WHITE PAPER

Exploring the evolution of 340B contract pharmacy policies

How pharma can adapt and succeed in a complex policy landscape

By Ricky Yuen and Nicholas Porter

The 340B Drug Pricing Program has grown significantly over the past several years, leading to gross-to-net erosion for the pharmaceutical industry. Some of the program's growth has been unintended: Watchdogs have reported numerous instances of duplicative discounts, "double dipping" and diversion of drugs to ineligible patients. Indecision from Health Resources and Services Administration (HRSA)—the program's regulating authority—has prompted many pharma companies to enact greater controls over their 340B distribution.[1] States have responded in turn with legislation, producing a complex policy landscape that has posed major challenges for both manufacturers and providers. As of May 2024, six states have barred manufacturers controls over the 340B program, and 20 states have similar legislation pending.[2] In this paper, we explore pharma and states policy responses to the 340B program, analyze how successful these responses have been and offer recommendations for how pharma can adapt to an evolving landscape going forward.

The evolution of 340B: intention, execution and expansion

Since its inception, the 340B Drug Pricing Program has aimed to provide financial support to healthcare facilities (known as "covered entities") treating a disproportionate share of low-income patients by offering discounted prices on brand-name drugs; on average, drugs are purchased at a ~60% discount off list.[3] Today, around 40% of U.S. hospitals participate in the program, and net sales of 340B drugs have more than tripled from 2017 to 2022, to over $50 billion.[4,5]

Audits of covered entities have exposed low rates of compliance (18% to 38%) with 340B Program requirements and a lack of transparency on how 340B revenue has been used.[6] While some studies suggest that covered entities have used the funding to expand healthcare access for low-income patients, others reveal that the revenue has been diverted toward acquiring physician practices.[7] The combination of these developments—the program's rapid growth, low levels of compliance and mixed benefits for patients—has inspired widespread debate over whether 340B is fulfilling its intended purpose.

At the center of the debate is the use of contract pharmacies—pharmacies that can dispense 340B drugs on behalf of covered entities. Because most covered entities do not have access to an in-house pharmacy, contract pharmacies play a critical role in the program's execution. In 2011, the Affordable Care Act lifted restrictions on the number of pharmacies a covered entity could contract with, leading to a surge from 1,000 contract pharmacies in 2010 to over 33,000 today.[8]

The rapid expansion of contract pharmacies has been associated with greater rates of noncompliance through duplicative discounts—where drugs are purchased at 340B prices, then receive Medicaid rebates—and the diversion of 340B drugs to ineligible patients; HRSA audits between 2012 and 2019 found more than 400 cases of duplicate discounts and 500 cases of diversion.[9] In response, many pharma manufacturers have taken action to limit the number of contract pharmacies they distribute to and have enacted more robust reporting protocols for monitoring 340B claims.

Manufacturer responses to contract pharmacies

In 2020, pharma manufacturers began restricting the number of contract pharmacies that could dispense 340B drugs, with some manufacturers banning them outright.[10] To improve oversight, several manufacturers started requiring that covered entities submit claims data to participate in the program. Today, 19 of the top 20 U.S. pharma manufacturers have adopted some form of contract pharmacy restrictions and seven have required covered entities to submit claims data.[11]

FIGURE 1:

Level of 340B contract pharmacy restrictions (top 20 pharma companies as of April 2024)

Source: ZS research and analysis, 340B reporting from Amerisource Bergen, as of April 2024.
Top 20 pharma companies by 2023 revenue.
Note: Moderna has not issued restrictions on contract pharmacies.

Figure 1 key takeaways:

- 14 of 20 manufacturers have restricted 340B volume to a single contract pharmacy per covered entity, excluding federal grantees.
- Eli Lilly and Amgen have included federal grantees in their restrictions, which account for 40% of covered entities.[12]
- Contract pharmacy restrictions apply to a vast majority of manufacturers' portfolios, though exemptions vary by case.

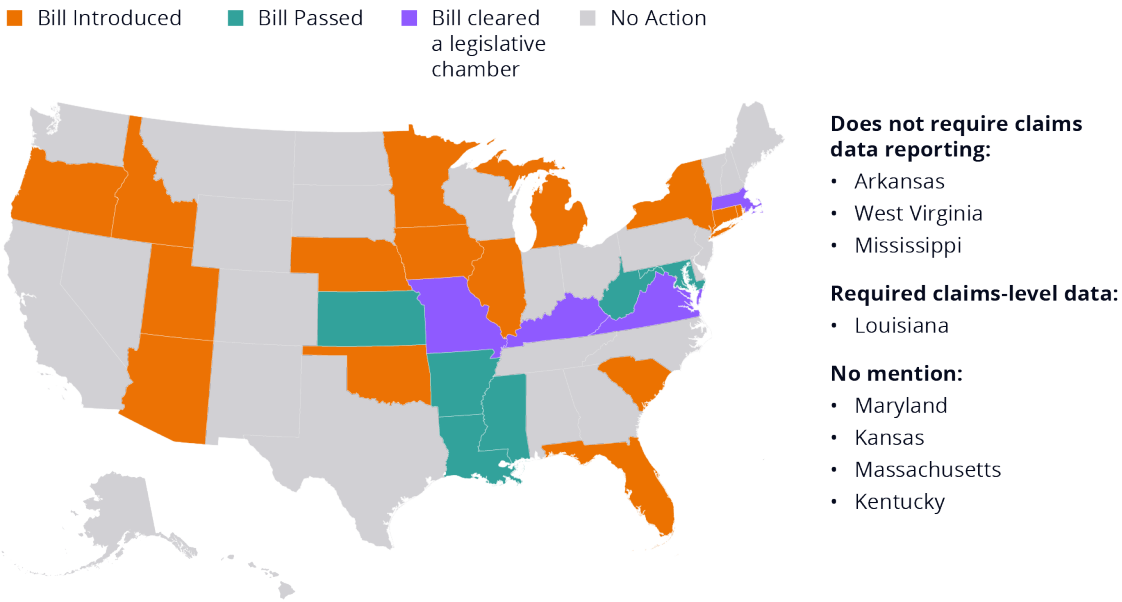
Legislative responses to manufacturers

The widespread manufacturer restrictions on 340B contract pharmacies have sounded alarms for state and federal lawmakers; legislators across the aisle argue that these restrictions disproportionately harm low-income patients and providers in need. As a result, six states have passed legislation barring contract pharmacy restrictions and several more have bills in progress.

As of May 2024, ZS's analysis of state policies found that 20 states have introduced legislation prohibiting contract pharmacy restrictions and four states have bills that have cleared a legislative chamber.

FIGURE 2:

340B Legislation tracker: State bill that prohibit manufacturer contract pharmacy restrictions



Source: America's Essential Hospitals, Legislative tracker - 340B Report, 340B Interactive Map (amerisourcebergen.com).

Figure 2 key takeaways:

- Arkansas was the first state to enact legislation in 2022, providing a framework for other states to follow.
- Arkansas, Louisiana, Mississippi, West Virginia, Kansas and Maryland have passed policies barring contract pharmacy restrictions.
- Missouri, Kentucky, Virginia and Massachusetts have bills that cleared a legislative chamber.

The speed and variance of new legislation has sharply increased the compliance burden for manufacturers. As an example, West Virginia and Mississippi both passed legislation in March 2024 barring contract pharmacy restrictions, but the bills' requirements for claims submissions were different; West Virginia barred claims requirements outright, while Mississippi excluded them from mention.[13]

State policies have led many pharma manufacturers to backpedal their contract pharmacy restrictions. However, because of sparse resourcing toward 340B policy monitoring and lengthy legal review processes, most manufacturers have adapted slowly to the evolving landscape. ZS's analysis of 340B policies for the top 20 U.S. pharma manufacturers found that only three have updated their contract pharmacy restrictions beyond Arkansas (Figure 3).

FIGURE 3:

State updates to 340B contract pharmacy restrictions (Top 20 pharma companies as of April 2024)

Source: ZS research and analysis, 340B reporting from Amerisource Bergen, as of April 2024.
Note: Top 20 pharma companies by 2023 revenue.
Moderna and Roche have not issued restrictions on contract pharmacies.

Figure 3 key takeaway:

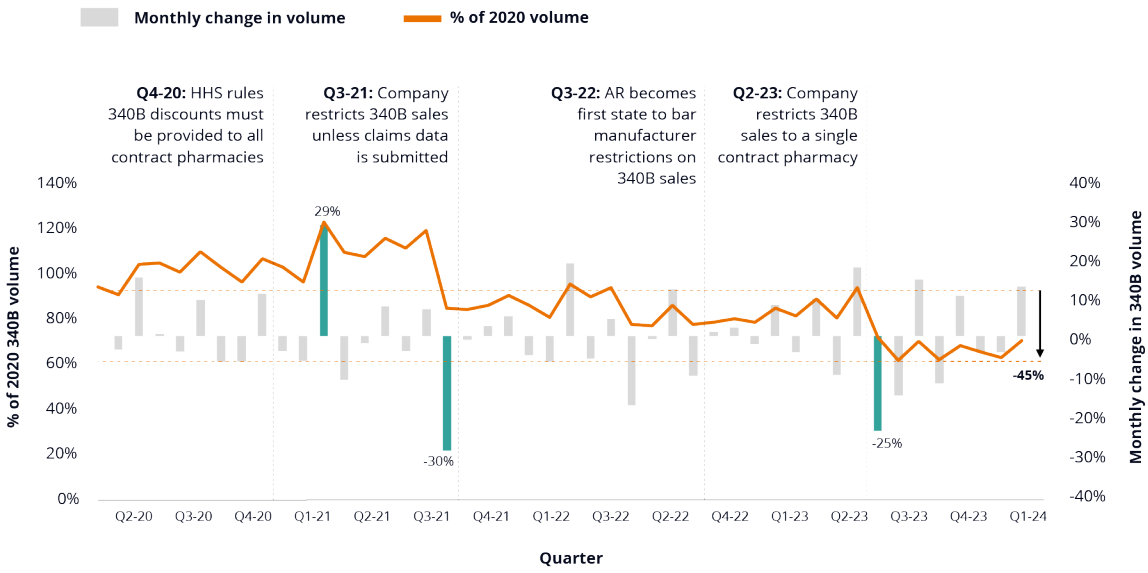
- Most manufacturers have reverted their 340B contract pharmacy restrictions in Arkansas but have been slow to adapt to ensuing legislation in other states.

Impact of contract pharmacy restrictions and state policies

While few studies on contract pharmacy restrictions are available today, preliminary analysis suggests their impact on 340B volume is significant. Through analyzing a Fortune 500 company's cardiovascular and metabolic (CVM) medication, **ZS found a 30% decline in monthly volume** following the institution of a claims submission requirement and **an additional 25% decline** following the restriction of 340B volume to a single contract pharmacy per covered entity.

FIGURE 4:

Policy impact on 340B sales volume (Fortune 500 company cardiovascular and metabolic medication)



Source: ZS analysis, company claims data accessed March 2024.

Figure 4 key takeaway:

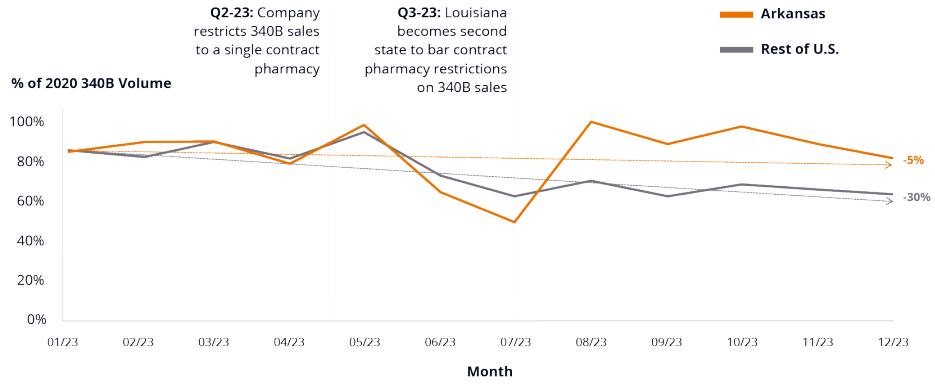
- The monthly 340B volume for this company's CVM medication has **declined ~45%** since the company enacted 340B restrictions in Q1 2021.

As states have responded to manufacturers by barring contract pharmacy restrictions, we have not observed 340B volume return to 2020 levels. Increased oversight of contract pharmacies from HRSA—and greater monitoring from manufacturers—may have contributed to this reduction in volume by ousting duplicative or fraudulent accounts. However, as providers continue to adopt to claims requirements and with court rulings enabling broader interpretations of who constitutes "eligible patients" (in *Genesis Healthcare, Inc. v. Becerra*), we anticipate 340B volume to surpass its historic peak in the future.[14]

To measure the impact of state policies on 340B volume, ZS compared 2023 volume for the same CVM medication in Arkansas to the rest of the country. We found the reversals in contract pharmacy restrictions in those states were associated with modest increases in 340B volume, though volume remained below 2020 levels.

FIGURE 5:

State policy impact on 340B sales volume in Arkansas (Fortune 500 CVM medication, 2023)



Source: ZS analysis, company claims data accessed March 2024.

Figure 5 key takeaway:

- The company's reversal of contract pharmacy restrictions in 2023 saw a ~5% decrease in 340B volume in Arkansas versus a ~30% decrease in the rest of the U.S.

Looking ahead: Navigating the changing 340B terrain

As drugmakers prepare to contend with an evolving 340B landscape, monitoring the progress of state legislation—and tracking each state's nuances with respect to claims reporting—will be critical. As states such as West Virginia ban claims submissions, manufacturers may need to separate their processes to monitor their 340B volumes by state. The threat of state and HRSA fines for contract pharmacy restrictions could prove costly for manufacturers if the proper capabilities are not developed.

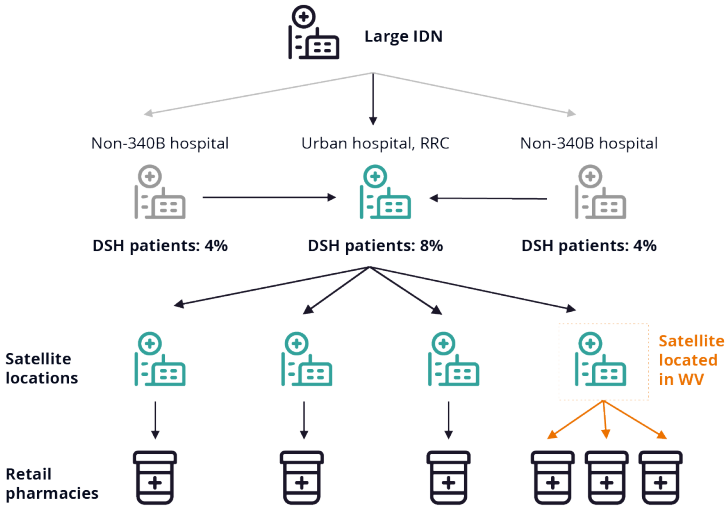
In addition to state policies, manufacturers should closely monitor the pathways that covered entities take to obtain 340B drugs. Rural referral centers (RRCs) are the fastest-growing type of covered entity by share of 340B purchases, increasing 400% between 2017 and 2022.[15]

As an example, Cleveland Clinic registered its flagship hospital in downtown Cleveland as an RRC in 2021. While the flagship location resides in a medically underserved area, dozens of the hospital's satellite sites are situated in geographies with higher household incomes and rates of private insurance.[16] Because HRSA imposes no geographic requirements between a parent hospital and its satellite sites, a large urban integrated delivery network hospital could theoretically expand its operations into states that have outlawed contract pharmacy restrictions, as Figure 6 illustrates.

FIGURE 6:

340B complexities with RRCs: Illustrative case study

RRC designation criteria:



Guidance on referral pathways may be provided at the corporate parent level

Other non-340B hospitals in the IDN network may refer lower-income patients to the flagship location

340B designation extends to each of the flagship's satellite sites, regardless of geography or patient demographic

Satellite sites with a 340B designation can contract with an unlimited number of pharmacies, depending on the state

Hospital must be private nonprofit treating patients under acute care.

Hospital has >275 beds.

Must treat a disproportionate share adjustment percentage at 8% or above.

Must classify itself as "rural," though an urban hospital may reclassify itself as rural if it would meet all requirements of an RRC.

Figure 6 key takeaways:

- The threshold to qualify for 340B benefits is comparatively lower for RRCs than for disproportionate share hospitals (DSHs)—only 8% of their patients need to qualify as low-income patients versus ~12% for DSHs.
- Despite their name, RRCs have no formal geographic requirements: ~80% of RRCs are located in urban areas and serve mostly urban patients.[17]

Absent intervention from HRSA, we expect RRCs to enable a greater proportion of urban hospitals, often serving higher-income patient profiles to benefit from 340B discounts. The rise in RRCs adds additional complexity for pharma manufacturers looking to monitor their claims volume.

Adapting to change: Recommendations for pharma amid 340B uncertainty

To navigate the inherent uncertainties about which states will protect manufacturers' rights to transparent claims reporting—and when HRSA may step in to settle the issue—manufacturers need to adopt a holistic approach toward addressing 340B policy. Here are three types of no-regrets moves pharma can take to stay ahead in the dynamic contract pharmacy landscape.

1. Develop robust 340B data management

- Create a unified 340B data system from various sources (e.g., HRSA, 340B claims vendor) to track entity purchases.
- Categorize 340B entities types (e.g., DSH, RRCs) and their locations and monitor changes over time.
- Merge account structures for a holistic view of 340B entities within their larger health systems.

2. Establish trend monitoring and anomaly detection

SIMPLE:

- Set up basic reporting to track 340B volume trends at different levels (e.g., covered entity, integrated delivery network or parent, state).
- Document changes in covered entity sites including shipping addresses, addition of child sites and changes to designated contract pharmacy.
- Monitor shifts in volume due to changes state policies.

COMPLEX:

- Discover connections with telehealth providers and referral networks.
- Analyze volume flows within an entity, between 340B and non-340B volumes, across care sites.
- Implement AI or machine learning to detect anomalies and behavior changes.
- Monitor shifts due to competitor policy changes.

3. Conduct ongoing assessment for strategy, operations and field execution

- Measure potential risks and returns of modifying contract pharmacy policies.
- Regularly review revenue management processes and systems for 340B program changes.
- Keep HQ and account executives updated with the latest policy changes and communication strategies.

While all stakeholders agree on the 340B Drug Pricing Program's mission to continue supporting low-income patients, the program must balance stakeholder needs to be sustainable. Low-income patients require access to pharmacies to obtain their treatments, providers require discounted drugs to service low-income patients and manufacturers require oversight to ensure their discounts are deployed appropriately. By employing a holistic 340B strategy, pharma can continue to sustainably provide patients and covered entities access to discounted drugs and serve the intent of the 340B Drug Pricing Program.

Notes

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Ricky Yuen is a principal in ZS's Princeton office who leads our value and access analytics practice. Ricky's expertise areas include U.S. market access, contracting, gross-to-net, revenue leakage strategy and execution, policy impact assessment (including IRA and 340B) and implementing data, analytics, AI and machine learning and decision support capabilities. Ricky has a deep understanding of the intricacies of the U.S. healthcare ecosystem flow of money and product dynamics across various customer and stakeholder types and segments.

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