# 340B Drug Pricing Program

*April 11, 2019*

## EXECUTIVE ORDER: WHAT ARE THE CHANGES TO THE 340B DRUG DISCOUNT PROGRAM?

The Executive Order directs the Department of Health Care Services (DHCS) to transition all pharmacy services for Medi-Cal managed care to Fee For Service (FFS) by January 2021, which could potentially end the savings health centers accrue through the managed care 340B program and ultimately limit access to services for California's low-income, vulnerable communities.

While we support the Governor's overall goal to lower the cost of drugs, we are concerned about the impact it could have on the 340B Drug Discount Program, covered entities, and the patients that benefit from the program.

## COSTS OF ENDING 340B

The Legislative Analyst's Office (LAO) released a report analyzing the Executive Order and its financial impact to the state. Although the LAO claims that the state would likely see an increase of savings by paying less for prescription drugs and increasing the drug rebates it receives, the report doesn't fully acknowledge the impact that losing 340B savings would have on the safety net and ultimately access to healthcare.

If the state does acquire larger savings, there is no guarantee that the funding will be reinvested into healthcare or the safety net providers who use 340B savings to deliver wrap around services to their patients. The administration also argues that the proposal will lower the costs of drugs and bring more money to the state. However through the 340B program health center patients, of which there are 7 million, are already receiving low to no cost drugs. Further, the savings accrued from 340B are dollar for dollar invested back into patient care and services, whereas savings accrued by the state must be shared with the federal government.

## INCREASING TRANSPARENCY: HOW 340B SAVINGS ARE USED AT HEALTH CENTERS

The Administration has stated that they want to see transparency in the program and understand how the 340B savings are being used by covered entities. For the last year, the California Primary Care Association (CPCA), has been working with health centers to build a process to show how the 340B savings are reinvested in patient services. Specifically, health centers have committed to reinvest their 340B savings into 6 areas: access to affordable medication & pharmacy programs, expanded Access to Healthcare Services, workforce, clinical care coordination, infrastructure support, and quality improvement.

## 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 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.

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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.

## 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.

## THE STATE ALREADY GETS 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.

## RESOLVING DUPLICATE DISCOUNTS

With encouragement from the legislature, in 2018 DHCS agreed to work with covered entities and the managed care plans to put forth an All Plan Letter (APL) that would help prevent duplicate discounts. Although DHCS circulated a draft APL in December 2018 with the intent to finalize it in early 2019, DHCS has now decided to cancel the release and not move forward.

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*Talking Points / April 11, 2019*

## BACKGROUND

- [INSERT YOUR HEALTH CENTER NAME] would like to share our support for the Governor's vision to reform the health care delivery system, provide affordable coverage and access and lower the total health care spend.

- The Governors Executive Order (N-01-19) to create a single-purchaser system of drugs in California is an important initiative to his larger vision.

- The Executive Order directs the Department of Health Care Services (DHCS) to transition all pharmacy services for Medi-Cal managed care to Fee for Service (FFS) by January 2021, which could potentially end the savings my health center accrues through the 340B program and ultimately limit access for California's low-income, vulnerable communities.

- The 340B program savings allows my health center to [INSERT EXPLANATION OF WHAT 340B SAVINGS MEANS TO YOU].

- Our goal is to partner with the state as they develop this proposal to ensure that health centers can continue to deliver the level and scope of services they do today- which is partially funded by 340B savings.

- We understand that transparency is important to the Administration and are working with our state association, CPCA, on a process to show how the 340B savings are used at health centers.

- As these important conversations continue, we remain committed and willing partners to find a solution which includes express provisions to protect health centers that currently operate 340B Drug Discount Programs.

## WHAT is 340B?

- 340B is a federal drug discount program created by Congress in 1992 that is designed to incentivize safety net providers to participate in the full spectrum of care, from issuing prescriptions to the dispersion of drugs.

- The program aims to support the mission of safety-net providers by providing prescription drug discounts that ensure low cost drugs to patients.

- Eligible providers, including community health centers, can participate in 340B in Medicare, Medicaid, and for the uninsured.

- Savings from 340B provide safety-net providers with additional resources they can invest into health care services.

- Health centers use program savings to expand a clinic's hours of operation, hire case workers for individuals experiencing homelessness, provide patients with transportation to specialty care appointments, and other vital unfunded programs. The Administration's proposal would eliminate our ability to provide these needed and necessary programs that help increase access to healthcare for low-income and hard to reach populations.

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## EXECUTIVE ORDER OVERVIEW

- Governor Newsom signed executive order N-01-19 to create a single-purchaser system for prescription drugs in California to leverage the state's purchasing power and drive down the increasing costs of pharmaceuticals.
- While we support the Governor's overall goal, we are concerned about the impact it could have on the 340B Drug Discount Program, covered entities, and the patients that benefit from the program.

- Under the signed executive order( N-01-19), the Governor directs the Department of Health Care Services (DHCS) to transition all pharmacy services for Medi-Cal managed care to Fee For Service (FFS) by January 2021, this could essentially end the savings received by covered entities, including health centers, through the 340B program and will ultimately limit access for California's low-income, vulnerable communities.
  - We are pleased that DHCS has committed to continue the 340B program until 2021, during this time we hope to be able to work with the Governor's Office and his administration to find a feasible solution.

- DHCS is also directed to review the state's purchasing initiatives and consider additional strategies to leverage the state's purchasing power by July 2019.

- The order directs the Department of General Services to compile a list of the 25 highest cost drugs and strategies to lower the costs by March 2019.

- By May 2019, the Department of General Services must provide a framework for how private purchasers can benefit from the state's bulk purchasing concept to the Governor's Office.

## GOVERNORS PROPOSED BUDGET

- The Governor's budget proposes to transition all pharmacy services for Medi-Cal managed care to a FFS benefit, which we believe will eliminate the ability for health centers to participate in the 340B program in Medi-Cal managed care.

- The budget further assumes greater monies to the state of California through claiming of Medi-Cal drug rebates.
  - Covered entities, however, are able to garner more funding from 340B savings than the state is able to accumulate in rebates. This is in part because the rebate monies received by the state must be shared with the federal government.

- The administration argues the proposal will lower the costs of drugs and bring more money to the state. However, we would like to point out that through 340B health center patients, of which there are 7 million, are already receiving low to no cost drugs. Further the savings accrued from 340B are 100% invested back into patient care and services.

- According to DHCS, this proposal would not impact the current 340B Medi-Cal managed care program until 2021. DHCS also shared that the All Plan Letter that was drafted in the fall of 2018 will NOT be finalized.
  - This means that MCOs and covered entities have not obtained guidance or rules from the state to help eliminate the duplicate discount issue that DHCS has voiced concerns with.

- Come 2021, DHCS has confirmed that covered entities can continue to participate in the 340B program, however, with the program operating under FFS, health centers would lose the 340B savings currently acquired under Medi-Cal Managed Care.

## IMPACT TO COMMUNITY HEALTH CENTERS

- We are supportive of the Administration's goals to lower prescription drug costs but are concerned that safety net providers, like community health centers, will no longer have the means to provide critical care coordination services currently funded by 340B savings.

- CPCA estimates that at least $100M in savings will be lost to health centers alone across the state resulting in a reduction of staff, services and hours of operation

- The 340B prescription drug program enables health centers to stretch scarce federal resources to underserved patients and provide comprehensive services to California's most vulnerable communities. It is a vital lifeline for safety-net providers across the state.

- Changes to the 340B program could be extremely detrimental to community health centers that rely on 340B savings to enhance patient services, expand hours of operation, access to medications and other services or add additional providers.

- A member survey conducted by CPCA in 2018 found that health centers use savings from the 340B program to provide low cost or free medications to all low-income patients who are uninsured or under-uninsured, subsidize and pay deductibles related to the cost of care for homeless and low income patients, establish and support in-house pharmacies, including extended pharmacy hours and pharmacy staff.

- The same survey found that health centers may have to cut back or eliminate these programs and services if 340B savings are no longer available.
  - Eleven health centers reported that they would need to close health center sites if they were to lose 340B savings while 19 reported that they would need to cancel new site openings.
  - Additionally, 46.8 percent (22 out of 47 respondents) stated that they would need to close their in-house pharmacy, which would decrease access for underserved populations, especially in rural communities.

- Changes to the 340B program that impact health centers will disproportionately impact California's most vulnerable communities as a majority of health center patients are at or below the federal poverty level.

## WHO WILL BE IMPACTED

If proposed program changes are pursued, millions of Californians receiving care at the following institutions, all of whom are federally defined 340B covered entities, will be impacted:

- Cancer Hospitals
- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Federally Qualified Health Centers
- Hemophilia Diagnostic Treatment Centers
- Ryan White HIV/AIDS Programs
- Sole Community Hospitals
- Sexually Transmitted Disease Clinics
- Title X Family Planning Clinics
- Tribal/Urban Indian Health Centers
- Tuberculosis Clinics