White Paper

Do 340B Contract Pharmacies Really “Increase Access” for 340B Patients?

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Table of contents

Abstract

Advocates for 340B hospitals and clinics assert that contract pharmacy arrangements increase patient access to medications. They also contend that manufacturer policies limiting such arrangements have substantially reduced patient access to those medications.

While patient access is multi-factorial, it often hinges on two key dimensions: drug affordability and drug availability. Our prior work has studied the role of contract pharmacies in affordability, and showed that 340B discounts are rarely shared with patients at contract pharmacies. This study focuses on the role of contract pharmacies in drug availability. We examine contract pharmacies that are "closed" (they serve only 340B patients) versus contract pharmacies that are "open" (they serve all patients regardless of their 340B status). Closed pharmacies may represent increased access, because they would not exist without the 340B program, while open pharmacies do not.

Using a national sample of drug sales data, we found that less than 1% of contract pharmacies were closed, and this proportion remained stable after manufacturer policies were implemented. Before the implementation of manufacturer policies limiting the use of contract pharmacies, 25 pharmacies were closed contract pharmacies (0.10%), while after manufacturer policies were implemented, 40 pharmacies were closed contract pharmacies (0.13%). During the same period, the number of non-contract pharmacies fell, and the number of prescriptions and 340B sales involving contract pharmacies — both open and closed — increased substantially.

In summary, for the vast majority of cases, drug availability at contract pharmacies does not depend on patients' 340B eligibility. We therefore find no evidence that 340B contract pharmacies increase drug availability in a meaningful way or that manufacturer policies reduced patient access at contract pharmacies.

Introduction

Recently, the Majority Staff of the Senate Health, Education, Labor, and Pensions Committee (HELP) issued a report on the 340B Drug Pricing Program ("340B program").[1] In doing so, the Committee addressed an issue that has been a source of dispute between 340B advocates and critics, who offer starkly different assessments of whether 340B contract pharmacies increase access for patients to drug therapy and whether manufacturer policies that seek to limit the use of those contract pharmacies have adversely affected patient drug access. Under controversial guidance issued by the Health Resources and Services Administration (HRSA) — the agency responsible for oversight of the 340B program — 340B hospitals and clinics have used contract pharmacies that the 340B covered entities do not own or operate to leverage 340B profits. Considering the importance of the issue of patient access to medicines, we set out to determine whether 340B contract pharmacies can be shown to have meaningfully expanded access and whether the subsequent introduction of manufacturer contract pharmacy policies decreased patient access.

A short history of contract pharmacies

The 340B program mandates that drug manufacturers provide significant discounts to a specified group of healthcare providers known as covered entities.[2] Enacted under the Public Health Service Act, the 340B program specifically limits the entities that may purchase at the heavily discounted price specified by statute.[2]

Notwithstanding that statutory restriction, HRSA permits 340B covered entities to expand their use of 340B priced drugs using contract pharmacies. Contract pharmacies often consist of large, for-profit national chain pharmacies or specialty pharmacies that are themselves affiliated with the largest national payers and pharmacy benefit managers.

Because, in most circumstances, covered entities and their contract pharmacies can bill third-party payors —

such as commercial plans, employer sponsors, and the Medicare program — at reimbursement rates that are not discounted for the lower 340B acquisition prices, the resulting "spread" between the 340B acquisition price and the reimbursement value is a source of enormous profits to both covered entities and contract pharmacies. Members of our group recently estimated that 340B acquisition costs in 2024 were $68.4 billion, the list price value of those drugs — a measure of reimbursement value — was $147.8 billion, and the resulting spread was $79.4 billion.[3]

After HRSA permitted an unlimited number of contract pharmacies in 2010,[4] the 340B program tripled in size over the following decade, even as the vulnerable population the statute was designed to assist halved in size.[5] In April 2010, there were approximately 2,321 contract pharmacy arrangements. By 2020, this figure had grown to over 100,000 such arrangements.[6]

As the number of contract pharmacies grew, government agencies and others expressed concerns that these arrangements were exposing the program to diversion and duplicate discounts.[2] For example, although drugs dispensed at an entity-owned pharmacy can be inferred as having been purchased through the 340B program, no such inference is possible at contract pharmacies. Uncertainty as to the 340B status of drugs

is the main reason duplicate discounts exist. Also, the Government Accountability Office concluded that "[t]he expansion of contract pharmacies … increases potential risks to the 340B program". The Office of the Inspector General for the Department of Health and Human Services (OIG) came to the same conclusion as early as 2014,[7] finding that two-thirds of HRSA identified diversion audit findings involved contract pharmacies.

Significantly, contract pharmacy transactions do not increase patient access to medications via increased affordability because they rarely result in the sharing of 340B discounts with patients at the pharmacy counter, regardless of their need. A 2022 study revealed that 340B contract pharmacy patients receive direct financial assistance at the pharmacy counter for only 1.4% of all branded 340B prescriptions.[8] A recently published follow-up study by our group showed that only 3.0% to 4.7% of branded 340B contract pharmacy prescriptions resulted in assistance to the patient at the pharmacy counter.[9] Those percentages compare quite unfavorably to the national combined rate of uninsured and underinsured in the U.S., which is 31%. Prior studies have demonstrated that many contract pharmacies are located in affluent areas,[10,11] and that 340B hospitals, which receive approximately 80% of the profits generated by the program, have very low rates of charity care, just 2.15% in 2022, the last year for which data is available.[12]

Manufacturers first began instituting contract pharmacy policies in the third quarter of 2020 in an attempt to limit contract pharmacy relationships and address concerns about diversion and duplicate discount risks created by these relationships. By the second quarter of 2024, several dozen drug makers had instituted a version of these policies.[13] 340B advocates have decried those policies, however, contending that they have harmed patient access to drugs.

HRSA attempted to prevent manufacturers from implementing their contract pharmacy policies, but multiple manufacturers sued the agency, arguing that HRSA lacked authority to prohibit the policies.[14,15] Although the agency was initially successful in defending its position before some district courts, the United States Courts of Appeal for the Third Circuit and the D.C. Circuit subsequently upheld the manufacturer policies.

340B advocates responded to those adverse decisions by lobbying state legislatures to mandate an unlimited number of contract pharmacies and contract pharmacy transactions at the 340B price as a matter of state law. Based in significant part on the claim that manufacturer policies adversely affect patient access to drugs, 17 states enacted these prohibitions.[16]

Manufacturers have, in turn, responded by filing numerous lawsuits challenging these state laws. To date, however, most courts have upheld the state laws, although the United States District Court for the District of West Virginia struck down that state's contract pharmacy law.[17]

Digging deeper into the competing narratives

The question of what, if any, impact manufacturer contract pharmacy policies have had on patient access to their medications has been contested.

1. THE CLAIMS MADE BY THE 340B COMMUNITY

340B advocates argue that there is a negative effect on patient access from any restriction on the unlimited use of contract pharmacies. For example, the American Hospital Association (AHA) argues that manufacturer contract pharmacy policies "have resulted in patients … losing access to … medications".[18] Manufacturer policies, it argues, have produced "significant challenges accessing drugs". Similarly, another 340B advocacy group contends that community pharmacies are needed to "ensure" that covered entity "patients have local, convenient options to access" their medications.[19]

2. SKEPTICISM FROM PROGRAM CRITICS

Critics of the program challenge the premise that limiting the number of contract pharmacy transactions diminishes access to medications. Specifically, manufacturers and other critics, including some patient groups, contend that most 340B contract pharmacies operate on an "open" basis, serving both 340B and non-340B eligible patients, such that 340B status does not have any meaningful effect on drug therapy access. In that regard, they also stress that a substantial percentage of contract pharmacies are located in affluent areas and that only small percentages of 340B contract pharmacy branded drug prescriptions include financial assistance.[11,20]

3. THE COURTS' PERSPECTIVE

Although litigation is ongoing, the question of what, if any, relationship exists between contract pharmacy policies and access to drugs for patients has been an important component of a number of judicial decisions to date. This access question was, for example, a central pillar of the decision by the U.S. Court of Appeals for the 8th Circuit in upholding an Arkansas state law prohibiting manufacturers from applying contract pharmacy restrictions in that state.[16] Highlighting the importance of the question, the 8th Circuit frames its decision by asserting, without citation or evidence, that the "outsourcing of pharmacy services" to contract pharmacies "has allowed for drug dispensation closer to where low-income residents reside."

Data and methods

Prescriptions were sourced from a national sample of prescriptions called Longitudinal Access and Adjudication Dataset (LAAD) offered by IQVIA. The sample included all types of self-administered branded drugs including specialty and traditional drugs, and small molecule products and biologics. We used IQVIA's DDD subnational sales database to estimate the percentage of drugs that were purchased using the 340B program. This is a national sample of manufacturer-direct and wholesaler sales to various stakeholders including hospitals, clinics, retail and mail pharmacies, and long-term care facilities.

We used this data, first, to determine the number of 340B contract pharmacies and the number of pharmacies that are not 340B contract pharmacies. We estimated the number of 340B contract pharmacies both before and after manufacturers implemented their policies.

Because those policies first began to be implemented in the third quarter of 2020, we studied the period from the first quarter of 2020 to the second quarter of 2024, by which time more than 30 manufacturers had implemented a 340B contract pharmacy policy. In order to report pre- and post-policy-implementation results, we chose the first quarter that we examined, the first quarter of 2020, as the pre-policy base quarter, and we used the last quarter that we examined, the second quarter of 2024, as the post-policy-implementation point of reference.

Next, we determined which 340B pharmacies were "closed," serving only 340B-eligible patients, and "open," serving both 340B and non-340B patients. We performed this analysis using the time period Q1 2020 through Q2 2024.

Having initially defined a "closed" contract pharmacy as a pharmacy for which 100% of its patients were determined to be 340B eligible, and thus would have prescriptions filled with 340B drugs, we then performed a sensitivity analysis. Under that analysis, we examined how the results would change should we define "closed" as allowing various percentages of non-340B patients, up to and including 20%.

Limitations

As a general matter, limited data is available from covered entities and pharmacies regarding 340B participation. Although some states now require 340B provider reporting, obligations are new and do not provide comprehensive data sets. There are no systematic federal reporting requirements that would facilitate analysis.

In assessing whether there are significant numbers of 340B contract pharmacies that are "closed" and serve only 340B patients, there is no industry-recognized standard definition of a 340B "closed" contract pharmacy. For this study, we examined 340B contract pharmacies whose share of 340B prescriptions ranged from 100% to as low as 80%. Our results were directionally the same for all the percentage cut-offs that we applied.

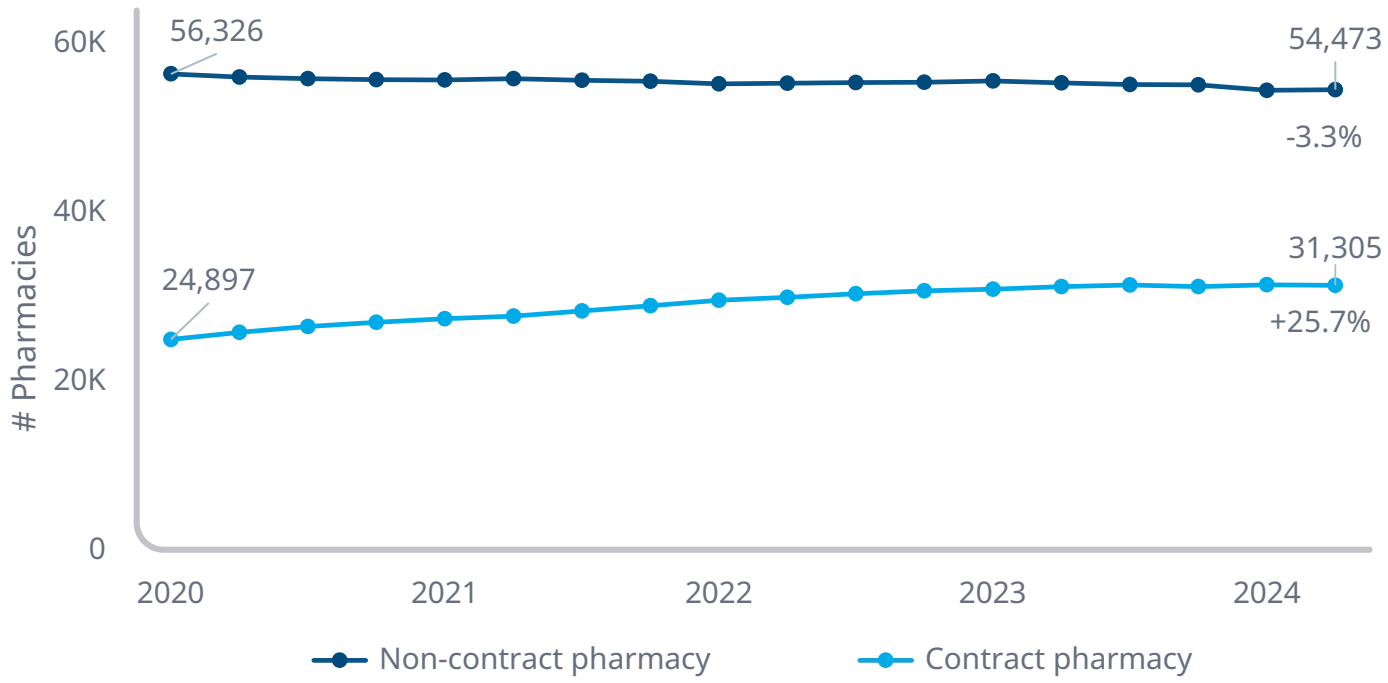
Our analysis relies on the LAAD and DDD samples. While both datasets offer large sample sizes and high market capture, they do not represent 100% of prescriptions or sales. In addition, although we can examine prescriptions in LAAD, we cannot determine which of them were filled with 340B product, since no such identifiers are available, as the 340B status of drugs is normally unknown at the point of sale to the patient.

Findings

After a review of our complete data set to examine the number of 340B contract pharmacies and the number of pharmacies that did not operate as 340B contract pharmacies, we found that the number of 340B contract pharmacies increased following the introduction of drug manufacturer contract pharmacy policies, even as the number of non-contract pharmacies fell. The number of "closed" contract pharmacies that served only 340B patients was very small both before and after the implementation of drug maker policies. Additionally, the number of prescriptions and associated dollars for 340B contract pharmacies, inclusive of both "open" and "closed" pharmacies, increased substantially following policy implementation (data not shown).

In order to determine the potential impact of 340B contract pharmacies on patient access and whether the access they provide was affected by the manufacturer contract pharmacy policies, we first examined the number of pharmacies that operate as 340B contract pharmacies and the number of pharmacies that do not act as 340B pharmacies both before and after the manufacturer policies were implemented. Before and after implementation, the number of 340B contract pharmacies grew from 24,897 to 31,305, while the number of non-contract pharmacies fell from 56,326 to 54,473, as shown in Figure 1.

Figure 1. Number of pharmacies by contract pharmacy status, from Q1 2020 to Q2 2024. Non-contract pharmacies include 340B entity-owned pharmacies



Given 340B advocates' suggestion that contract pharmacy policies substantially decreased patient access, we expected that the number of contract pharmacies would have decreased sharply following the introduction of those policies. Our findings, however, are fundamentally in the opposite direction, as both the number and percentage of contract pharmacies increased following the introduction of manufacturer policies.

Although contract pharmacies represent a minority of all pharmacies and the access provided in aggregate to patients, both before and after drug maker policies were introduced, contract pharmacies increased by 26% from Q1 2020 to Q2 2024. The number of non-contract pharmacies decreased by 3.3% over the same period.

We next determined, for the same period, what percentage of contract pharmacies were closed and open. As indicated above, a significant percentage of closed 340B contract pharmacies might suggest that patient access is dependent on those pharmacies and 340B patient eligibility.

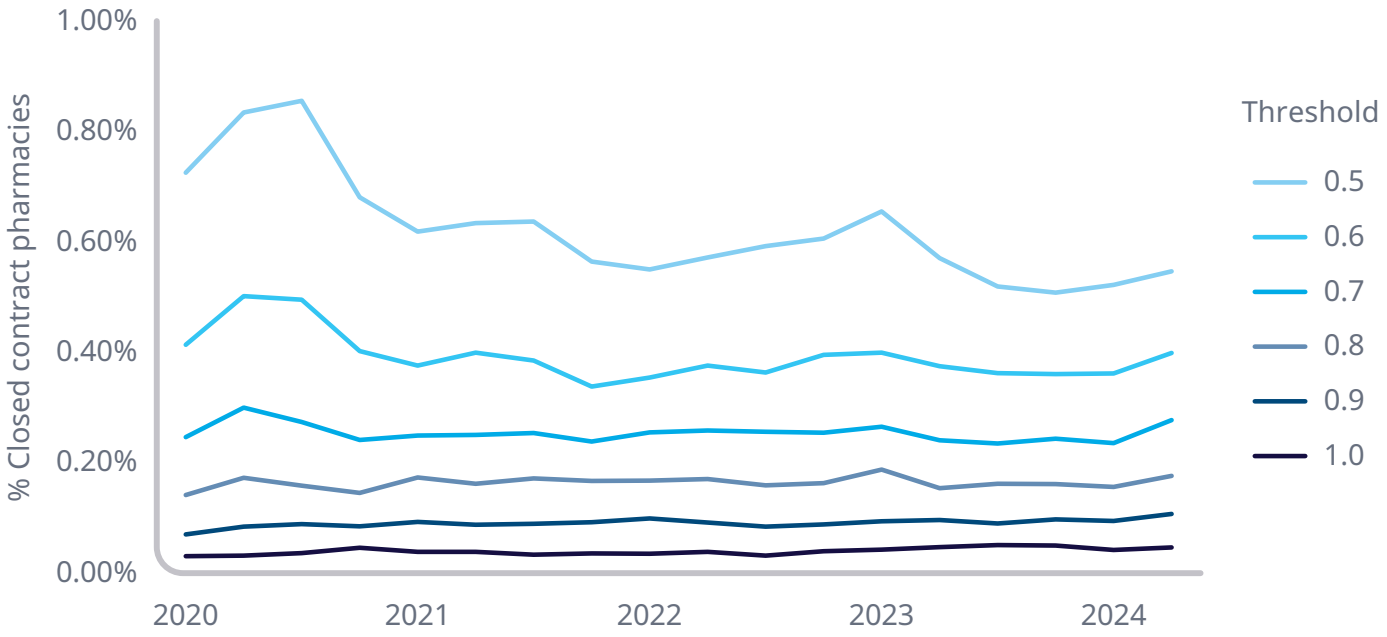
Based on our review, however, closed contract pharmacies that serve only 340B patients were exceptionally rare, both before and after implementation of the manufacturer policies. Nationally, there were just 25 such contract pharmacies pre-policy implementation (in Q1 2020) and just 40 post-policy implementation (in Q2 2024).

Closed 340B contract pharmacies represented just 0.10% of all contract pharmacies pre-policy implementation and 0.13% of all contract pharmacies post-implementation. Thus, we found that 99.9% of contract pharmacies operated on an "open" basis, providing access to both 340B and non-340B patients before and after manufacturer policies were implemented. These findings are reflected below in Figure 2.

We performed a sensitivity analysis by using different cut-offs for open versus closed pharmacies. Our primary analysis was based on identifying closed pharmacies where 100% of sales shipped to the pharmacy involved 340B drugs. We applied alternative cut-offs as low as 50%, and our results were directionally the same. Even when we defined a closed 340B contract pharmacy as having non-340B sales as high as 20%, this segment represented just 0.14% of all pharmacies before manufacturer policy implementation (in Q1 2020), and 0.18%, after implementation (Q2 2024). These findings are reflected on the next page in Figure 3.

Figure 2. The number (bars) and percentage (lines) of closed contract pharmacies, from Q1 2020 to Q2 2024

Figure 3. Percentage of closed contract pharmacies for various values of the threshold parameter for contract pharmacies being "closed"



Discussion

We can find no evidence to support the contention by 340B advocates that 340B contract pharmacy relationships meaningfully increase patient access to drugs or that the introduction of manufacturer contract pharmacy policies adversely affected patient access. 340B contract pharmacies, which were a minority of all pharmacies, both before and after the policies were implemented, increased substantially after policy implementation (+6,408 or +25.7%), even as the number of non-contract pharmacies fell (-1,853 or -3.3%).

Further, the number of closed 340B pharmacies was very small both before (25) and after (40) policy implementation. Our finding that the number of contract pharmacies that serve only 340B patients is small confirms a 2016 report by the Office of the Inspector General for the Department of Health and Human Services, which concluded that "[m]ost contract pharmacies … serve the general public as well as patients of the covered entities with which they contract".[21] In the vast majority of cases, 340B eligibility appears to have no impact on patient access to medications.

340B advocates might contend that, notwithstanding the fact that 340B contract pharmacies do not increase drug availability, they increase affordability. Our prior research, however, has demonstrated that there is little basis to support this contention. Our original study, in 2022, found that only 1.4% of branded 340B contract pharmacy prescriptions could be shown to have resulted in financial assistance to those drug patients.[8] A follow-up study confirmed limited assistance, ranging between 3.0% and 4.7% of branded prescriptions, well below the 31% combined national rate of the uninsured and the underinsured.[9]

Significantly, the rate of uninsured and underinsured people seen by most 340B covered entities is likely to be higher than the national average of 31%. This underscores the dramatic gap between the level of 340B contract pharmacy assistance we have found and the needs of 340B patients.

The relatively low level of assistance provided to 340B patients at contract pharmacies may also be available to non-340B patients via coupons and patient assistance programs, but no study to our knowledge has addressed

this question. Even if the low level of assistance provided for 340B contract pharmacy dispenses does represent some net gain in drug assistance, it is marginal, at best.

The contrast between 340B advocates' claims and our findings, which do not support either that 340B contract pharmacies meaningfully increase patient availability to drugs or that manufacturer policies adversely affected access, is important to consider in the context of the ongoing litigation related to those policies. It suggests that the drug availability arguments made to the courts reviewing state laws that prohibit those policies are incorrect.

Given that almost all contract pharmacies serve both 340B and non-340B patients, we can find no data to support the 8th Circuit's assertion, which framed its decision upholding the original state contract pharmacy law, that the "outsourcing of pharmacy services" to contract pharmacies "has allowed for drug dispensation closer to where low-income residents reside" so as to improve access to drug therapy.[16] Based on our data and the prior studies showing a high percentage of contract pharmacies located in affluent areas,[11,20] that drug availability contention appears to be a contrafactual assertion.

Significantly, the law upheld by the 8th Circuit served as a template for all subsequent, similar state laws enacted.[16] Moreover, other court decisions upholding challenges to those other state contract pharmacy laws have relied heavily on the 8th Circuit's decision.

Conclusion

With the exception of a very small number of 340B contract pharmacies that serve only 340B patients, the vast majority of these pharmacies serve both 340B and non-340B patients. Patients' ability to access drugs at 340B contract pharmacies is, with few exceptions, not dependent on 340B eligibility. Further, the number of contract pharmacies increased substantially after manufacturer policies were implemented.

These findings may have important implications for ongoing litigation and legislative efforts. Claims that manufacturer policies have broadly reduced patient access are not supported by the data, and courts and policymakers should be cautious in accepting arguments that equate the presence of contract pharmacies with increased access for vulnerable populations.

As states consider legislation mandating unrestricted contract pharmacy arrangements, and as federal agencies evaluate their oversight, it is crucial that decisions be based on empirical evidence. Our analysis suggests that the 340B program's expansion via contract pharmacies has not translated into meaningful gains in drug availability or affordability for 340B patients. Future reforms should focus on transparency, accountability, and direct patient benefit.

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Conflicts of interest

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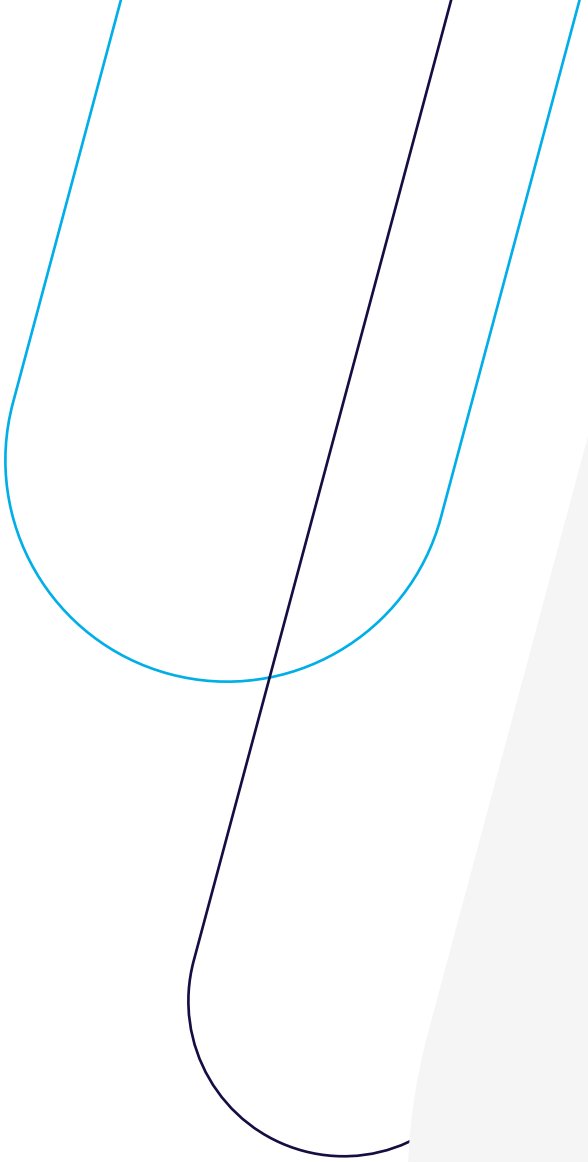

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