NAVIGATING 340B AMIDST POLICY CHANGES: AN EXPLAINER

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In light of proposed and actual changes in Federal and State policy that have the potential to affect the 340B program, we conducted a rapid response study, exploring the impact to facilities that serve people living with or at risk for HIV. We interviewed 6 individuals who work closely with 340B from within HIV service organizations and clinics across California, including community health and pharmacy leadership, and providers and staff directly involved in clinical and financial operations.

We aimed to better understand:

- the factors influencing 340B revenue and how they relate to service variables (e.g., patient mix, payer mix, agency size, diversity of revenue streams [clinical revenue as well as grants and contracts, non-clinical services, donations, etc.], and relative proportion of revenues derived from, or expenses dedicated to, specific programs);
- how these factors and relationships have impacted 340B revenue differently for different service environments;
- what those impacts mean for the current and future delivery of HIV care and related services;
- what innovative and adaptive strategies service leaders are exploring to adjust to changes and protect themselves from future restrictions and loss of 340B revenue.

Based on what we learned, we developed two companion products. The first is a toolkit for 340B covered entities of any size to self-assess their areas of risk and stability in the current and anticipated 340B climate and to consider concrete strategies to strengthen areas of vulnerability. The second product is this Explainer, which takes a closer look at the answers to these three questions:

1. How does 340B work?
2. What is the relationship between 340B and HIV services?
3. What are the current factors impacting 340B revenue for HIV clinical and service organizations?

How does 340B work?

The 340B program provides a revenue source for eligible health facilities serving safety net populations through a special medication cost/reimbursement structure. The facility purchases the medication at a discounted rate but receives a higher amount in reimbursement and can use those additional funds to support programs and services for underserved patients. But how does this work?

The 340B program establishes a "**ceiling price**," or a maximum price that drug manufacturers can charge 340B-covered healthcare entities for a 340B-covered drug. This ceiling price is established by first calculating the **average manufacturer price (AMP)** for a drug, and then reducing that AMP by a set "**rebate percentage**" (23.1% for brand name drugs and 13% for generic). That amount is then reduced further by an **inflation penalty**, which applies to drugs with prices rising faster than inflation. This final amount is the ceiling price—a significantly reduced price at which 340B-covered entities purchase the drug, while getting reimbursed for the drug at market value.

What we call "**340B revenue**," then, is the difference between the discounted purchase price and the reimbursement amount.

340B revenue is flexible and is meant to be used by covered facilities to provide services often not well-supported by traditional insurance, such as home visits, transportation, mobile clinics, and healthy food programs. These funds can also be invested back into the services, through expansion of programs or providers, or emergency response.

What is the relationship between 340B and HIV services?

Embedded in the 340B program is a difficult economic paradox: the 340B program was designed to leverage the high cost of prescription drugs to generate revenue for healthcare entities serving the most under-served communities, to be re-invested in patient services and programming. Meanwhile, lower drug prices—widely understood to be a goal of health policy—are meant to increase access to prescription medications for all Americans. Within 340B, however, lower drug prices lead to less revenue for health systems and threaten the continued availability of care and services to people who need them most.

For HIV providers, the impact of reduced 340B revenue is directly proportional to how much of their operating budget comes from 340B. For the most heavily impacted, some programs may close, and some entire clinics may close. The reality of health system economics—particularly safety net health systems—is not that money is more important than lives, but that without money, services shut down.

> *"Without margin there is no mission."*

> *"It costs us more to provide the services than we actually make from the services. We disproportionately serve people who are uninsured or under-insured … 340B is our biggest revenue stream."*

Further, in a reimbursement-based health system economy, fewer funds readily available up front translates to broad functional restrictions. It hampers the ability to invest in programs and the ability to cover some medications up front prior to reimbursement. It hampers emergency response and the ability for community clinics to meet emergent needs. A Southern California clinic, for example, used 340B funds to launch their emergency Mpox response, including vaccination, testing, and treatment, in just 2 weeks.

The reimbursements and grant funding to support that ultimately took time to come in, and in some cases didn't come in at all. Were it not for 340B revenue, that critical emergency response could not have happened.

"It's so hard to explain what we use 340B for because we use it for everything that makes sense. It touches everything that we do. "	*"340B pricing and HIV, they basically save our clinics. They pay for the lion's share of our services. Behavioral health, prenatal, optometry, dentistry. All of these are funded by 340B money."*

What are the current factors impacting 340B revenue for HIV clinical and service organizations?

From a policy perspective, there are two main threat categories that loom: 1) concrete policy changes that directly reduce the 340B revenue flowing in to covered healthcare entities; and 2) a lack of clarity in policy language, hampering the ability of covered entities to anticipate how policy events on the horizon will impact revenue.

Below are summaries of the most active factors:

1. *Inflation Reduction Act (IRA)*

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. In the context of 340B, this brings up two potential issues.

The *first* is reduced 340B revenue through reduced medication prices. No HIV medications are currently up for price negotiation through the IRA, but this could change within the next 5 years; some estimate that HIV medications may come up for negotiation as soon as 2028.

The *second* issue is duplicate discounts for Medicare beneficiaries. One cannot benefit from both the Medicare discounted price and the 340B ceiling price. This is a conflict that must be reconciled, but at present, Medicare has not yet clarified what procedures they will put in place to avoid duplicate discounts, which creates uncertainty around the revenue that will come from 340B for Medicare patients.

It should also be noted that the specter of reduced 340B revenue from HIV medications is a threat not just to HIV treatment and services, as HIV revenue supports many other programs. In that same vein, threats to revenue from non-HIV medications similarly impact

other services supported in whole or in part by those funds, including programs that support people living with and at risk for HIV and related health conditions.

Reductions in revenue from non-HIV medications can further indirectly impact HIV services when entire clinics or divisions of clinical care, like sexual health services, rely on 340B revenue.

1. *Governor's Executive Order, Medicaid carve-outs*

California Governor Newsom's Executive Order N-01-19 transitioned all pharmacy services for Medi-Cal managed care to a fee-for-service benefit beginning in 2021. The intention of this EO was to "create significant negotiating leverage on behalf of over 13 million Californians and generate substantial annual savings." For 340B covered entities, this EO eliminated financial benefit for dispensing 340B drugs to their entire patient population of Medi-Cal beneficiaries. HIV service entities with a high proportion of Medi-Cal patients experienced a profound loss in revenue, virtually overnight.

> *"We're not able to offer some programs [now]. We used to have a psychology unit. You know, we have the whole building. The plan was to have a dental clinic on-site and also have a behavior health clinic on-site, and have a case manager on-site. Now we don't have any [of that]."*

The impact of this change was proportional to the size of Medicaid in the agency's payer mix. This informant expressed gratitude that they did not have an even higher proportion of Medicaid patients when the EO took effect:

> *"Imagine [if] we had 90% of Medi-Cal patients, I mean, the pharmacy probably [wouldn't] stand today."*

To help remediate this loss, $105 million in supplemental state funds was made available, but this amount has been deemed insufficient, and accessing those funds has proven problematic:

> *"As part of losing 340B Medicaid, we have something called a supplemental pool of funds that equals $105 million that [340B-covered entities are] able to split amongst ourselves. But no one's really happy with that, for a number of reasons. Like for one, you may have clinics that were making a lot, that were very high Medicaid that relied on a lot of 340B revenue to keep going. But then the way the $105 million is split is not [proportional], is not the same amount of money. So it could be that your clinic was making, like $10 million a year from 340B Medicaid and then here's $105 million that we have to split amongst all the clinics in California. … That also includes many other groups … There's a lot more people that that are being included in the $105 million. But clinics are not being made whole."*

2. *Changes to Gilead's Patient Assistance Program*

Gilead changed the reimbursement structure of its Patient Assistance Program such that participating prescribers no longer earn 340B savings. Instead, they are reimbursed their cost plus a dispensing and administrative fee, which is nominal and sometimes not sufficient to cover the real costs of administration and dispensing the drug. This change does not impact everybody, but it tends to hit Ryan White HIV providers hardest.

> *"I can't speak for everyone else, but for us, [changes to Gilead's PAP] cost us about a third of our 340B revenue overnight like <snaps> that. Yeah, it's very, very, very detrimental, but that's not something that a non-Ryan White HIV Provider would have experienced necessarily."*

This informant went on to describe how the hit to revenue was immediate, but that the impact has been delayed, because they got approval from their board to run in a deficit for the last 2 years. The reduction in revenue constituted such a grave emergency that they were not able to absorb it.

> *"So we're working on our budget for the next fiscal year, and we are looking at cutting out programs and other things. We're looking at a large deficit almost exactly equivalent to what we lost from Gilead, that we now have to make choices about. Those choices haven't been made yet, or at least I'm not — they haven't gotten to my level of leadership yet. But it will be very significant. Yeah, and negative."*

3. *High-cost drugs, like Truvada, going generic.*

While the goal of generic medications is to increase affordability and accessibility, there are counterintuitive, and in some cases dire, implications within the 340B context. Generic medications yield significantly lower 340B revenue, due to both a lower average manufacturer price *and* a lower rebate percentage. Currently, patients on PrEP may be prescribed generic Truvada or switched to Descovy, though the ethics of encouraging patients to switch to a name brand medication rather than a generic for the purposes of revenue is a matter of debate. While prescribers have handled this in various ways, the specter of what it would mean to 340B revenue should some high-cost, high-utilization HIV drugs go generic looms large.

> *"Biktarvy is the most popular med we put out, almost 40%. If they went generic, that would devastate us."*

> *"You have to wonder, you know, what's gonna happen when Descovy goes generic? What's gonna happen when Biktarvy goes generic?"*

4. *Shift to long-acting injectables*

Similarly, the shift to long-acting injectable ART hasn't yet become widespread, but informants suggested that A) they are likely to become increasingly popular in the future, and that B) accessing 340B reimbursement for these medications can introduce complications.

Because long-acting injectable ART is often injected by a clinician in-clinic, it is typically billed as medical benefit, which is a more challenging and less predictable billing process than billing a pharmacy benefit. There are exceptions to this, depending on the payer (Medicaid vs. private, for example), and there may be some strategies, like getting insurance prior authorization, or injecting in the pharmacy and billing as a pharmacy benefit, that lessen this burden.

5. *Pharmacy issues*

When a 340B-covered entity prescribes a medication to a patient, that patient can fill that prescription in one of three ways: 1) at the facility's in-house pharmacy (if available); 2) at an external pharmacy that is contracted with the facility; or 3) at any other unaffiliated pharmacy or medication delivery service. The facility will receive the highest 340B revenue from an in-house pharmacy, reduced revenue from a contract pharmacy, and no revenue from an unaffiliated pharmacy.

Informants reported broad threats to pharmacies generally as well as restrictions on pharmacy contracting put out by pharmaceutical companies, and a lack of the regulatory clarity necessary to protect or predict how contract pharmacies factor into a facility's future.

> *"Pharma is blocking us at contract pharmacies. Let's say we have 100 drugs we got 340B revenue on — now, because of pharma blocks, it's down to 50-60."*

One informant in pharmacy leadership explained that there is increasing competition with online pharmacies and big box store pharmacies like Costco, where the convenience factor for patients is undeniable and extremely attractive, but that as a result, community-based pharmacies are really struggling to stay in business. Small pharmacies benefit from FQHCs contracting with them, but that gets restricted with pharmaceutical companies imposing limits on contract pharmacies, complicated further by the fact that when a clinic contracts with a pharmacy, the clinic loses about 25% of the 340B revenue compared to if they had billed from an in-house pharmacy. Not all covered healthcare entities are able to have their own in-house pharmacies, and for those that do, not all patients are able or willing to use them. As one informant pointed out, "*better to have everybody use in-house, but also better to keep your clients*."

A combination of in-house pharmacies, high-cost medications, and a payer mix that reimburses at the full 340B reimbursement rate can constitute a huge proportion of total clinic revenue. One informant said of their in-house pharmacy:

> *"Our HIV community probably accounts for 75% of the revenue that comes into the pharmacy. Just the HIV piece accounts for 5% of the scripts that we do. So when you start putting in a big picture, if we're doing roughly, let's say 11-12,000 scripts a month, you're doing 400 to 600 scripts that are HIV. That accounts for 75% of your total revenue coming to the pharmacy."*

⚠ Cautions to contract pharmacy use ⚠

A major threat, particularly to organizations that do not have an in-house pharmacy, are current and potential restrictions on the use of contract pharmacies by all covered entities. These restrictions also pose a threat to clinics that *do* have in-house pharmacies, but whose patients are spread geographically far from their brick-and-mortar healthcare center, or who have other access- or preference-related barriers to using the in-house pharmacy.

At issue is this: the language of the 340B statute does not explicitly lay out allowances or restrictions on distribution networks for covered entities. Put another way, 340B does not come with instructions on how contract pharmacies may or may not be 340B covered healthcare entities. The Chevron doctrine, a 1984 supreme court ruling in Chevron v. NRDC, has long held that when federal legislation is ambiguous on regulatory administration, as it is in this case, the law defers to the regulatory agency's interpretation. However, in June 2024, the US Supreme Court overturned the Chevron doctrine, calling into question the legal authority of those interpretations, with uncertain implications for existing and future contract pharmacy cases. While there are several state and federal bills in process that could prohibit pharmaceutical manufacturers from putting restrictions on the use of contract pharmacies, and one that would seek to formalize restrictions, it is **critical to note that no protections are in place at this time**. If the two major manufacturers of HIV drugs were to restrict 340B access to contract pharmacies, all HIV providers who use contract pharmacies would be at risk.

6. Delayed impacts due to COVID

Finally, it is important to note that some covered entities may experience delayed impacts of 340B revenue reduction from 2021 onwards. We heard examples of agencies that saw revenue changes, but were insulated from the full force of their impacts, largely due to the timing lining up with COVID-related grants that kept some operations afloat. This was particularly the case for HIV-related programming that did not itself bring in pharmacy or fee-for-service revenue, like those associated with social determinants of health and the provision of essential services (e.g., food pantries, housing assistance). Now that those grants have ended, the full weight of the 340B revenue loss is, for some, becoming apparent.

"The first salvos with 340B for Pharma happened like right during the pandemic. And we were able to survive because we had COVID funds. But now that the COVID funds are—we don't have access to those anymore … it's starting to become very polarized where it's harder and harder to get revenue from other sources and make things work. Because now, the State government took our 340B savings with Medicaid, the Inflation Reduction Act—the Federal government is gonna target 340B savings for themselves for some drugs. So I think at some point, it's gonna reach like a—I just think something's gonna break at some point. It could be that we face a really bad recession. And there's just gonna be a lot more people who are uninsured. A lot more people on Medicaid. But I think something at some point is gonna break, unless there's a resolution."

Key take-aways

- Variation = protection. The more varied your payer mix, the less vulnerable you are to fluctuations in related policies. The more varied the array of medications you prescribe, the less vulnerable you are to price negotiations and generics.
- The greater reliance on contract pharmacies, the greater the risk.
- The greatest returns on investments can come from investing in things that enhance stability.

Additional References and Acknowledgements

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