kalderos

Whitepaper

Current industry pressures & their impact on drug manufacturer operations teams

Compounding challenges pave the way for change

08 2023

Executive Summary

Financial pressures are closing in on every side for pharmaceutical manufacturers. The Inflation Reduction Act (IRA), signed into law in August 2022, introduced three new drug pricing provisions and mandated rebates. These provisions will inevitably create more scrutiny around the costly duplicate discounts that cause revenue loss, disrupt business operations and threaten growth. Furthermore, the widening chasm between drug list prices and net prices fuels the ever-growing gross-to-net revenue bubble.

Historically, drug manufacturers' operations teams have been charged with solving for timeliness and efficiency. Given that identifying and disputing noncompliant discounts at scale has always been a time-consuming, costly and largely inefficient process, these teams have instead often focused their resources on paying invoices promptly, even with the knowledge that a percentage of these claims were incorrect. Within this paradigm, some loss from drug discount programs has always been expected and is even factored into financial planning. In the past, these losses were simply the cost of doing business.

But as the financial strain of duplicate discounts increases year over year, company leadership and executive teams are shifting their focus beyond just forecasting the impact of revenue leakage from these inaccurate payments to now solving the problem. This new approach necessitates changes to workflows and internal business dynamics in ways that are keenly felt by operations.

Operations teams now have the opportunity to deliver even more meaningful impact by moving beyond just timeliness and efficiency to lifting net revenues and crediting money back to the balance sheet. Succeeding in this regard doesn't only earn them a seat at the table; it also allows them to carry more influence, access more resources and have a hand in defining future organization-wide strategies.

In this report, we'll investigate the external pressures that are changing the game across the industry, study the shortcomings of the status quo response and explore the proven tech-enabled solutions that will help operations teams rise to the simultaneous challenges of doing more with less under tight deadlines and recapturing leaked revenue to make a quantifiable contribution to their organizations.

Ongoing considerations for operations teams

Operations teams have typically been measured on their ability to improve efficiency and pay invoices quickly. This focus is motivated in part by the 38-day window allotted to pay Medicaid rebates as outlined in the Medicaid Drug Rebate Program (MDRP).[1] Paying invoices outside this mandated window subjects manufacturers to interest penalties that accrue over time. It has become increasingly difficult to make rebate determinations within this time frame, however, because of the sheer volume of prescriptions written in the U.S. today. Between Q1 2022 and Q4 2022, states collected $42.9 billion in manufacturer rebates on a total drug spend of $77.6 billion, or 55.3% of total drug spending.[2]

55.3%

percentage of manufacturer rebates collected by states on total drug spending in 2022

In the past, manufacturers had to choose between paying invoices and suffering a percentage of revenue leakage or initiating the complicated, time-consuming process of collecting and digesting detailed data to dispute the invoices — conflicting challenges that amount to some loss either way. Based on the unlikelihood of making accurate rebate determinations within 38 days, operations teams have generally chosen timeliness over accuracy, aside from big-picture checks to identify any egregious errors.

Noncompliance isn't just a problem for drug manufacturers; it's also a burden on the nation's healthcare system, which must absorb the costs of noncompliant discounts. Some estimates suggest that noncompliant rebates — including 340B duplicate discounts — account for as much as $12.5 billion each year, or about 5% of the drug discounts being paid. This projection does not include the time and effort that manufacturers expend to validate and process rebate claims.

$12.5B

in estimated noncompliant discounts each year

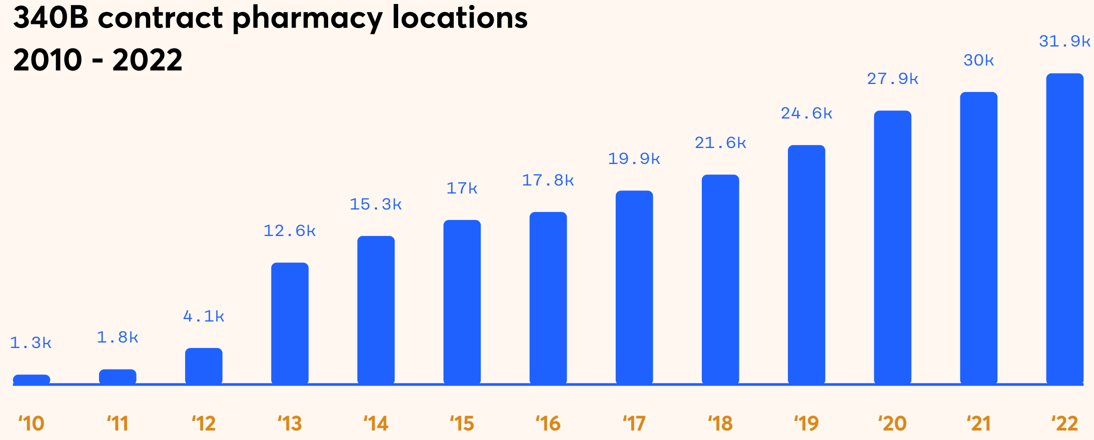
Let's look at some of the compounding challenges that manufacturers face in the current drug discount program landscape.

Operations teams face compounding pressures and new challenges

Across the industry, the gross-to-net revenue bubble — the gap between manufacturers' gross revenue (received from drug sales at the wholesale acquisition cost or list price) and net revenue (the actual amount received after reductions like rebates and discounts) — grew by 8% in 2021[3] and 7% in 2022.[4] In 2022, the gross-to-net bubble for patent-protected brand-name drugs in the U.S. reached $223 billion; when considering brand-name drugs that have lost patent protection, that number rises to $256 billion.[5] For manufacturers, this means that profit margins are shrinking while risks grow exponentially and the threat of penalties increases.

The growth in the 340B Drug Pricing Program and subsequent duplicate discounts has been a major contributor to the gross-to-net gap. When the 340B program began, covered entities made up just a fraction of all U.S. healthcare providers. But over the years, government guidance and legislation have broadened the covered entity definition. In 2010, fewer than 9,700 covered entities participated in the 340B program; in 2020, participation grew to 12,700.[6] Now, covered entities may work with external "contract pharmacies" to dispense 340B drugs. In January 2010, there were fewer than 1,300 unique contract pharmacy locations; by July 2022, that number was closer to 32,000.[7]

340B contract pharmacy locations 2010 - 2022



Sources: Government Accountability Office (2010-2012); Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (2013-2022). Data show number of unique contract pharmacy locations as of January (GAO) or June/July (DCI).

Published on Drug Channels on July 12, 2022.

This uptick in the number of covered entities and contract pharmacies has widened patient access to 340B discounted drugs while also generating a rise in spending. The 340B Drug Pricing Program experienced a compounded annual growth rate of 23.8% between 2015 and 2021.[8] In 2021, discounted purchases in the 340B program reached a staggering $43.9 billion — a 15.6% increase from the previous year.[9] The list-price value of those same 340B purchases was $93.6 billion. For reference, spending for the 340B program in 2010 was just $5.3 billion.[10]

23.8%

compounded annual growth rate of 340B between 2015 & 2021

$43.9B

of discounted purchases in the 340B program in 2021

Additional pricing concessions mandated by the IRA's drug pricing provisions are increasing scrutiny around revenue leakage. The expansion of drug discount programs could lead to a rise in duplicate — and even triplicate — discounts and other inaccurately paid drug discount claims.[11] In fact, The Wall Street Journal recently reported on a Wells Fargo analysis that estimated a 5% drop in manufacturer revenue in the IRA's first three years of implementation,[12] which would disrupt business operations and threaten the growth of small and emerging companies.

As revenue leakage totals skyrocket, operations teams are under even greater pressure to detect noncompliant rebates, often without sufficient tools and resources. Organizations are left scrambling to cut costs and bring revenue leakage under control, challenging the long-term viability of operations teams and other core functions that could be automated or outsourced.

Established approaches to Drug Discount Management are no longer sustainable

For operations teams that have customarily indexed around timeliness and efficiency, the status quo approach to finding and disputing duplicate discounts comprises many unwieldy processes.

Manually identifying noncompliance

Without the appropriate tools to manage disparate data sources, finding duplicate discounts is arduous; individuals must manually scrub the data to find instances of noncompliance through automated rules. If manufacturers can actually find the necessary rebate data, the process of codifying it introduces additional complexity due to varying data input requirements; the data fields required and formats in which the data is presented are inconsistent from state to state.

This approach is costly, time-consuming and prone to human error. Operations teams lose untold hours entering generalized summary invoices into their electronic systems and then requesting claims-level data (CLD) from every labeler in each state's Medicaid program. Then they must comb through hundreds of itemized invoices to re-enter the data and identify rebates among those initial summary amounts.

Meanwhile, the clock is ticking. As manufacturers address each inefficient step in the process and then finally prepare formal disputes with paperwork like Reconciliation of State Invoices (ROSI) and Prior Quarter Adjustment (PQA) statements, the aforementioned government-mandated 38-day window is quickly closing.

The incompatibility between CLD and legacy software systems keeps operations trapped in a minefield of spreadsheets. And the fact that it can take several quarters for rebates related to dispenses under Medicaid managed care organizations (MCOs) to show up on Medicaid Drug Rebate Program invoices compounds these challenges even further.

"Pay and chase"

To mitigate these issues and avoid interest penalties, operations teams have largely adopted a "pay and chase" approach of paying invoices even when they can't manually reconcile them within the MDRP's 38-day time frame.

This approach is, in effect, kicking the can down the road. If manufacturers later determine that they overpaid on noncompliant discounts, they have to forward paperwork to the state with the hope of potentially recovering the money they've already paid. Not only is the recovery of those sums never promised, but the inefficiency of the process also drains even more time and resources from operations teams after the fact.

Money on the table

While operations teams have been as resourceful as possible with the tools available to them, today's predominant reconciliation practices are too cumbersome to scale up in either speed or efficiency. When considering the conventional Drug Discount Management approach, it makes perfect sense that operations may choose to simply minimize the extent of their exposure to this process — even if it means leaving some money on the table.

Risks of staying the course

While the number of 340B duplicate discounts grows and revenue pressures come to a head, organizations are losing more money to drug discount programs than they have in the past. As this trend continues, leadership will look more closely at operations teams and question what they are doing to minimize revenue leakage.

The drive to reduce costs and increase revenue has prompted major changes in the pharmaceutical industry workforce. In 2022, 119 U.S. pharmaceutical manufacturers conducted layoffs.[13] This downsizing trend has already made its mark on 2023: More than 90 manufacturers have either slashed staff dramatically or shut down completely in the first half,[14] and one major manufacturer recently announced that it was cutting an additional 450 jobs in its second round of layoffs this year.[15]

For many of these companies, layoffs and outsourcing are part of holistic organizational changes designed to save hundreds of thousands of dollars in operating costs. As manufacturers shift their focus to solving for duplicate discounts and revenue leakage, operations teams face a more pressing issue: To maintain their position and sustain access to company resources, they must now quantify their financial contributions to the organization.

A paradigm shift will empower operations teams

These external pressures — from recent government-mandated pricing provisions to a growing gross-to-net bubble — have created an opening for a paradigm shift. A new Drug Discount Management solution allows operations teams to streamline workflows, credit money back to their company's balance sheet and ultimately lift net revenues. Re-examining and utterly transforming the status quo processes would secure company standing for operations teams, guaranteeing them a proverbial seat at the table for the foreseeable future.

Company D

87%

percentage of noncompliance directly confirmed by Kalderos' covered entity network, with funds being delivered in the form of agree to credits

Company W

45M

dollar amount of commercial exclusions Kalderos identified in a four-year period

With our collaborative data-driven solutions, Kalderos is uniquely positioned to help operations teams:

01

Uncover potential sources of revenue leakage

02

Control where they devote their valuable resources

03

Dispute with confidence and pay with accuracy

Using Kalderos' tech-enabled platform, operations teams can recover more substantial revenue leakage for their organizations — a quantifiable contribution that will give them a say in future strategy and greater access to company resources.

Kalderos delivers unique value to drug manufacturers

Since 2016, Kalderos has identified more than $1 billion in inaccurate claims. In that time, covered entities have reviewed more than 842,637 individual claims on the Kalderos platform and verified $110 million in duplicate discounts. Thousands of covered entities engage in Kalderos' platform, responding to good faith inquiries on Discount Hub faster each year: The average number of days it took for covered entities to respond to inquiries decreased by 49% between 2022 and 2023.

The Kalderos team has also invested in building relationships with states and refining our dispute resolution processes to better support each state's unique policies, procedures and workflows. From 2021 to 2022, Kalderos saw a 10.2-fold increase in state responses and a 348% decrease in state response time.

Kalderos' solution suite is built on connecting stakeholders to streamline communication and data flow, bringing together disparate data sources to power Drug Discount Management solutions for all. We partner with drug manufacturers, and operations teams in particular, to identify and resolve noncompliant drug discounts and rebates, improving gross-to-net forecasting and lifting net revenues.

$1B

dollar amount of inaccurate claims identified by Kalderos

842,637

individual claims reviewed by covered entities on the Kalderos platform

$110m

in duplicate discounts verified by covered entities

348%

decrease in state response time between 2021 & 2022

MDRP Discount Monitoring

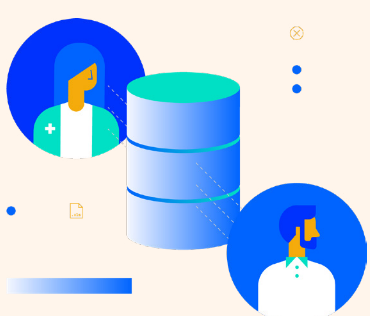
Kalderos' MDRP Discount Monitoring solution offers manufacturers a transparent view of Medicaid claims data to dispute duplicate discounts and other inaccurate claims with confidence. The solution provides a collaborative platform that enables manufacturers to dispute directly with states. This helps operations teams to:

- Eliminate the need to manually cross-check spreadsheets or internal systems for noncompliance
- Improve engagement from states on disputes and dispute resolution
- Reduce revenue leakage

Commercial Discount Monitoring

Kalderos' Commercial Discount Monitoring solution brings visibility and confidence to creating and enforcing contract terms and supports manufacturers throughout the entire contracting life cycle to:

- Streamline the identification of ineligible commercial rebates with one central solution
- Surface the information needed for a data-driven contract strategy
- Negotiate commercial contract terms with confidence



Want to learn more?

Let's discuss your Drug Discount Management needs. Visit kalderos.com/contact to schedule a meeting with our team.

End Notes

[1] Interest Calculation for Late Rebate Payments, Medicaid.gov, November 8, 2021

[2] Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, Federal Register, May 26, 2023

[3] Warped Incentives Update: The Gross-to-Net Bubble Exceeded $200 Billion in 2021. Drug Channels, March 22, 2022.

[4] The 340B Program Climbed to $44 Billion in 2021 — With Hospitals Grabbing Most of the Money. Drug Channels, August 15, 2022.

[5] Four Trends That Will Pop the $250 Billion Gross-to-Net Bubble — and Transform PBMs, Market Access, and Benefit Design. Drug Channels, April 4, 2022.

[6] Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements. United States Government Accountability Office, December 2020.

[7] "Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming 340B Contract Pharmacy Market," Drug Channels Institute. December 16, 2022.

[8] Drug Channels. "The 340B Program Climbed to $44 Billion in 2021."

[9] Ibid.

End Notes

[10] Sarah Jane Tribble and Emily Featherston. "As Big Pharma and Hospitals Battle Over Drug Discounts, Patients Miss Out on Millions in Benefits." KFF Health News, November 16, 2021.

[11] 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. United States Government Accountability Office, January 2020.

[12] As Washington Clamps Down on Big Pharma, Small is Beautiful Again. The Wall Street Journal, June 8, 2023.

[13] Fierce Biotceh Layoff Tracker: Layoffs Strike 119 Companies in 2022. Armstrong, Masson and Bayer, Fierce Biotech, January 3, 2023.

[14] Fierce Biotech Layoff Tracker 2023: Intercept Lays Off a Third of Staff; BAKX Dissolves, Fierce Biotech, June 29, 2023.

[15] Biotech firm Amgen to Layoff an Additional 450 Employees Amid Inflation Woes. International Business Times, March 17, 2023.

Kalderos is a data infrastructure and analytics company that created the world's first Drug Discount Management platform, simplifying drug discount program compliance for all stakeholders. The platform applies sophisticated data models and machine learning to identify and resolve noncompliance, with collaboration-oriented solutions built for both drug manufacturers and covered entities.

Based in Chicago, Kalderos was founded in 2016 by a team dedicated to reducing inefficiencies in the U.S. healthcare system, empowering everyone to focus on the health of people.

Learn more at **kalderos.com**.