, yes, can use 340B-priced drugs if the patient meets the patient definition.	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 your state Medicaid agency as specified in state policy.
Medicaid Managed Care	If you have elected to carve-in, then, yes, can use 340B-priced drugs if the 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 (Hotline: 1-888-340-2787 or apexusanswers@340bpvp.com)
- National Family Planning and Reproductive Health Association 340B Resources
- 340B Educational Resources
- 340B Eligibility & Registration

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