

340B AND MEDICAID: AN EXPLANATION FOR FAMILY PLANNING PROVIDERS

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The intersection of the federal 340B drug pricing program and Medicaid is complex, leading to confusion among publicly funded family planning providers as to their rights and responsibilities with regard to the use of 340B drugs for their Medicaid patients. To help address this problem, this guide explains key aspects of the 340B program, outlines important elements of current federal law and guidance, and describes the potential variation between states with regard to how that law and guidance are being implemented to provide a practical understanding that will help providers maximize their benefit from the use of 340B drugs in Medicaid.

What Is the 340B Program and its Purpose?

The purpose of the 340B program is to allow safety-net providers to stretch scarce federal resources as far as possible to reach more eligible patients and provide more comprehensive services. The 340B program is administered by the Office of Pharmacy Affairs at the federal Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services. Federal law mandates that drug manufacturers provide discounts on their drugs to certain health centers, known as covered entities, which primarily serve low-income or medically underserved individuals. Covered entities are eligible for these discounts if they receive any one of a specified group of federal funding streams. Title X-funded health centers are among the covered entities that can receive these discounts. Other covered entities include federally qualified health centers (FQHCs) and FQHC look-alikes, Ryan White HIV/AIDS program grantees, children's hospitals, disproportionate share hospitals, and Section 318-funded sexually transmitted disease (STD) clinics. Accepting Medicaid patients does not, in and of itself, make a provider eligible for 340B, but Medicaid patients are not precluded from getting 340B drugs if they are receiving care through a covered entity and otherwise eligible under the 340B program. Therefore, Title X-funded health centers and other covered entities can and do use 340B drugs with Medicaid patients, but there are additional considerations which are outlined throughout this document.

How Does the Program Work?

Federal law sets a ceiling price for 340B drugs. Manufacturers may charge less than, but cannot exceed, this ceiling price. There are a variety of ways that a covered entity can purchase 340B-priced drugs, such as by purchasing directly from the

manufacturer or a wholesaler. One common route is for the covered entity to purchase the drugs through a group purchasing organization (GPO). Some notable examples of GPOs are:

- The Afaxys Group Services (AGS) GPO focuses solely on the needs of public health and safety-net providers, offering a diverse portfolio of discounted products and services. In addition to members-only 340B and non-340B pricing, the AGS GPO also has a relationship with MedAssets, a major national GPO, offering members access to MedAssets' expansive portfolio of offerings, including office supplies, medical supplies, equipment, and services. Membership to the AGS GPO is free and open to all safety-net providers.
- Apexus is a company contracted by HRSA's Office of Population Affairs to run the 340B prime vendor program. The prime vendor program negotiates discounts on 340B drugs and devices below the 340B ceiling price. To purchase drugs through the prime vendor program, a covered entity must be registered with the prime vendor. Membership is free and open to all 340B covered entities. The prime vendor also negotiates discounts for "value-added products" that are not 340B eligible, such as vaccines and condoms.
- California Family Health Council (CFHC), the Title X grantee in California, operates a co-op program in partnership with Council Connections, a nationwide GPO. The CFHC co-op is open to health care organizations, as well as social service, education, and hospitality organizations across the country, and membership is free. Participation in the CFHC co-op provides access to discounted 340B and non-340B priced drugs to all its members. 340B covered entities may become members of the co-op for free after completing a membership application.

Which Patients Can Receive the Discounted Drugs?

In order to receive a 340B drug, an individual must meet the three-pronged definition of an eligible patient established in HRSA guidance. The patient must:

1. Receive services from a health care professional employed by or in contract with the covered entity¹;
2. Have an established relationship with the covered entity, as demonstrated by the covered entity maintaining a medical record for the patient; and
3. Receive a service or services that are consistent with the grant by which the covered entity is eligible for 340B.

As long as an individual meets the eligible patient definition above, any drug provided to that patient can be a 340B drug, so long as the drug is a covered outpatient drug (more on that in the next section). In the Title X context, any patient that would be counted as a “family planning user” on the Family Planning Annual Report (FPAR) would potentially qualify as a 340B patient, depending on the specific circumstances of the services the patient receives at a particular visit.² For example, a patient presents at a Title X-funded health center for a well-woman visit and asks to initiate hormonal contraception, but upon examination, the patient is found to have an infection that requires antibiotics. The clinician performing the exam may use 340B drugs not only for that patient’s contraceptive method of choice, but also for the antibiotics necessary to treat the infection. The same is true for a patient interested in a drug to assist with smoking cessation.

In addition to meeting the definition of an eligible patient, the individual must receive services beyond just receiving a drug. For example, in the Title X context, emergency contraception provided to an individual on a walk-in basis (e.g. without an exam or other health care services provided) would not

¹ Other arrangements may include a “referral for consultation” arrangement, under which the responsibility for the care of the patient remains with the covered entity.

² For the FPAR, a “family planning user” is an individual who has at least one family planning encounter at a Title X service site during the reporting period. This is true regardless of whether the patient has commercial insurance coverage, Medicaid coverage, or is uninsured, and applies to both male and female clients.

A “family planning encounter” is documented, face-to-face contact between an individual and a family planning provider that takes place in a Title X service site with the outcome of providing family planning and related preventive health services to clients who want to avoid unintended pregnancies or achieve intended pregnancies. A written record of the service(s) provided during the family planning encounter must be documented in the client record. Any “family planning user” would qualify as a 340B patient.

Thus, a “family planning user” would always meet at least one of the three prongs of the 340B patient definition (having an established relationship as demonstrated by the maintaining of a medical record). However, whether the family planning user meets the other two prongs (concerning services received) would need to be determined on a visit-by-visit basis, depending on the specific services received at each visit.

constitute a “service” under the definition. Therefore, the individual would not be considered an eligible patient under those circumstances. However, providers may use 340B-priced drugs for refills, as long as the patient meets the 340B patient definition when the drug is originally prescribed.

When 340B drugs are given to patients that do not meet the above criteria, the covered entity has engaged in what is called “diversion.” Diversion is prohibited, so the covered entity may be liable for repayment of the cost of drugs used for this purpose. Audits will include a review of 340B drugs dispensed, patient records, and other information and materials to ensure that diversion has not occurred. HRSA auditors will specifically want to see stand-alone 340B policies and procedures that specifically address the prevention of diversion (giving 340B-priced drugs to patients that don’t meet the patient definition) and duplicate discount (see page 4 for more information on duplicate discount).

Which Drugs Can Be Discounted under 340B?

As stated previously, any drug can qualify as a 340B drug, as long as the following requirements are met:

1. The drug must meet the definition of a covered outpatient drug, as defined by the Medicaid statute;³ and
2. The individual receiving the drug must meet the definition of an eligible patient, as previously outlined.

How Do I Use 340B Drugs with Commercially Insured or Self-pay Patients?

A covered entity has the ability to set a reasonable and customary fee for each drug it dispenses above the actual cost to the covered entity for each drug in order to cover the associated overhead costs of dispensing drugs on-site. This amount is included in fee schedules that are used to bill claims to commercial insurers and self-pay patients. The source of a patient’s coverage has no bearing on her or his ability to meet the 340B patient definition (see below for more information).

How Do I Determine the Charge for Self-pay Patients?

Title X providers should refer to the Title X program requirements regarding the schedule of discounts for patients to determine how to charge self-pay patients for 340B drugs. The basic parameters are as follows: Self-pay patients whose income is at or below 100% of the federal poverty level (FPL) would not be charged for the drug. Patients whose income is more than 100% and up to 250% FPL should be charged the appropriate portion of the reasonable charge based on the pre-determined

³ Defined as: an FDA-approved prescription drug, an over-the-counter (OTC) drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin.

schedule of discounts. Self-pay patients with incomes above 250% FPL should be charged the full reasonable charge.

How Do You Determine What to Charge Commercial Insurers?

Title X-funded health centers have historically performed cost analyses of their programs, which often include data on the cost of acquiring the contraceptive methods themselves. Data from these cost analyses can be used to set an agency's rates in its fee schedule. Covered entities initiating contract negotiations with commercial insurers ideally should bring in data from their cost analyses and current fee schedules to help assess the adequacy of the insurer's proposed rates.⁴ Offering beneficiaries a robust network of providers is one tool for commercial insurers to remain competitive in the market. Therefore, it is in the best interest of the commercial insurer to offer providers in their network competitive reimbursement rates. These rates are not necessarily contingent upon the covered entity's specific acquisition costs.⁵

Can I Use 340B Drugs with Medicaid Patients?

Yes, 340B drugs can be used with Medicaid patients. However, there are multiple factors that may impact a covered entity's decision to use 340B drugs with their Medicaid patients. Medicaid law requires manufacturers to provide the state Medicaid agency with rebates on the purchase price of drugs for Medicaid patients. However, the manufacturer is not required to provide that rebate when the drug is sold at the discounted 340B price. "Duplicate discount" is the term used by HRSA to describe the situation in which a manufacturer pays a Medicaid rebate on a drug that was sold at a 340B price.

Covered entities that choose to use 340B drugs with their Medicaid patients play an important role in avoiding duplicate discounts. Covered entities should make sure they are in compliance with 340B guidance governing the prevention of duplicate discounts, which requires covered entities to inform the state Medicaid agency that they are using 340B drugs for Medicaid patients.

What Does "Carve-in" and "Carve-out" Mean?

HRSA guidance allows covered entities to choose whether or not to use 340B drugs for their Medicaid patients. When a covered entity chooses to use 340B drugs for their Medicaid patients, it is referred to as "carving in." Covered entities

that choose not to provide 340B drugs to Medicaid patients are "carving out." When the participating provider is a 340B covered entity, the state can only collect a rebate from manufacturers on drugs provided by that health center if it has chosen to carve out.

Can a State Dictate a 340B Covered Entity's Carve-in/Carve-out Choice?

Many interpret current law and guidance as prohibiting a state from dictating whether a covered entity carves in or out. However, some states have implemented policies requiring one or the other, either for all Medicaid patients or for Medicaid managed care patients.⁶ Thus, covered entities should check the Medicaid policies in their state to determine any requirements governing carving in or out.

Does the Covered Entity Have to Make Carve-in/Carve-out Decisions for All Medicaid Beneficiaries or Can it Be Done on a Case-by-case Basis?

For Medicaid fee-for-service patients, a covered entity must decide to make its decision about carving in or out for all its Medicaid patients. This is not currently a decision that can be made on a patient-by-patient or drug-by-drug basis. In fee-for-service Medicaid, covered entities that have chosen to carve-in must record their National Provider Identifier (NPI) numbers in the federal Medicaid Exclusion File during 340B registration⁷, which state Medicaid agencies and manufacturers reference to determine which drugs are eligible for a rebate.⁸ There is currently no guidance in effect concerning Medicaid managed care patients, other than that covered entities should work with their managed care organizations to determine a process for carving in or out.⁹

⁶ In its proposed omnibus guidance for the 340B program, HRSA has articulated that the choice to carve in or carve out should belong solely to the covered entity. Additionally, HRSA has proposed that covered entities should be able to make different choices regarding carving in or carving out for Medicaid MCO patients by payer or by site. The guidance would also allow covered entities to make a different election with respect to their fee-for-service and Medicaid managed care patients. However, this guidance has not been finalized and does not yet apply.

⁷ "A change to the Medicaid Exclusion File may be requested at any time, but changes do not take effect until the first day of the following quarter and only if approved by OPA before the time it takes the quarterly snapshot of carve-in/carve-out decisions."

⁸ This is a one-time action that providers have to do (unless they want to change their decision on carving in or carving out), not something that happens with each prescription or each patient.

⁹ The proposed omnibus guidance also addresses developing a process for avoiding duplicate discount for Medicaid MCO patients. HRSA has sought public comment on whether it would be feasible to use the Medicaid Exclusion File for MCO patients, or if there is another process that would work better.

⁴ New contracts with new commercial insurers are typically one year in length. At the end of the life of the contract, covered entities will have the opportunity to request rate increases.

⁵ NFPRHA has additional resources regarding contracting with third-party payers and revenue cycle management available at: https://www.nationalfamilyplanning.org/health_care_delivery/revenue_cycle.

How Do You Determine Which Is Right for Your Health Center?

The first consideration is whether your state has any requirements for carving in or out. If your state allows health centers to make their own decisions, then the determining factor should be based on which is the better financial choice for your health center. Answering that question requires consideration of multiple factors, such as:

1. The size of your health center's Medicaid population;
2. What drugs your health center is most frequently providing that population;
3. The differences in available pricing for 340B versus non-340B drugs;
4. Reimbursement rates and requirements for 340B versus non-340B drugs; and
5. Whether or not you dispense on site.

Does the Program Work Differently for Fee-for-service Versus Managed Care Patients?

Under both circumstances, if the covered entity provides a 340B drug to a Medicaid patient, the covered entity must let the state know so that the state does not collect a rebate from the manufacturer for that drug.

Currently, there is no official federal policy on how to avoid duplicate discounts in the Medicaid managed care context. States have been directed to work with providers and managed care organizations (MCOs) to develop a process. Covered entities should consult with their state Medicaid agency and the MCOs with which they have contracts to determine the rules in their state.

How Is the Reimbursement Rate for Fee-for-service Medicaid Patients Determined? Can States Require Providers to Bill at Actual Acquisition Cost for 340B Drugs?

In the recently released Medicaid Covered Outpatient Drug final rule¹, the Centers for Medicare and Medicaid Services are now requiring that all states base their reimbursement for Medicaid covered outpatient drugs in fee-for-service Medicaid (whether those drugs are purchased at a 340B price or not) on actual acquisition cost² plus a professional dispensing fee. Furthermore, the rule states that for 340B providers that carve-in, the reimbursement from the state shall not exceed the 340B ceiling price. For 340B providers carving out, the

reimbursement shall not exceed the actual acquisition cost. States have the flexibility to provide different professional dispensing fees to different types of providers, so there is an opportunity for 340B providers to advocate for enhanced dispensing fees moving forward.

For more information on the 340B program, please visit the NFPRHA website, nationalfamilyplanning.org.

¹ The final rule is available at: <https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

² In this context, AAC is actually an aggregate price determined by the state based on one of several different methodologies, not necessarily the price each individual provider is paying.

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