

# 340B Drug Pricing Program

March 29, 2018



## WHAT IS THE PROPOSAL IN THE ADMINISTRATION'S PROPOSED STATE BUDGET?

The Administration's proposed budget eliminates the 340B Drug Discount Program (340B) from Medi-Cal Fee-For-Service (FFS) and Managed Care. The state argues that this proposal is intended to comply with federal law, however federal law does not require an elimination of 340B but rather that states do their due diligence to avoid duplicate discounts - to identify and exclude 340B drug claims when seeking Medi-Cal drug rebates.

## WHAT IS 340B?

Section 340B of the federal Public Health Service Act created a drug discount program to allow certain types of health care providers – called covered entities - to buy outpatient drugs at reduced prices. A manufacturer's 340B price is dependent on a maximum (ceiling price) determined by a formula outlined in Section 340B of the Public Health Service Act.

## WHAT IS A COVERED ENTITY?

340B calls an eligible provider a "covered entity." Federally qualified health centers (FQHCs) are covered entities, along with several other types of providers including comprehensive hemophilia diagnostic treatment centers, certain types of hospitals serving low income individuals including some children's hospitals and cancer hospitals, family planning programs, tribal and urban Indian health organizations, Ryan White HIV /AIDS Program sites, and entities receiving funds for treatment of sexually transmitted diseases or tuberculosis. To participate in 340B, eligible organizations must register and be enrolled with 340B and comply with all 340B requirements.

## WHICH DRUGS ARE 340B DRUGS?

With limited exceptions, any outpatient prescription drug written at the covered entity site, for a patient of the covered entity, qualifies as a 340B drug.

## DOESN'T THE STATE ALREADY GET DRUG DISCOUNTS?

The state can secure lower prices on drugs purchased for Medi-Cal, but this comes largely through manufacturer rebates (i.e. "after purchase") and are referred to as Medi-Cal drug rebates. Manufacturers offer rebates to ensure their drugs are sold in the Medicaid program.

The discount a provider receives through 340B however is different. 340B is for eligible providers and discounts are applied "before purchase" price. Manufacturers are required to provide a 340B discount to eligible providers known as covered entities.

## WHAT IS A DUPLICATE DISCOUNT?

Duplicate discounts are prohibited in 340B. There are federal rules that covered entities and states must comply with to avoid such violations. "Duplicate discount" is defined as a drug transaction in which the drug is billed at the 340B price and also submitted by the state for a rebate.

## 340B PRICING AND BILLING

The mechanics of 340B pricing and billing vary depending on the type of drug and whether the covered entity is using an in-house pharmacy or a contract pharmacy. As a result, pricing and billing vary across covered entities depending on the medication being prescribed and whether or not they have an in-house pharmacy.

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FQHCs participating in 340B use both in-house pharmacies and contract pharmacies.

- **In-house Pharmacy Billing:** The covered entity pays the manufacturer directly in exchange for the drug.
- **Contract Pharmacy Billing:** The covered entity pays the manufacturer the 340B price but also pays a distribution fee to the contract pharmacy. These transactions can become very complicated with third party vendors also playing a role to ensure covered entities avoid duplicate discounts and diversions; sometimes a contract pharmacy will play both roles.

## 340B DRUGS HAVE A POSITIVE IMPACT ON HEALTH CENTERS AND THE PATIENTS THEY SERVE

As a requirement of the program, covered entities, like FQHCs, use their 340B savings to provide additional services to improve the health of their patients. While covered entities do not often have a budget line item that directly attributes 340B savings to the cost of new services or infrastructure, health centers report the program savings cover extending hour of operations or hiring additional case workers for homeless patients. Here are two more detailed examples:

- **Strengthening Health Center Pharmacies:** Many health centers have a pharmacy inside the health center. A patient who can fill a prescription at the same time and at the same place as the medical appointment is more likely to pick up the prescription and take that medication. Several health centers report they would have to close their in-house pharmacies without the discount, the pharmacy would be too expensive to maintain.
- **Expanding Access to Care:** One rural north health center uses their savings from 340B to fund their transportation program to help take people to specialty appointments far from the clinic.

340B has become part of the operational base of revenue health centers rely on to meet their patients' health care needs. The resources cover essential services not covered by Medicaid rates. Eliminating the program will have direct impact on patient access to care and services.