

Chapter 4

Prices, Charges, and Savings

Note: This entire chapter is new as of the Second Edition of this Manual (March 2018), and **Section 5B is updated as of December 2019.**

A. Purchase Prices for 340B Drugs

1. How prices are set for 340B drugs

Under the law, participating manufacturers may charge no more than a “ceiling price” for 340B eligible drugs and devices provided to 340B providers. The ceiling price is determined by a formula, which varies depending on whether the drugs are generic or brand-name. (See [Section 4.A.2](#) for the specific formulas.) Note that the ceiling price is the *maximum* amount that a manufacturer may charge a 340B provider *for the drug itself*; it may charge less. One reason why some 340B providers choose to purchase drugs through a group purchasing arrangement, such as the Prime Vendor or 340Better (see Sections [3.C.7](#) and [3.C.8](#)), is that these organizations can often negotiate additional discounts (beyond the mandatory 340B discounts) from manufacturers. These discounts are called “sub-ceiling” discounts, and the final price for a drug that receives a sub-ceiling discount is the “sub-ceiling price.”

Also, note that distributors generally charge a fee for their services, which is added to the 340B price for the drugs. Therefore, the 340B price usually does not represent the full price that an FQHC pays for a drug.

Thus, the actual acquisition cost (AAC) for a 340B drug is calculated as:

- the 340B ceiling price (see below)
- minus any sub-ceiling discount
- plus any distributor fees

2. The formula for calculating 340B ceiling prices

Per the 340B statute, the ceiling price is defined as **the lower of** the following two options:

Option One: AMP - URA: Average Manufacturer Price (AMP) minus the Unit Rebate Amount (URA.)
The URA consists of two parts:

- **The minimum rebate percentage**, which equals:
 - 23.1% of the AMP for most brand-name drugs
 - 13% of for generics

PLUS

- **An inflation penalty.** This applies only if the “sticker price” of the drug has been increasing faster than inflation. While the inflation penalty previously applied only to brand-name drugs, in 2015 Congress expanded it to generic drugs.

In other words, Option One equals:

(AMP) - (minimum rebate percentage) – (inflation penalty, if any).

Option Two: Best Price: The lowest price that **any** purchaser pays the manufacturer for the drug, factoring in all rebates, discounts, and other pricing adjustments. However, the statute contains a long list of exceptions to this “best price” requirement — for example, prices charged to other parts of the Federal government (e.g., Veterans Affairs, Indian Health Service) and state-run nursing homes are not considered.

3. What is “penny pricing”? Which drugs does it apply to?

If a drug’s sticker price rises significantly faster than inflation, the inflation penalty could become large enough that the 340B pricing formula above yields a price that is less than zero. At the time of this Manual revision (winter 2018), manufacturers may charge one penny per unit for drugs for which the formula would result in a negative price. This policy is called “penny pricing.”

It is important to note that OPA has requested input on alternatives to penny pricing. OPA finalized this policy in a regulation that was published in the final days of the Obama Administration, and was scheduled to go into effect early in the Trump Administration. However, the effective date has repeatedly been delayed by the Trump Administration. As of February 2018, media reports suggest that OPA will soon propose an alternative to “penny pricing.”

4. Finding the ceiling price for a 340B drug

At the time of this Manual revision (February 2018), there is no easy way to determine the correct ceiling price for a drug purchased under 340B. This is because the AMP (a key factor in calculating ceiling prices) is considered proprietary information and is not available publicly. In 2010, Congress instructed OPA to establish a database with this information; however, that database has yet to become available. It is anticipated that this database will eventually become part of the larger OPAIS system (see [Chapter 5](#).)

5. Factors that determine a drug’s Actual Acquisition Cost drug

In summary, a health center’s Actual Acquisition Cost (AAC) for a specific drug is determined as follows:

- Start with the Average Manufacturer Price (AMP) for the specific quarter
- Subtract the minimum rebate percentage (23.1% for brand drugs, 13% for generics)
- Subtract the inflation penalty if applicable
- If this calculation results in a price that is below zero, raise the price to one penny per unit.

- Compare the results of this calculation above to the manufacturer’s “Best Price” for the drug; take the lower of the two amounts.
- Subtract any sub-ceiling discounts.
- Add distributor fees.

6. Why can prices vary for the same 340B drug?

There are many reasons why the price of a 340B drug may vary over time, as well as at a single point in time. These include:

- Manufacturers often change the AMP for a drug, which leads to changes in the 340B price on a quarterly basis.
- Different purchasing groups may be able to negotiate different sub-ceiling discounts. (See discussion of Apexus and 340Better in sections [3.C.7](#) and [3.C.8](#).)
- Different distributors charge different fees.

Nonetheless, the ceiling price for a specific drug should be consistent across all health centers (and other 340B providers) during any given quarter. If different health centers are being charged significantly different amounts for the same drug at the same time (more than can be accounted for by differences in sub-ceiling discounts and distributor fees), this suggests an error on how the ceiling price is being calculated for some of the health centers.

B. Charging patients for drugs purchased under 340B

1. Factors to consider when setting patient charges for 340B drugs

The 340B statute does not dictate how covered entities should charge patients for drugs purchased under 340B. Nonetheless, there are multiple factors that FQHCs should consider when determining how much to charge patients for drugs purchased under 340B. These include:

- Section 330 Sliding Fee Scale requirements and prohibitions
 - Health Centers’ mission of providing affordable, accessible care to all, regardless of ability to pay
- The following sections address each of these elements in detail.

2. How Section 330 Sliding Fee rules impact drug charges

As a reminder, Section 330 requirements around the Sliding Fee Discount Schedule (SFDS) state that:

- No patient shall be denied services due to an inability to pay.

- Uninsured and underinsured patients with incomes at or below 100% of the Federal Poverty Level (FPL) may be charged no more than a nominal fee for services;
- Uninsured and underinsured patients with incomes between 101% and 200% FPL must be charged for services based on a SFDS;
- Patients with incomes above 200% FPL are not eligible for discounts funded with Section 330 grant funds.

Note that HRSA/BPHC has stated that the SFDS requirements apply to the “service” part of the costs associated with providing a drug – namely, the dispensing costs. BPHC does not explicitly require FQHCs to apply the SFDS to the cost of the drugs themselves (called the “ingredient cost”), as they are considered supplies rather than services. However, BPHC permits such discounts, and the law clearly states that health centers must ensure that no patient is denied services due to an inability to pay.

3. Underinsured patients qualify for the Sliding Fee Discounts

A patient is considered underinsured if the amount they would pay for a service with their insurance coverage is more than what they would be charged under the SFDS, based on their income. This can occur if an insured patient has a high deductible or copay. BPHC requires that all underinsured patients be charged based on the SFDS.

4. How the Health Center mission impacts 340B charges

The health center mission — to ensure affordable access to required services for underserved populations — indicates that health centers have a responsibility to ensure that SFDS-eligible patients are able to afford their prescriptions. For this reason, **health centers should ensure that charges to SFDS-eligible patients for drugs purchased under 340B do not pose a financial barrier.**

5. Must FQHCs charge SFDS patients exactly the 340B price? **Note updates made 12/19**

Health centers are not restricted to charging the patient only their 340B purchase price; however, developing a SFDS is a delicate balance of affordability for the patient and financial viability of the program for the health center. To ensure affordability, health centers must ensure that the amount the patient is charged does not create a barrier to that patient accessing care - in this case prescription medication. To ensure financial viability of the program, it is both permissible and appropriate for the health center to recoup the costs associated with acquiring the drugs dispensed or administered to the patient, keeping in mind that costs associated with acquiring the drugs and devices may include more than the purchase price. Acquisition costs may include vendor fees as well as costs associated with stocking and maintaining adequate inventory.

In some cases, the 340B price of the drug may be so low (e.g., one penny) that it is appropriate to use a cost-plus pricing methodology to determine the ingredient cost. In other cases, the 340B price may be so high as to be unaffordable for a SFDS patient. In this case, the health center is expected to find a way to offset enough of that cost (e.g., through Patient Assistance Programs or other funding sources) to make the drug affordable. In addition, health centers are also ~~expected~~ **permitted (but not required)** to charge a separate fee to cover the costs of dispensing the drug (called a professional

dispensing fee, or pdf.) As stated above, BPHC considers dispensing costs to be a service, and ***if patients are charged a separate pdf, as such the SFDS must be applied to it.***

6. Models for pricing 340B drugs for SFDS-eligible patients

While there are various models for pricing 340B drugs for SFDS patients, they all share one common element: they are **designed to ensure that charges to SFDS-eligible patients for drugs purchased under 340B do not pose a financial barrier.**

As stated above, it is permissible and appropriate for the health center to recoup the cost of acquiring the drugs, particularly in the case of drugs with relatively low 340B prices.

7. Different charges allowed at in-house versus contract pharmacies

Health centers are permitted to charge the SFDS-eligible patients different amounts for the same 340B drug depending on whether they purchase it at an in-house or contract pharmacy. Professional dispensing fees (PDF) can be significantly higher at contract pharmacies than in-house pharmacies, and health centers may adjust their charges to reflect these differences. Because of these higher fees, many contract pharmacy arrangements do not include generic drugs.

Also, some contract pharmacy arrangements are not able or willing to accommodate a SFDS. While it is possible to create SFDS groups at some contract pharmacies, a concise protocol must be created. The health center must work with the contract pharmacy to implement a clearly-defined procedure to indicate how a prescription will be categorized and identified to each respective group.

Though there is no requirement that all contract pharmacy arrangements provide a sliding fee, ***it is the health center's responsibility to ensure that the uninsured and underinsured patients below 200% FPL have access to affordable prescription medication.*** If this is not possible through a contract pharmacy, it must be achieved through another avenue