

The Role of the 340B Drug Pricing Program in HIV-Related Services in California



CALIFORNIA
HIV/AIDS POLICY
RESEARCH CENTERS

May 2018 Rapid Assessment | Northern California HIV/AIDS Policy Research Center

Valerie B. Kirby, Emma Wilde Botta, Wayne T. Steward

Executive Summary

The 340B Drug Pricing Program allows safety net health care entities to access discounts on medications they provide, and to use the savings to invest in expanded programs and services for patients. We conducted a rapid assessment study to characterize the current use of the 340B Drug Pricing Program by health care entities that serve people living with HIV (PLWH) and vulnerable to HIV in California, and to assess possible changes to current HIV-related services and programs that may occur if a proposal by California's Governor Jerry Brown to eliminate the use of 340B discounts on Medi-Cal transactions is enacted.

From March to April 2018, we interviewed 7 key informants across California. All informants had familiarity and experience with the 340B Program and could speak to the likely effects of the proposal on their organizations. Informants reported use of the 340B Program consistent with its initial aims to strengthen and expand services for vulnerable patient populations. 340B savings supported the provision of medications for free or at low cost to uninsured individuals, including PLWH, and savings reinvested by health care entities supported a range of services and staff positions geared towards increasing patient engagement, maintaining strong clinic infrastructure, and raising the standard of care. All of these activities are particularly crucial for PLWH.

Informants expressed a desire to continue participating in the 340B Program despite the significant administrative burden required to manage program participation and maintain compliance. Several informants expressed interest in working with the State to improve 340B functionality and avoid compliance issues. Our findings strongly support maintaining access to robust 340B savings as a vital source of support for comprehensive HIV-related services.

What is the 340B Program?

The 340B Drug Pricing Program is a federally-administered program that requires drug manufacturers to supply up-front discounts on covered medications purchased by organizations serving vulnerable patient populations.¹ Participating organizations, known within the 340B Program as "covered entities," include but are not limited to: Ryan White HIV/AIDS Program-funded clinics and programs, family planning and sexual health clinics, Federally-Qualified Health Centers (FQHCs), and hospitals serving a disproportionate share of low-income patients (known as "Disproportionate Share Hospitals", or DSHs).² Covered entities purchase medications with 340B discounts and then are allowed to bill third parties, including Medicaid programs and managed care organizations, for a higher rate of

reimbursement. This generates savings that they are expected to reinvest into expanded or additional programs and services that allow them to better serve their patients.

Proposed Changes to the Use of 340B

Background

The 340B Program was enacted in 1992.³ It has grown significantly in size and scope since that time. As it has expanded, the number of stakeholders involved with the program has increased and nationwide dialogue has intensified around how the program is used and how it might be improved or changed.⁴

The 340B Program’s intersection with Medicaid has received particular attention. Under federal law, drug manufacturers also are required to allow Medicaid programs a discount on the medications they purchase.³ This discount is not a part of the 340B Program and does not directly benefit covered entities. Medicaid drug discounts are provided in the form of post-purchase rebates and are shared between states and the federal government.⁵ Drugs purchased for Medicaid enrollees who access care at 340B covered entities are therefore eligible for both the up-front 340B discount and the post-purchase Medicaid rebate, but under federal regulations only one can be claimed per drug dispensed. This dual eligibility introduces the potential for what are known as “duplicate discount” claims, in which a state Medicaid program seeks a rebate on a dispensed drug without the knowledge that a covered entity has already received an up-front discount on the drug under 340B.³

In California

California Governor Jerry Brown has issued a 2018-19 state budget proposal that includes a provision seeking to eliminate the use of 340B discounts on Medi-Cal (California’s Medicaid program) transactions in favor of exclusive use of the Medicaid rebate program. Under this proposal, Medi-Cal-related drug discount savings would no longer go directly to covered entities. The Governor’s proposal cites duplicate discount avoidance and the potential to increase state revenues as factors influencing this proposal.³

The primary intention of this proposal is the complete elimination of 340B discounts on Medi-Cal transactions. However, this goal is dependent on federal approval, so the proposal also contains an alternative option:

Step 1: Seek federal approval to eliminate the use of 340B discounts on Medi-Cal transactions. If federal approval is obtained, eliminate the use of 340B discounts on Medi-Cal transactions as of January 1, 2019 or later, pending timing of federal approval.

Step 2: If federal approval for elimination is not obtained, seek federal approval to eliminate the use of 340B discounts on drugs dispensed to Medi-Cal enrollees by pharmacies contracted with covered entities, and/or by some pharmacies owned and operated by covered entities (known as “in-house pharmacies), at the discretion of the State. Limit 340B reimbursement for remaining Medi-Cal

transactions to actual acquisition costs (AAC), which are generally lower than the level of reimbursement covered entities are currently receiving.⁶

This proposal would primarily affect Medi-Cal managed care. In California, the majority of the Medi-Cal population is enrolled in managed care.⁷ Fee-for-service 340B reimbursement is limited under preexisting law to AAC plus a dispensing fee but in managed care, covered entities can currently bill for more than AAC, resulting in additional savings they can reinvest.³ The amount of savings retained by covered entities varies depending on contracts negotiated between managed care organizations and covered entities, as well as with contract pharmacies, when they are used.³

The Brown Administration has estimated that this proposal would save the State \$16.6 million annually but has not yet provided specific information on how state revenues would be generated and used.⁸ If the State seeks Medi-Cal drug rebates but does not reinvest rebate funds into the Medi-Cal program, funds will have to be shared with the federal government and may, in combination with the loss of 340B savings for covered entities, result in a net reduction in health care dollars available in California. However, it is possible the Administration may seek to leverage additional federal support by reinvesting rebate funds into Medi-Cal, which is funded through matched investments of state and federal dollars.³

Nationally

While not the focus of this report, we note that as of the time of this report’s writing in May 2018, a number of changes to the 340B Program are under discussion at the federal level. In general, these efforts are aimed at scaling back the program.

Our Study: 340B and HIV-related services

Over six weeks from March to April 2018, we interviewed employees of 340B covered entities in California to find out more about how covered entities use the program to support HIV-related services, and how they would envision those services might change, should the Governor’s proposal be enacted. We primarily sought interviews with potential informants who were known to our research team or our California HIV/AIDS Research Center community partners, but in a

few cases, we reached out directly to previously-unknown individuals listed as 340B contacts for covered entities on a federally-maintained 340B registry.⁹ We approached individuals across California's Northern, Southern, Bay Area, Central Valley, and Central Coast regions.

Seven informants from six covered entities agreed to and completed an interview.¹⁰ Interviews were conducted over the telephone with two members of our research team and lasted from 45 to 90 minutes. Interviews were recorded and transcribed. The research team completed analysis through collaborative memos on the themes that emerged from these interviews. These memos were refined through transcript review and formed the basis of this report.

Findings

Informants and Covered Entities

The seven interviewees were representatives of six different covered entities in the Northern California, Southern California, and California Bay Area regions. These covered entities included FQHCs and outpatient HIV clinics associated with DSHs. Interviewees' roles and organization types are outlined in Table 1.

Currently, covered entities can choose whether or not to dispense medications discounted through 340B to Medi-Cal enrollees.³ This choice, in combination with the type of pharmacy used (in-house or contract) and the form of the proposal ultimately granted federal approval, will affect how significantly a covered entity may be affected by the Governor's proposal. Medi-Cal dispensing and pharmacy arrangements among the six covered entities represented in our study are outlined in Table 2.

Experiences with the 340B Program

While all informants demonstrated familiarity with the 340B Program, five informants were highly familiar with the program and were responsible for or oversaw management of the program and compliance with 340B regulations.

In general, informants expressed the view that the 340B Program is vital to the functioning of their clinics and that their clinics use the program as it was intended to be used: to serve more people and offer needed

services they otherwise would not be able to afford. However, informants also explained that they carry out this mission of the program under a high, and growing, administrative burden. Depending on the size of the covered entity, several full- or part-time employees are needed to manage 340B oversight, compliance with federal 340B and state Medi-Cal regulations, auditing, contracting and communications with outside pharmacies, documentation, and duplicate discount avoidance. While 340B savings did exceed related administrative costs, informants reported annual 340B administrative and compliance costs ranging from hundreds of thousands to millions of dollars, depending on the size of the covered entity. Despite an expressed desire to use Medi-Cal-related 340B savings as a source of support for important patient programs and services, one covered entity did not dispense under 340B to Medi-Cal enrollees at all, and three only did so through in-house pharmacies, citing the administrative difficulties of working with contract pharmacies and managed care organizations and maintaining compliance with duplicate discount avoidance under Medi-Cal as significant drivers of these arrangements. Yet, most informants emphasized that they continue to participate in the program and specifically, to dispense to Medi-Cal enrollees, because the savings generated through 340B allow them to expand service for vulnerable patients, including PLWH, and provide a higher standard of care.

"Maintaining a compliant program is very, very difficult. And from the drug manufacturer and from HRSA they're always asking more from the covered entities to demonstrate compliance and to demonstrate that they're using the savings. And it's too much, right? The onus is on the covered entity, and at the end of the day we're just trying to take care of a vulnerable population. That's all we're trying to do is to take care of people that otherwise would have nowhere else to go." - DSH

Provision of Discounted Drugs

One of the primary ways in which all covered entities reported using the 340B Program was to provide medications to uninsured individuals, including PLWH, free of charge or at a low cost to these clients. Two clinics provided medications as needed to patients otherwise unable to pay for them. Two others used 340B savings to cover the entire cost of a 30-day supply of HIV medications for newly-diagnosed individuals, those new to care, or those reentering care, while their eligibility workers pursued insurance coverage and AIDS

Drug Assistance Program (ADAP) enrollment. In addition, two covered entities used 340B savings to support provision of a broad formulary of medications for PLWH who were not eligible for insurance, in conjunction with the support of locally-administered safety net health programs for the uninsured.

“We furnish a 30-day supply of medications to those patients that [need] to be helped with [insurance enrollment]. And we supply much-needed medications for those patients free of charge. [They] may not be newly diagnosed; they just might be homeless and are now back into medical care. So, we're able to provide them with services that if medication was not 340B, we would have to think twice about providing free medication.” - FQHC

Current Use of the 340B Program in HIV-Related Services

In addition to provision of free and low-cost medications, informants reported utilizing 340B savings to support a robust array of expanded or enriched services and staff positions. Generally, these activities fell into three categories: patient engagement activities, efforts to maintain strong clinic infrastructure, and services aimed at raising the standard of care. Examples included:

Patient Engagement

- HIV patient navigation
- Transportation for clinic visits
- Case management services
- In-home medication delivery
- Clinical pharmacists to provide patient treatment education and develop individualized treatment plans
- Pharmacy technicians to assist patients with enrollment in drug manufacturers' patient assistance programs for HIV and Hepatitis C (HCV) treatment and Pre-Exposure Prophylaxis (PrEP)
- Dietician services

Maintaining Clinic Infrastructure

- Quality improvement and population management activities
- Maintenance of in-house pharmacy
- Coverage for overhead and administration costs not sufficiently compensated under Ryan White HIV/AIDS Program grants
- Offsetting uncompensated care costs

- Support for 340B oversight, management, and compliance

Raising the standard of care

- Provision of vaccines appropriate for an HIV-impacted population but not covered by insurance for patient age group (including human papillomavirus, meningitis, Hepatitis A and B, shingles)
- Provision of in-clinic, point-of-care medications for sexually-transmitted infections
- Support for staffing and equipment for hypertension management project
- Clinical pharmacists to assist patients with pain management
- Substance use services, including opioid abuse management and naloxone distribution
- Funding medications for comorbidities not otherwise supported by Ryan White Part A

This list includes many programs and services that are considered key elements of comprehensive, quality HIV care.

Anticipated Impacts of the Governor's 340B Proposal on HIV-Related Services

All informants expressed significant concern over the potential impacts of Governor's proposal. Five of the covered entities currently dispense 340B-discounted medications to Medi-Cal enrollees, and reported that the loss of related 340B savings would be sizeable enough to partially or significantly undermine their services. These informants affirmed that, if these savings are lost, one of their primary goals would be to maintain comprehensive care for vulnerable, uninsured patients, even though this would mean eliminating other services for those with coverage.

“We would want to maintain the care of those vulnerable patients so what we probably would have to do is for those patients who are insured, [we] would have to look at scaling back on some of the services and save money there, so we can use that money to purchase more expensive drugs to take care of the same folks. The money has to come from somewhere, right? ... So, I don't know if your Hep C patient would necessarily be impacted because we'd still find a way to take care of that person, but somebody else will suffer and I don't know who that other person will be.” - DSH

For insured PLWH, informants affirmed a commitment to maintaining core medical services, but generally reported the view that any of the expanded or enriched services mentioned previously in this report would be vulnerable to elimination without Medi-Cal-related 340B savings support. Notably, one participant reflected on the role that the expanded services play in achieving viral load suppression among PLWH.

“I’m sure you’ve seen the CDC data talk about the ultimate goal is viral suppression. And the reason why [our clinic] is so successful [at viral load suppression] is because every department is working on retention of care. A lot of those enabling services, and those are the ones that are going to be cut So that’s kind of the scary part....” - FQHC

We asked informants where else the PLWH they serve could access services comparable to those that may be eliminated, or what other funding sources covered entities might seek out to retain these services. Informants reported no awareness of funding sources they do not already pursue as safety-net providers. They generally noted a unique role as a comprehensive HIV provider in their community, and were not aware of readily available, equivalent services.

Many of those interviewed reported a lack of clarity regarding whether or how California would use funds acquired through Medi-Cal rebates, in lieu of 340B savings, to continue to support the most vulnerable patients currently benefitting from the 340B Program through covered entities. Several informants expressed a desire to work with California and federal authorities to help the 340B Program work better, function more smoothly in conjunction with Medi-Cal, and more easily avoid duplicate discount risk. Some noted program improvements made in other states (such as the development of a 340B discount data clearinghouse in Oregon) and expressed the desire for California to first pursue improvements, with the collaboration of covered entities, before seeking to eliminate the use of 340B in Medi-Cal.

“But that’s kind of the conversation that I would like to have with Governor Brown. I would certainly love to talk to him about what he thinks the challenges are and how we can solve them [instead of] ‘let’s just not do it,’ without understanding how that’s going to hurt [covered entities].” - FQHC

Finally, informants also noted concern over the potential impacts that federal efforts to reform the 340B Program may have on their ability to provide comprehensive services to PLWH in the future.

Implications

Recent studies of the 340B Program have provided a range of findings on whether and in which contexts covered entities are fulfilling the program’s mission to expand and enhance healthcare services for underserved patients.^{11,12} The informants we interviewed reported extensive use of the 340B Program—against considerable administrative odds—to support their patients in a manner consistent with the intention of the program, by providing medications for free or at low cost to uninsured individuals, and investing in expanded and additional services that address critical needs adjacent to core medical care.

In particular, informants noted that the sort of service expansion made possible through the 340B Program may be of particular importance to PLWH, who often have complex medical and ancillary care needs that must be addressed if viral load suppression is to be achieved. The services they currently provide with the support of the 340B Program are consistent with the recommended actions in California’s *Integrated HIV Surveillance, Prevention, and Care Plan*, which encourage improved retention in care and an increase in viral load suppression rates as steps to reduce new HIV infections and improve HIV-related health outcomes.¹³ The loss of Medi-Cal-related 340B savings would significantly disrupt the ability of the covered entities we interviewed to achieve these goals.

Rather than eliminate the use of the 340B Program in Medi-Cal, as the Governor proposes, informants expressed the hope that California policymakers would work with covered entities to identify, design, and enact changes that would relieve administrative burden and improve the functioning of the program for all stakeholders, while continuing to allow covered entities to make use of 340B savings to expand and enhance healthcare services for patients most in need. Our findings strongly support ongoing covered entity access to Medi-Cal-related 340B savings as a significant source of support for comprehensive HIV care, and as a critical tool for reducing new HIV infections and improving viral load suppression in California.

Acknowledgements

This product was developed using funds from the California HIV/AIDS Research Program, Office of the President, University of California, Grant Number RP15-SF-096.

Table 1: Covered Entity Types and Interviewees' Roles¹⁴

Entity Type	Location	Interviewees' Roles (N=7)
FQHC	Northern CA	Medical director
FQHC	Northern CA	Pharmacy manager
Local health department system	Bay Area	System pharmacy director
Local health department system	Bay Area	System pharmacy director
FQHC	Southern CA	Chief financial officer
FQHC	Southern CA	Pharmacy manager HIV services manager

Table 2: Pharmacy Types and Medi-Cal Dispensing Among Covered Entities

Number of Covered Entities	In-House Pharmacy?	Contract Pharmacy?	Dispense to Medi-Cal Enrollees In-House?	Dispense to Medi-Cal Enrollees at Contract?
3	Yes	Yes	Yes	No
1	No	Yes	N/A	Yes
1	No	Yes	N/A	No
1	Yes	No	Yes	N/A

REFERENCES and NOTES

¹ National Alliance of State & Territorial AIDS Directors. Back to the Basics: ADAP and the 340B Program – 101. September 2016.

<https://www.nastad.org/sites/default/files/ADAP-340B-Program-101.pdf>. (Accessed May 3, 2018).

² For a full list of organizations eligible for 340B, please visit <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>. (Accessed May 3, 2018).

³ California Legislative Analyst's Office. The 2018-19 Budget: The Governor's Proposal for the 340B Drug Pricing Program. March 2018.

<http://www.lao.ca.gov/Publications/Report/3790>. (Accessed May 3, 2018).

⁴ Tribble, SJ. Heated and Deep-Pocketed Battle Erupts Over 340B Drug Discount Program. *Kaiser Health News*. Published online November 28, 2017.

<https://khn.org/news/heated-and-deep-pocketed-battle-erupts-over-340b-drug-discount-program/>. (Accessed May 3, 2018).

⁵ Medicaid Drug Rebate Program. <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

(Accessed May 15, 2018).

⁶ California Department of Finance. Governor's Budget Trailer Bill Language.

http://www.dof.ca.gov/budget/Trailer_Bill_Language/documents/340BDrugReimbursementintheMedi-CalProgram.pdf. (Accessed May 3, 2018).

⁷ Kaiser Family Foundation. Medicaid Managed Care Penetration Rates by Eligibility Group. <https://www.kff.org/medicaid/state-indicator/managed-care-penetration-rates-by-eligibility-group/>. (Accessed May 15, 2018). At the time this resource was accessed, penetration rate data were from July 1, 2017. As of that date, 78.9 percent of California's Medicaid population was enrolled in managed care.

⁸ California Governor Brown's 2018-19 Budget: May Revision. <http://www.ebudget.ca.gov/2018-19/pdf/Revised/BudgetSummary/FullBudgetSummary.pdf>. (Accessed May 15, 2018).

⁹ To access this database, visit <https://340bopais.hrsa.gov/coveredentitysearch>. (Accessed May 3, 2018).

¹⁰ In all, we approached 23 individuals for an interview during a short recruitment period (averaging two weeks). Incentives were not offered for interviews. In addition to the seven who agreed to be interviewed, two individuals responded to our inquiries but did not complete interview scheduling, three responded but felt their organization was not a good fit for our study, two responded that they did not have time to complete an interview during the study period, and nine did not respond to our inquiries during the study period. No potential informants we contacted in the Central Valley and Central Coast regions completed an interview.

¹¹ Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med*. 2018;378:539-548.

¹² Slafsky T, Ross SL, Krishnamurthy B. The 340B Drug Discount Program is fulfilling its original purpose. *Health Affairs Blog*. Published online March 22, 2018. <https://www.healthaffairs.org/doi/10.1377/hblog20180321.524566/full/>. (Accessed May 3, 2018).

¹³ California Department of Public Health. Laying a Foundation for Getting to Zero: California's Integrated HIV Surveillance, Prevention, and Care Plan. September 2016. https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/IP_2016_Final.pdf. (Accessed May 3, 2018).

¹⁴ The local health department systems included disproportionate-share hospital with a comprehensive, outpatient HIV clinic. All FQHCs provided comprehensive HIV medical and support services.