NAVIGATING CHANGES TO THE 340B DRUG PRICING PROGRAM:

A TOOLKIT FOR HIV-RELATED HEALTHCARE ENTITIES IN CALIFORNIA

Northern California HIV/AIDS Policy Research Center | October 2024

Lissa Moran, Wayne T. Steward, Emily A. Arnold

Summary

The 340B Drug Pricing Program allows safety net health care entities to access discounts on medications they provide, get reimbursed based on the undiscounted cost of the medication, and use the savings to invest in expanded programs and services for clients.

In 2024, the Northern California HIV/AIDS Policy Research Center 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 and at risk for contracting HIV in California, and how changes to 340B may impact services.

Changes to state and federal policy have reshaped the 340B landscape in multiple intersecting and mutually-informing ways. At the Federal level, the Inflation Reduction Act of 2022 introduced several provisions to reduce spending on prescription drugs, one of which allows Medicare to negotiate prescription drug prices directly with pharmaceutical companies, and caps price increases such that they do not exceed inflation rates. At the state level, the Governor of California enacted an executive order barring the use of 340B discounts on Medi-Cal transactions, effectively eliminating 340B revenue for a covered entity's Medi-Cal patient population. Set among other shifting conditions like changes to Gilead's Patient Assistance Program and community pharmacies struggling to survive the competition of larger chains and delivery services, the net effect of these changes for 340B covered entities is a sharp reduction in operating budget, with no change to operational costs.

It is important to acknowledge two truths, and the tension between them. The first truth is that prescription drug costs are very high and getting higher, presenting a tremendous strain on government spending and a critical barrier to access for many people who need their prescriptions to get well and stay well. The other truth is that reduced drug prices mean reduced 340B revenue for health care entities that serve the most under-resourced patients, and their ability to continue offering what have become essential programs and services to these patients relies on 340B revenue.

For 340B-covered entities, core to the challenge of navigating these changes is the complexity of how multiple variables interact differently with each covered health care entity based on its unique makeup of services, funding, patient population, and payer mix. It can be difficult to see the full picture of an agency's strengths and vulnerabilities related to its 340B revenue and spending, to forecast how changes on the horizon may further impact services, and to proactively put protective measures in place.

With this in mind, and with the goal of maintaining the availability of critical community health programs and services, the following toolkit aims to assist 340B covered entities in understanding their current areas of funding stability and where they are vulnerable, and to plan for the future.

We offer a companion to this toolkit, *Navigating 340B Amidst Policy Changes: An Explainer*, which offers a more in-depth exploration of the factors referenced here.

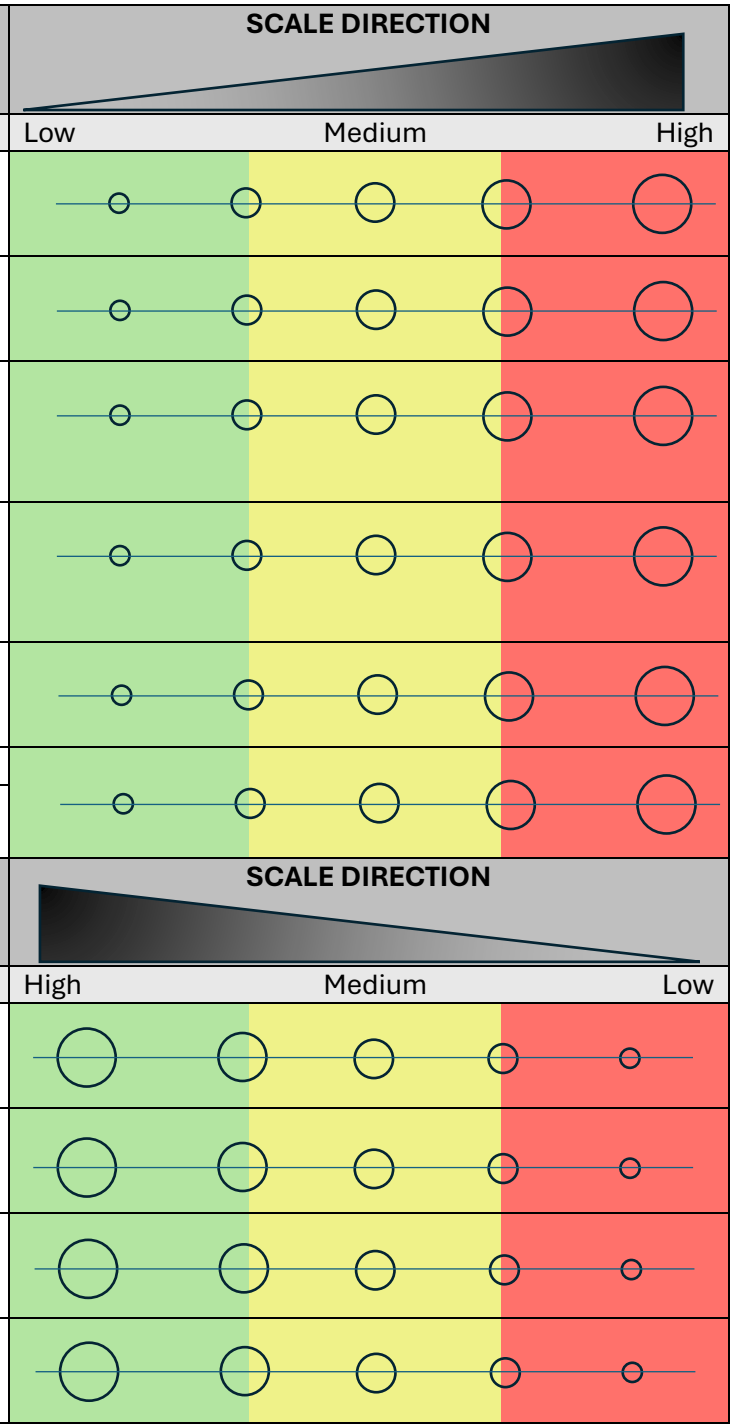
Step One: ASSESS

Consider some of the key factors that may influence how changes to 340B policies and revenue impacts your services.

Fill in the bubble for each factor. Please note that the scale direction changes.

Click on the hyperlink for each factor for more information and assessment guidance.

	SCALE DIRECTION
	Low — Medium — High
Reliance on 340B revenue for operation	
Reliance of non-revenue generating programs/services on 340B revenue	
Likelihood of frequently prescribed 340B revenue drugs to be up for price negotiation	
Likelihood of frequently prescribed brand name 340B revenue drugs to go generic	
Importance of Gilead's Patient Assistance Program	
Payer mix:	
Proportion of patients covered by Medi-Cal	
	SCALE DIRECTION
	High — Medium — Low
Proportion of patients covered by ADAP / 340B-eligible payers	
Diversity of 340B prescriptions (strong mix of eligible drugs being prescribed)	
Utilization of in-house pharmacy	
Utilization of contract pharmacies	



Step Two: PROCESS

Now that you have filled in the bubbles next to each influential factor, you have a visual representation of how many and which factors suggest vulnerability to (or protection against) dynamics that could impact your agency's 340B revenue. The green zone represents factors that facilitate security, and the red zone represents relative risk or vulnerability.

As a first step in processing your assessment, what patterns do you see? Are the dots you filled out clustered towards one side or the other? Are they scattered relatively evenly from left to right? This preliminary glance can give you a snapshot of how relatively stable or vulnerable your agency is when it comes to 340B revenue.

The factors you considered above do not exist independently of one another, so next, consider how they relate to one another, and if that changes the picture. For example, you may serve a client population with a very high proportion of Medi-Cal recipients, so you may have filled in the largest bubble, which occupies the red area because of the Governor's executive order rendering Medi-Cal reimbursements ineligible for 340B pricing. However, depending on the diversity and price point of medications that *do* get reimbursed at 340B levels (via ADAP, private insurance, etc.), the demographics of your patient population, the total costs of programming supported by 340B funding, and the other revenue streams that fund your agency's services, there may be a unique tipping point for a proportion of Medi-Cal recipients in your payer mix that is sustainable versus not. One finance officer we talked to said that in their agency, 80% Medi-Cal payers were okay, but 90% were not.

Consider also, for example, the items assessing utilization of in-house pharmacy and contract pharmacies. The items ask you to consider the overall utilization of these resources, regardless of whether utilization *could* be increased. The processing of Step 2 invites you to consider at this point whether those utilization rates could be higher, or if they represent the maximum utilization potential.

Consider further the interpretation of these items, and how risky or beneficial your ratings may be in the context of your agency. To continue the example of the in-house and contract pharmacy items, we have organized the survey to suggest that the higher the utilization rate of contract pharmacies, the more stable (or "in the green") you are. This may be true, in the sense that contract pharmacies are resources, and the more you can utilize a revenue resource, the better. However, if you have both an in-house pharmacy and contract pharmacies, and the high contract pharmacy utilization rate is paired with an under-utilization of the in-house pharmacy, the high contract pharmacy utilization may reflect an *under*-utilization of the higher revenue-generating in-house pharmacy, and may therefore be less a case of high resource utilization, and more a case of sub-optimal utilization share of multiple resources. Importantly, policy fluctuations make reliance on contract pharmacies risky (see the companion Explainer for more on this).

Based on where you understand your areas of greatest security and your areas of greatest vulnerability to be, you can move to Step 3, where you can consider strategies to address existing risk factors, leverage existing strengths, and prepare for uncertainties ahead.

Step Three: ADDRESS

Below are some adaptive and protective strategies recommended by individuals we interviewed or consulted with who were closely involved in 340B management at their agency.

Pharmacies

In-house pharmacies allow for the highest possible net 340B revenue for an agency. Ways to maximize this resource include:

- Opening an in-house pharmacy if you do not have one already;
- Expanding the size, capacity, or services provided at an in-house pharmacy (e.g., introducing a vaccination and injection clinic; serving as a specialty pharmacy for injectable ART or PrEP);
- Communicating to providers the importance of sending client prescriptions to the in-house pharmacy whenever possible;
- Communicating to clients the benefit to the clinic—and to the services the clinic can continue to provide—if clients choose to fill their prescriptions at the in-house pharmacy.

Contract pharmacies

Contracts with external pharmacies do not generate as much 340B revenue, but for agencies without in-house pharmacies, they are a valuable resource. Some strategies to use contract pharmacies wisely:

- Work with providers to send prescriptions to contract pharmacies whenever possible;
- For clients who prefer other pharmacies, proactively reach out to these pharmacies and initiate a contract relationship if possible. This can be beneficial both to your agency and to the pharmacy, as especially small pharmacies are facing fierce competition from online big box options.

Investing in high-revenue clinics, services, or programs

Depending on the needs, demographic, and payer mix of your client population, some clinics or services may generate a disproportionately high revenue, such as PrEP or sexual health clinics. Assess whether there are signals that expanding these services could lead to higher utilization (e.g., is there a wait time to get an appointment at a particular clinic, or a cap on taking new patients?). Model what potential revenue would look like at different levels of program/service expansion (e.g., expanding clinician headcount, adding patient rooms, expanding hours, etc.). Consider investing more heavily in these areas.

Explore other "verticals" for pharmaceutical revenue

As reimbursement rates for some medications face uncertain futures, consider if there are unexplored opportunities for expanding the scope of your agency's pharmaceutical capacity. For example, new weight management medications are an emerging treatment area that some health care entities are exploring. Assess the needs of your patient population and surrounding communities, taking into consideration whether there could be services or treatment areas beneficial to clients that are also revenue-generating for your agency.

ASSESSMENT ITEM LEGEND

Reliance on 340B revenue for operation:

This item asks you to consider the proportion of your total program and service operating budget that comes from 340B reimbursements.

Reliance of non-revenue-generating programs/services on 340B revenue:

This item asks you to consider the *weight* or *spread* of 340B revenue across various services. Consider two example agencies:

Agency 1 provides 8 services (a sexual health clinic, a mobile testing van, primary care, MOUD, mental health services, a food pantry, dental, and harm reduction), and about half of the funding for each of those services comes from the 340B revenue generated from reimbursements from just 2 high-cost medications highly prescribed to ADAP-covered patients.

- ◊ Assessment guidance: One might assess this risk as medium-high (e.g., the 4th bubble) based on a balance of factors. First, that *all* of the services are vulnerable to 340B reimbursement disruption. Second, that the proportion of each program's funding is substantial (about 50%), suggesting medium-high, though not total, reliance on 340B to operate. And third, because the revenue is generated from just 2 medications that are popular among a payer mix eligible for 340B reimbursement, any disruption to that combination (one of those medications going generic or being price-reduced under the Inflation Reduction Act, or the payer mix shifting away from 340B eligible coverage). Where you gauge the weight of this reliance will depend on what you believe the relative importance of these variables to be.

Agency 2 provides the same 8 services as Agency 1. Five of the services generate a variety of revenue and, along with 340B revenue, are largely self-sustaining. However, the remaining 3 services were only started because a surplus of 340B revenue in prior years allowed for the addition and expansion of programs, and—as is the purpose of 340B—that revenue was re-invested in agency operations and client care. Those 3 services are funded 100% by 340B revenue, and disruption to 340B would minorly impact the 5 self-sustaining services, but could be an existential threat to the other 3.

- ◊ Assessment guidance: One might assess this reliance as anywhere from low to high, depending on A) how essential the most at-risk services are and/or how integrated they are into overall client care, and B) whether there is other revenue easily leveraged to supplement or replace lost 340B revenue.

Likelihood of frequently prescribed 340B revenue drugs to be up for price negotiation:

This item asks you to consider the menu of drugs that bring in your agency's 340B revenue, and assess which if any of them are among the 10 drugs negotiated under the Inflation Reduction Act for price reduction effective January 1, 2026, or are on the schedule to be up for price negotiation in future years. You can access updated information at this CMS.gov link.

Likelihood of frequently prescribed brand name 340B revenue drugs to go generic:

This item asks you to consider your perceived likelihood that which if any of the drugs that bring in your agency's 340B revenue may see generic versions come to market. How you assess this could be based on verifiable information, conventional wisdom as you perceive it among your colleagues and within your field, and/or your opinion based on your observations and understanding of healthcare policy trends.

Importance of Gilead's Patient Assistance Program:

This item is included in this self-assessment because the role of Gilead's PAP may be not important at all to some agencies while being gravely important to others, depending on a variety of factors including to what extent your agency deals directly with Gilead and how big your patient population is.

Proportion of patients covered by Medi-Cal:

In California, an Executive Order from the Governor rendered Medi-Cal patients ineligible for 340B reimbursement pricing. This change has already happened, so the impact to overall revenue will for many agencies already be known/experienced. The purpose of including this item in the overall assessment is two-fold:

1) As a forecasting device, to understand this proportion should there be a shift in the payer mix (e.g., a large influx of Medi-Cal patients) or a loss of Medi-Cal coverage for patients as part of Medi-Cal unwinding;
2) As a tool to mindfully assess current 340B health. Example: If you have an 85% Medi-Cal payer proportion, but you also have a hefty share of ADAP-covered PrEP patients (even 5% for some agencies would make a big difference), you may have enough revenue to be doing okay, but in a way that hides how vulnerable your 340B revenue for medications other than ADAP-covered PrEP may be.

Proportion of patients covered by ADAP / 340B-eligible payers:

Consider the proportion of patients/clients who are covered by payers that *are* eligible for 340B reimbursement. While the costs of the drugs being prescribed to these patients, as well as the stability of those prices (e.g., potential to go generic, potential to come up for price negotiation under the Inflation Reduction Act) represent crucial factors in the overall size and stability of 340B revenue coming in, this item asks you to consider just the 340B reimbursement-eligible proportion of your agency's payer mix.

Diversity of 340B prescriptions (strong mix of eligible drugs being prescribed):

This item asks you to consider the diversity of 340B-eligible drugs that are being prescribed to your patient population as a whole. We recommend considering both the total number (Many drugs? Few drugs?), as well as the distribution of prescriptions among the total pool of drugs. Are most of the drugs prescribed to patients in approximately equal amounts? Do a small handful of drugs represent a disproportionate share of total prescriptions? Balance these considerations to determine the overall diversity of 340B-eligble drugs being prescribed.

Utilization of in-house pharmacy:

By design of the 340B program, a covered entity must be using an in-house pharmacy and/or a contract pharmacy. It is important to note that A) revenue from in-house pharmacies may be higher than revenue from contract pharmacies, and B) providers may prescribe to a contract pharmacy if it is the preference of the patient without having further discussion of options or explaining the benefits of using the in-house pharmacy. If your agency does not have an in-house pharmacy, leave this item blank. If it does have an in-house pharmacy, consider the extent to which that pharmacy is used relative to outside pharmacies (contract or non-contract).

Utilization of contract pharmacies:

Whether or not an agency has an in-house pharmacy, consider the extent to which contract pharmacies are utilized, relative to non-contract pharmacies and in-house pharmacies. Utilization of contract pharmacies has benefits and risks; take note of cautions discussed in the companion Explainer.