'22 Annual Report

kalderos

Conquering the "Great Unknown"

Connecting the data gaps that keep us from knowing the true price of drugs

Table of Contents

A letter from Kalderos CEO Brent Dover

In America, the debate over unaffordable prescription drugs echoes from congressional hearings to the kitchen tables of stressed families. We have—understandably—sought to lower drug prices by taking aim at the prices themselves. But like any stubborn challenge, the solution can often be more complicated than what's right in front of you.

It has become increasingly clear that nobody, not even the experts, can offer up a definitive fix for the country's prescription drug affordability crisis. In order to truly address it, there is an urgent need to learn more about what is obstructing us from finding a solution.

The problem lies in enormous gaps in knowledge, data and technology that keep the goal of affordable medications in the U.S. far out of reach.

These "known unknowns" not only hamstring policy efforts to make drugs more affordable, but they also impair the operational efficiency of key stakeholders throughout the system, including care providers, drug manufacturers and state Medicaid agencies. This information impasse is the focus of the Kalderos 2022 annual report—"Conquering the 'Great Unknown': Connecting the data gaps that keep us from knowing the true price of drugs."

In this report, we look at how deficiencies in data and technology cause many of the pain points that impact multiple participants in the complex ecosystem of drug distribution.

Since our founding in 2016 by a group dedicated to reducing inefficiencies in the healthcare system, Kalderos has worked closely with multiple stakeholder groups and learned of specific challenges tied to data that was inaccessible for one reason or another. We've also done the dutiful work of using our tech-enabled platform to illuminate some of these data gaps. The startling revelations we've uncovered are discussed in detail in this report.

It is a personal privilege to introduce this report, following in the footsteps of Kalderos co-founder and former CEO Jeremy Docken. It has been a great honor to succeed Jeremy as CEO of Kalderos this year. Stepping into this role, I remain tremendously proud of the opportunities I've had over the past two decades to take three emerging health tech companies through rapid growth trajectories. Kalderos is at a similarly pivotal moment of progress right now, and I am truly grateful to be able to count on Jeremy's expertise in his new role as Founder & Chief Strategy Officer as we build on our remarkable success.

In last year's introduction, Jeremy outlined the simple yet novel approach of Kalderos: connecting stakeholders, streamlining communication and using platform technology to ensure drug discount programs are working as intended.

100%
customer retention over two years

A year later, that approach has proven to be a formula for success for our platform users. Since our 2021 annual report, Kalderos has experienced accelerated growth—more than doubling our customer count and tripling sales. For two straight years we have maintained 100% customer retention. In 2021 we identified as much noncompliance in one year as we had in the previous four... combined. All of this is due to the incredible team we have here at Kalderos.

Looking ahead, I am thrilled by the opportunities we have to reduce inefficiencies in the U.S. healthcare system in a way that empowers everyone to focus on the health of people. We are poised to expand our portfolio of solutions in ways that will provide stakeholder groups with end-to-end control and visibility of their Drug Discount Management workflow.

In this report we will lay out an aspirational—but attainable—future where necessary data is made ubiquitous for all stakeholders and the unknowns are diminished and less destructive. We envision a future where drug discount programs operate as seamlessly as intended, leaving today's costly and inefficient "retroactive fixes" firmly in the rearview mirror.

From its inception, Kalderos has been devoted to eliminating waste and enhancing efficiency for all prescription drug stakeholders so they can spend more time improving patients' lives. By shining a spotlight on the hazy knowledge gaps of our industry, we can make data more accessible, ultimately benefiting patients everywhere.

Brent Dover
Chief Executive Officer

Part 1:

Unknown

Ohio, 2018

The state senator from Akron had heard enough.

"We're talking about hundreds of millions of dollars, and I sit here as a senator that represents a lot of poor people and taxpayers... They just can't even imagine how much money this is."

Ohio State Senator Vernon Sykes expressed his indignation[1] as he questioned the state's Medicaid officials at the Ohio State House in the wake of the revelation that the Ohio Department of Medicaid had seemingly overpaid for prescription drugs by some $223.7 million. Prescription drug spending in the Ohio Medicaid managed care program increased 20% over two years[2], even as the prices of generic drugs were undergoing a steady decline[3].

This contentious discovery wasn't an easy one to make. It required considerable digging through mountains of data from *Columbus Dispatch*[4] journalists and drug pricing non-profit 46brooklyn[5]. Without their many hours of focused effort to reveal the true signals in the noise, this hearing might not have happened at all.

At the hearing, Ohio Medicaid Director Barbara Sears reaffirmed her commitment to the state's 3 million Medicaid beneficiaries and insisted that one of their greatest challenges to fixing the broken system was a lack of information. "We don't know if we've got enough answers to the questions that we are asking... to change the program for the very folks that we are trying to serve," Spears explained.[6]

"The answer that we are going to ultimately find is not there yet."

The stubborn challenge of high US drug prices

Across the system, there is a data crisis in the world of prescription drugs. And the timing couldn't be worse.

The U.S. healthcare system is in the midst of a stress test unlike anything seen in its history.[7] Burnout among healthcare workers has increased between 10%-20% since before the pandemic.[8] Professionals from physicians[9] to the president of the AMA[10] have raised concerns about overworked providers, systemic inequities, data silos and exorbitant costs for essential care. Plus, prescription drug prices are still 2.5 times higher in the U.S. than in comparable countries.[11]

The American population is in broad, bipartisan agreement that "the cost of prescription drugs is unreasonable."[12] Policymakers from both sides of the aisle have offered varying solutions, but have been unable to come to agreement on the best path forward. The longer it takes to reach a bipartisan solution, the more doubt increases across the healthcare continuum that these efforts will truly make drugs accessible to the 1 in 4 Americans who say they can't afford their medicine.[13]

Why have so many efforts to lower drug costs fallen short of success? Or—to put it bluntly—why do we continue to fail as a nation to make prescription drugs affordable?

One reason: the Grand Canyon-sized data gaps that make the truth around drug prices so hard to pin down. Every stakeholder in the system is drowning in data while desperately searching for signals in the noise. Some information is purposefully obscured, even illegal to disclose; other key data is hiding in plain sight, inaccessible in its volume.

This drought of actionable data is pervasive enough that in order to better identify it, explore it and ultimately conquer it we have given it a name. We call it the Great Unknown.

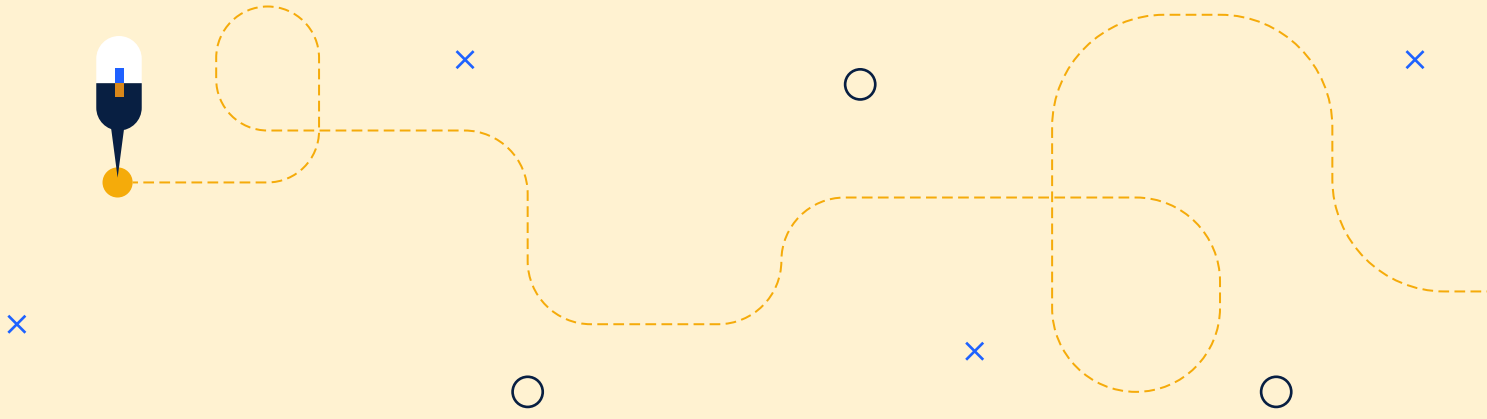
What is the Great Unknown?

The Great Unknown is an umbrella term for the data gaps surrounding prescription drug pricing.

While a broad term for such a complex issue may risk oversimplification, when used with intention it allows us to discern an overall pattern—and consider big solutions—from a mass of detail.

The industry's data gaps have been in Kalderos' sights from our earliest days. Since our founding, we have seen how unavailable data challenges stakeholders and creates pain points for all. We've watched as yawning chasms of data have grown, making it difficult for those both inside and outside the system to improve operational efficiencies.

This report seeks to summarize these data gaps, reveal and quantify their impact, and explore solutions that enable more ubiquitous data sharing and bring the root causes of drug unaffordability into the light.



Into the data gaps

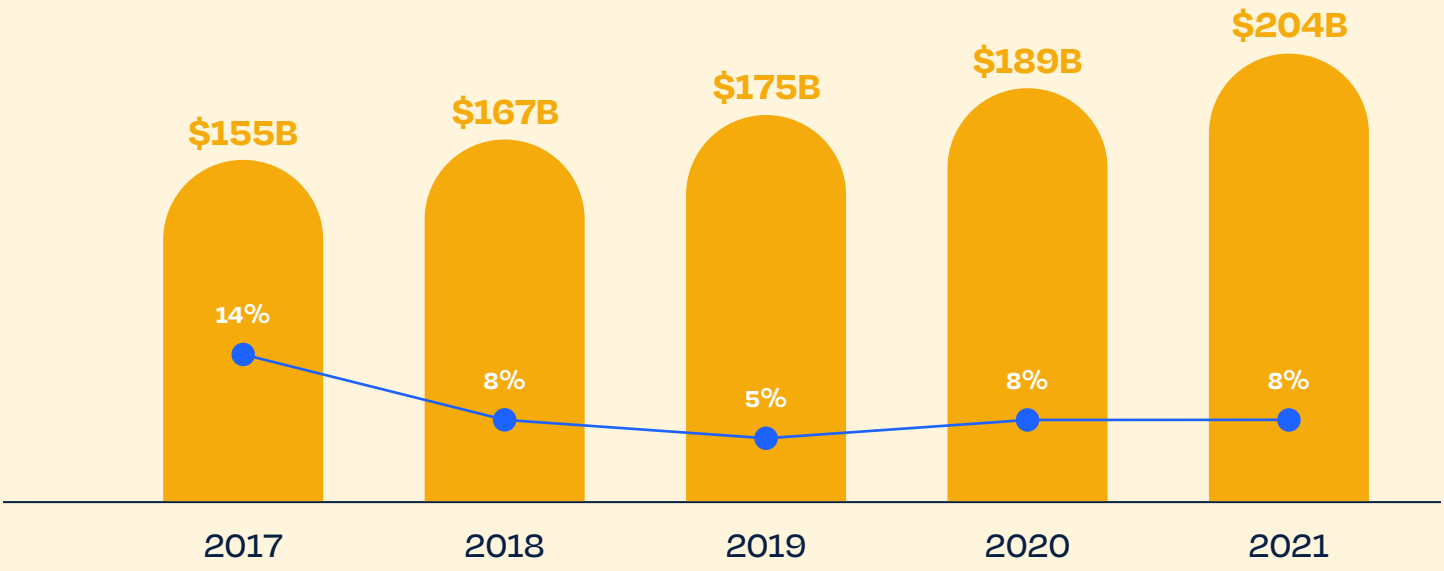
The Great Unknown is wide-ranging, but there are a few major data gaps that impact every drug pricing discussion. These "known unknowns" decrease our collective ability to understand the drug distribution system and to make improvements that ease administrative burdens and open the door to more affordable drugs.

The uncharted gap between list prices and net prices

There may be no better example of the perplexing nature of finding the "true" prices of drugs than the enigmatic gap between list prices and net prices.

The list price is the price that a manufacturer sets for a drug, but is not a reflection of the price that a patient will actually pay for a drug, nor is it the amount of money a manufacturer actually receives for a drug. What a manufacturer actually takes home on any given drug is called the net price.Here the plot thickens: net prices for brand name drugs have actually gone down in recent years, while list prices grew just less than the rate of inflation.[14] There is a growing gap between the gross revenue of manufacturers from list prices and their net prices; in 2021 this gap reached a record $204 billion, an 8% change from the previous year.

Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Patent-Protected, Brand-Name Drugs, 2017 to 2021



Total value of gross-to-net reductions for patent-protected brand-name drugs ($ billions)

Percentage change from previous year

Source: Drug Channels' *2022 Economic Report on U.S Pharmacies and Pharmacy Benefit Managers;* also published on Drug Channels on March 22, 2022.; https://www.drugchannels.net/2022/03/warped-incentives-update-gross-to-net.html

Exactly where is that $204 billion going? That's part of the Great Unknown.

A major share of the $204 billion goes toward drug manufacturers' obligations to government-established drug discount programs, such as the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. These programs are essential in helping vulnerable communities access the care they need. But they also create opportunities for costly errors that drive up costs for everybody.

Another big piece of the $204 billion goes to pharmacy benefits managers (PBMs), who hold considerable power in the drug channel due to their ability to decide which drugs are covered by major health insurers. As part of this process, PBMs negotiate rebates to be paid by drug manufacturers back to the plan.

Further impacting the price of any given drug is the often hard-to-pin-down cost of research and development that it takes to bring a drug to market. Estimates have put the median cost of developing a new drug at $985 million.[15]

Bottom line, there's a big difference between the "list price" of a drug and what a drug will actually cost the patient and the payer.

What does any drug really "cost"? That's part of the Great Unknown too.

Data gap 2:

The unknown cost of noncompliant drug discounts

Everyone wants to ensure that patients can access the medicines they need at a price they can afford and for vulnerable communities to have access to essential health services. To support these goals, policymakers have enacted legislation creating a number of government pricing programs. The largest of these programs are the Medicaid Drug Rebate Program and the 340B Drug Pricing Program.

MDRP entitles Medicaid to the lowest available prices on most drugs[16]; when Medicaid covers a prescription for an enrollee, the state Medicaid office then invoices the drug manufacturer to cover the difference between the upfront cost and the lower price.

In 2019, Medicaid spent about $67 billion on outpatient drugs and was reimbursed about $37 billion in manufacturer-paid rebates.[17]

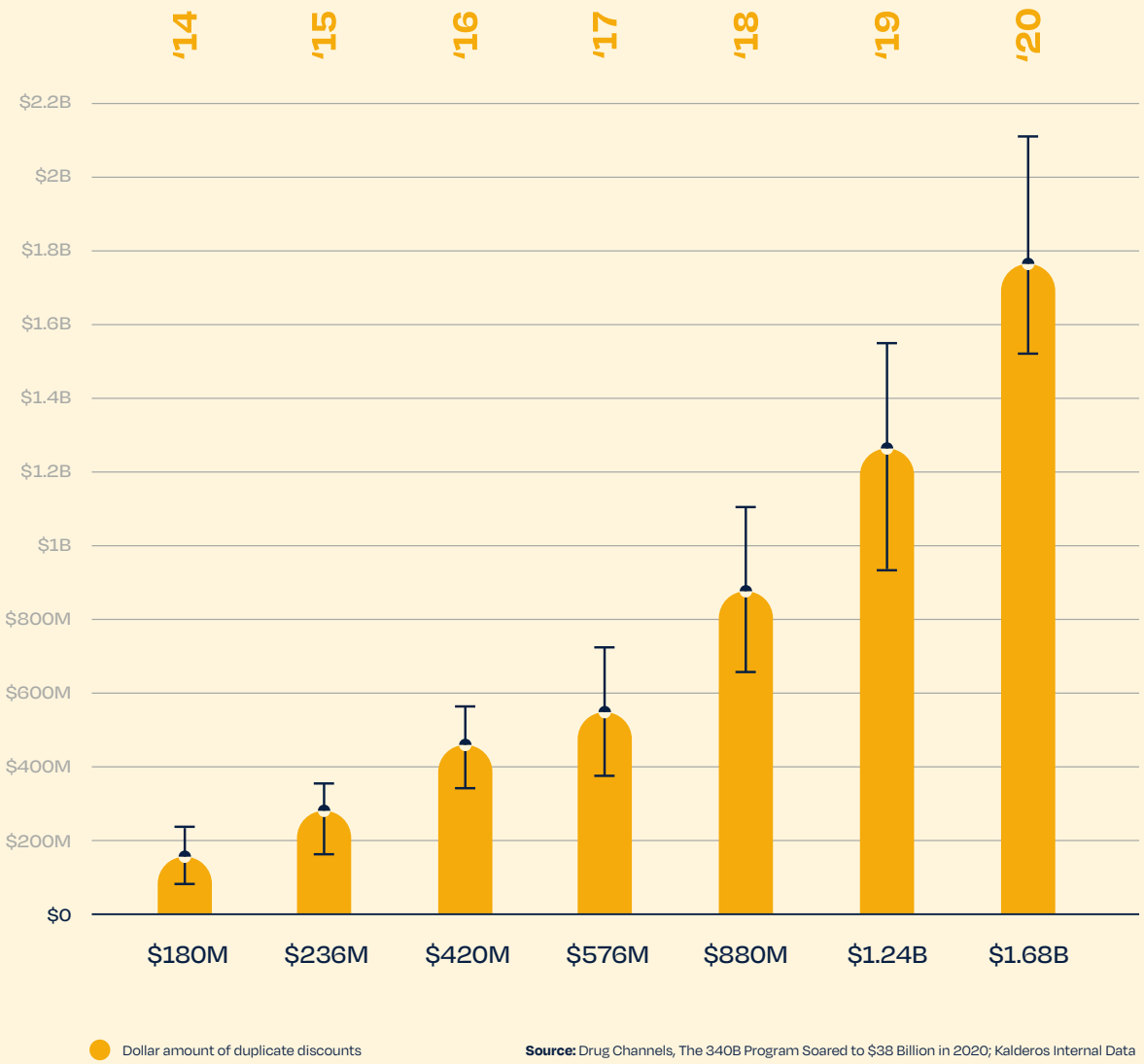
Meanwhile, 340B enables healthcare providers who serve especially vulnerable communities to purchase deeply discounted drugs for outpatient dispense. The savings allow these healthcare providers, called "covered entities," to deliver vital services. This program has grown immensely over the past few years. In 2020, discounted purchases made under the program totalled around $38 billion.[18] The list price value of these 340B drugs was around $80 billion.[19]

Because these programs are established by the government, there are laws that govern how they operate. Discounts that fall outside the law are called "noncompliant."

One example of a noncompliant discount is a duplicate discount paid to both Medicaid and 340B. The law says that only one program should receive the discount. But this can be surprisingly challenging to coordinate.

Kalderos' analysis suggests that at least 3-5% of 340B discounts and Medicaid rebates are duplicates. As the 340B program has grown, the financial impact of duplicate discounts has grown, too. As of 2020, that 3-5% adds up to at least $1.3 billion in duplicate discounts, potentially as high as $2.1 billion.

Estimated duplicate discounts between 340B and Medicaid



Source: Drug Channels, The 340B Program Soared to $38 Billion in 2020; Kalderos Internal Data

The PBM money gap

Today an estimated 77% of the marketplace (covering 270 million patients) is controlled by the three largest pharmacy benefit managers,[20] giving them significant power in the drug channel. Much of the money at stake in the drug channel flows through PBMs, but their finances are so opaque to outsiders that Axios characterized it as a black box: "'You, as a customer, will never understand what's in there,' one person familiar with the pharmacy benefits industry said about the algorithm."[21]

These commercial rebates make up the biggest portion of the $204 billion gap between list and net drug prices. The exact dollar amount of the rebates collected by PBMs is unknown. It's also not clear exactly how much goes toward keeping premiums lower, and how much goes toward PBM profits (or occasionally, plan sponsors such as employers).

Medicare Part D, which is drug coverage available to seniors and accounts for around 1/3 of U.S. prescription drug spending, is affected as well. A recent JAMA article explains the impact: "Researchers have examined a variety of strategies to limit [Medicare Part D] spending... Studies modeling the effects of such policy changes on Medicare Part D spending have a common limitation: none can fully account for confidential rebates or other discounts that drug manufacturers and pharmacies provide to Medicare Part D plans."[22]

In an article titled "Shrouded in secrecy, pharmacy benefit managers' practices come under scrutiny," the *Times-Tribune* pointed to some of the criticisms of this secretive industry.[23] "Their actual value is hard to independently confirm, though, because they operate in secrecy, said Erin Taylor, a health policy researcher with the Rand Corp., a nonprofit public research group based in California." Taylor adds, "There are estimates of how much PBMs receive back in rebates, but because there is no requirement for disclosure of that information, at least to researchers, ... it's hard to say."

77%

of the marketplace is controlled by the three largest pharmacy benefit managers

$204B

gap between list and net drug prices

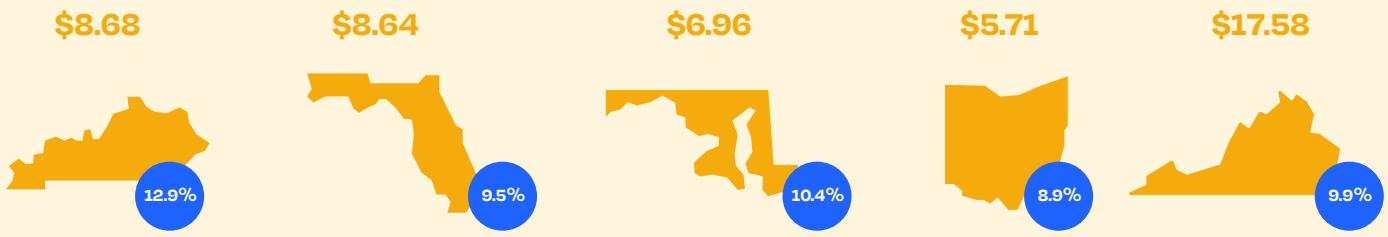
The managed care spread pricing gap

PBMs also play a role in Medicaid, a joint state and federal program that makes free or low-cost health coverage available to people with low income. Many states now choose to partner with outside vendors to provide Medicaid services. These Managed Medicaid programs now make up the majority of Medicaid spending, and rely on PBMs to manage prescription drug coverage.

This dynamic has led to the prevalence of "spread pricing," and resulting controversy such as the one in Ohio. The "spread" is the difference between what the PBM charges the state and what it compensates the pharmacy.

The dramatic scene that played out in Ohio in 2018 over the spread pricing audit was the result of hidden data coming to light. When constituents learned the extent of the spread pricing at play in Ohio's Medicaid program—in other words, the extra amount that states and by extension taxpayers were being charged for prescriptions—no one was happy. They'd conquered a piece of the Great Unknown, and they didn't like what they found.

Average PBM Spread in Medicaid Managed Care, by State, 2018-2019



Average PBM network spread in Medicaid managed care

PBM spread as a % of prescription cost to state Medicaid program

Source: Drug Channels' *2021 Economic Report on U.S Pharmacies and Pharmacy Benefit Managers.*

A federal proposal to eliminate PBM spread pricing in Medicaid:

"... would lead to approximately $900 million in federal savings over 10 years, while some state analyses indicate higher degrees of spread pricing."

Ohio isn't alone. A 46brooklyn heatmap shows that plenty of state Medicaid agencies are contending with spread pricing.[24] A study in Florida put the state's cost of PBM spread pricing at $113 million[25], while another report in Kentucky found their state paid $123 million in PBM spread pricing in 2018[26].

According to KFF, estimates of a federal proposal to eliminate PBM spread pricing in Medicaid "would lead to approximately $900 million in federal savings over 10 years, while some state analyses indicate higher degrees of spread pricing."[27] The report goes on to say "it is unclear what analysis or assumptions went into these estimates, but they are highly dependent on assumptions or understanding of the extent to which spread pricing currently exists in Medicaid." Some states (such as Ohio) have seen much higher Medicaid costs due to spread pricing, leading their savings estimates to vary widely from the federal CBO estimates. Without the comprehensive data to know which assumptions are correct, it's hard to truly predict the outcome of specific policy actions. More of the Great Unknown in action.

Some level of spread pricing is reasonable. PBMs need to be able to cover their costs in implementing the program. But when the full extent of the spread pricing is hidden from the public and even state administrators (as it was in Ohio), decisionmakers won't have the data they need to keep drug costs low.

The public information gap: "shooting in the dark"

There is widespread agreement in the U.S. that action should be taken to lower the prices of prescription drugs.[28] Where there is little accord, however, is what specific laws or regulations could be enacted to bring down drug prices without causing disruption to those who depend on the system.

However, a growing chorus of experts are making the case that efforts to lower drug prices are an uphill battle as long as the Great Unknown impedes our ability to understand drug prices as they are today.

One example is a drug pricing controversy from 2019. A study published in *Health Affairs* sought to determine the cause of increases in drug prices, and whether they stemmed from new or existing drugs.[29] The authors examined drug pricing data from 2005-2016. The paper's conclusion that rising costs of brand-name drugs were driven by existing drugs was widely reported by many media outlets.

However, the paper itself noted a few significant limitations with the study. First and foremost:

> "[B]ecause the US health care system is market based, data on actual transaction prices or on proprietary rebates are not accessible. As a result, we used wholesale acquisition costs as cost estimates; they represent manufacturers' list prices for a drug to wholesalers but do not capture rebates or other types of discounts. Because rebates are often greater once several exchangeable products within the same therapeutic class have reached the market, our estimates for the relative contribution of existing drugs to the rising costs of brand-name drugs may be upward biased."

In other words, the widely-reported conclusion of the study may have been inaccurate due to the limitations of the data available.

These concerns were unpacked in much greater detail by Robert Dubois, also in *Health Affairs*.[30] In an extensive critique of the study, Dubois stated, "given the well-known and well-documented flaws inherent in list prices, analyses based upon this category of information should not be conducted or at most should be done only for internal exploration."

The problem is obvious—if even specialized scholars and top industry experts don't have the full data to accurately analyze the true drivers of rising drug costs, or to agree on what they find—then how can policymakers begin to address the issue?

Drug Pricing Laws

166

Laws passed between 2018-2019

35

included a directive for transparency

Writing for *The Hill* in 2019, Neeraj Sood—vice dean of research at the USC Price School of Public Policy—phrased it perfectly with a piece titled "It's hard to lower drug prices, if you don't know what they are."[31]

> "The net prices manufacturers receive after all discounts and rebates are more useful, but the difference between what manufacturers receive and what consumers and insurers pay is still shrouded in mystery," wrote Sood.
>
> "Until regulators and legislators understand where the profits are flowing in the drug business, writing bills to control prices risks serious misfires that could target the wrong participants in the distribution chain."

Sood pointed out from his own study published in JAMA that some 166 drug pricing laws were passed from 2018 to 2019, but only 35 of those included a directive for transparency, and of those only 7 laws in total were deemed potent in actually creating transparency.[32]

All the laws passed to reduce drug prices, Sood proclaimed, were "shooting in the dark."

Part 2:

Discovery

“I would think this is a scam”

The trouble with so much unknown is that it leads to a waste of time and resources—which has its own price tag. Unnecessary expenses cascade like an avalanche across the system, burying all stakeholders under the weight of extra work, higher costs and undue systemic burdens... with the greatest hardship landing on patients.

Take this story from AARP of retired Delaware City EMT Mike McMichael who was prescribed Eliquis for a heart condition.[33] When originally prescribed to McMichael, it was $380 for a 30-day supply. Balking at the sticker shock, McMichael decided to try to find Eliquis at a lower price. He found a three-month supply for $125, but upon re-ordering it became $261 for a three-month supply, though that price dropped to $45 for one month after he complained. The next month that same supply cost $75.

The Social Security recipient could not believe, and could not afford, the roller coaster of prices. McMichael came to his own conclusion after dealing with the frustrating price jumps for a necessary blood thinner—"If I didn't know better, I would think this is a scam."

Mapping the great unknown

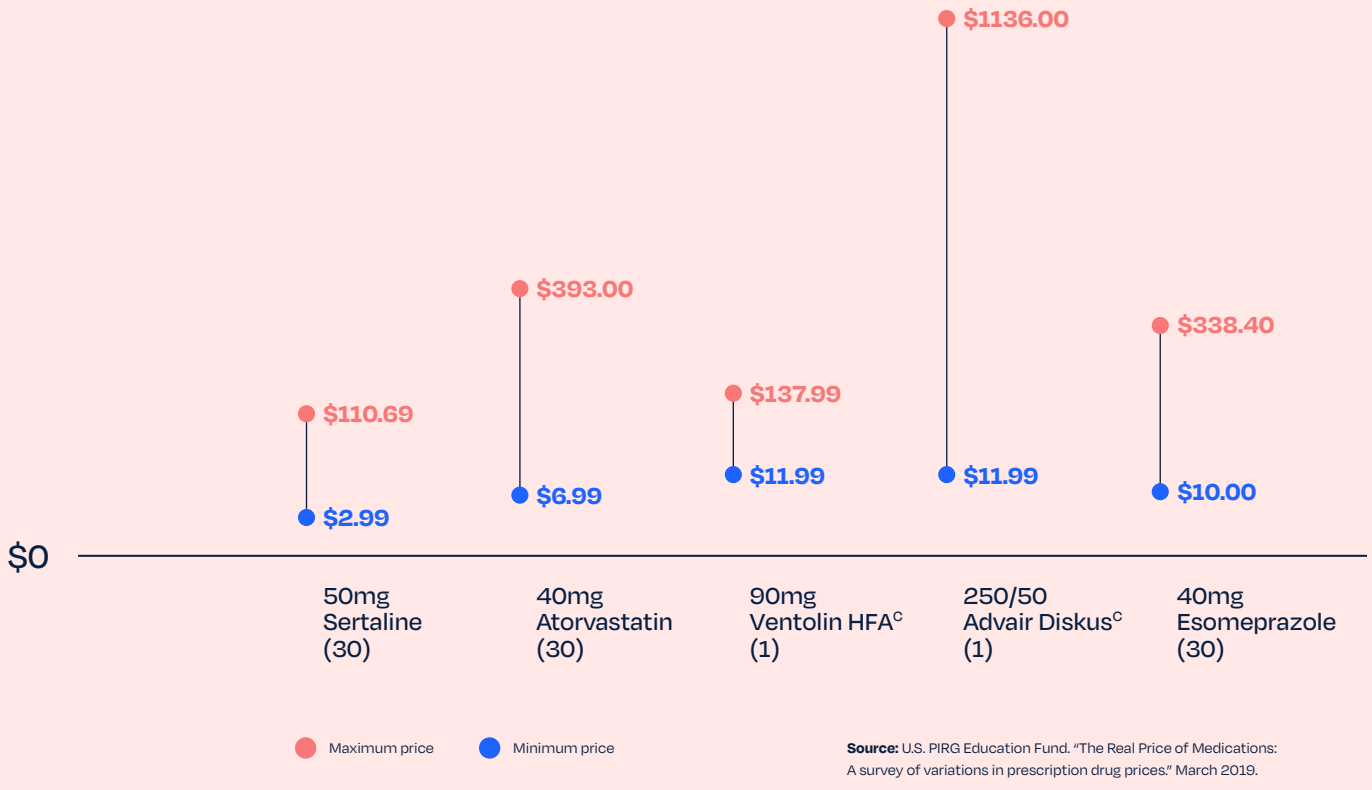
For patients, drug pricing remains a confusing house of mirrors

Unaffordable and inconsistent drug prices are a visceral repercussion of the Great Unknown for patients. Patients aren't sure how much their prescription drugs should cost, where they should go to get the best price, or if they will be able to afford them at all.

A 2019 study investigated prescription drug pricing variances and found that consumers of prescription drugs could "save hundreds or even thousands of dollars every year by shopping around."[34] A look at 12 commonly prescribed medications from 250 pharmacies across 11 states revealed that the minimum price and median price differed by an average of 892%.

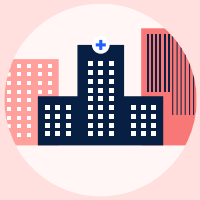
Patients, the report found, could save $102 - $5,400 a year depending on where they purchase their drugs.[35]

Variations in prescription drug prices



Source: U.S. PIRG Education Fund. "The Real Price of Medications: A survey of variations in prescription drug prices." March 2019.

Providers must traverse a rocky path of uncertain prices



Patients aren't the only ones to be taken by surprise by rising drug costs. Unpredictable drug pricing impacts healthcare providers too.

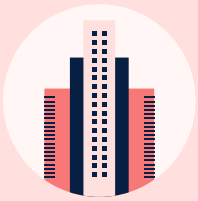
Patients aren't the only ones to be taken by surprise by rising drug costs. Unpredictable drug pricing impacts healthcare providers too.

An AHA study tracked the effect of rising drug costs on hospitals from 2015 to 2017.[36] The study found that "hospital budget pressures resulting from the continued dramatic increases in drug prices have negative impacts on patient care, with hospitals being forced to delay infrastructure investments, reduce staffing, and identify alternative therapies." According to the report, "[o]ne in four hospitals had to cut staff to mitigate budget pressures."

The AHA study also noted that interviewees, many of whom had roles in oversight of pharmaceutical procurement and management at community hospitals, raised "substantial concerns about the lack of transparency in pharmaceutical pricing."

Unexpected or unexplained price jumps add extra challenges to officials at covered entity healthcare providers, who already walk a precarious tightrope of managing vital care and operational finances.

Without greater clarity into the cost of prescription drugs, providers will continue to feel the pressure of the Great Unknown.



Drug discount stakeholders are navigating their own data gaps—with a lack of guidance

To ensure compliance with the laws around drug discount programs like 340B and Medicaid, 340B covered entities and state Medicaid agencies have to work together. But often, despite the best efforts of both parties, data gaps stand between them.

One example: covered entities don't always know which patients are Medicaid patients, because there are no federal requirements for states to use unique plan identifiers for these patients. This key piece of data could help prevent duplicate discounts, but there's no infrastructure to enable it.

Rules and recommended practices also vary from state to state, creating even more challenges for covered entities and state Medicaid agencies when patients cross state lines for care.

Inadequate infrastructure and incompatible systems are the source of many data gaps. Both covered entities and state Medicaid agencies often work with third-party vendors, all of whom have their own tech systems, file formats and ways of communicating data. As the data traverses these not-quite-compatible systems, it's easy for key pieces of information to slip between the cracks.

Maury Anderson, former pharmacy organization director of rebate operations and now senior director of product strategy at Kalderos, saw this firsthand in her nearly 15 years supporting state Medicaid programs. In her experience, "Nobody's systems easily talk to each other." Anderson notes how simple issues can become expensive problems. "Failing to input a single modifier on a form," Anderson explains, "can lead to plenty of frustration and extra costs."

Both covered entities and state Medicaid agencies often feel they're operating without clear guidance on how exactly to proceed. Because the 340B program is administered by the Health Resources and Services Administration (HRSA) and Medicaid is administered by the Centers for Medicare and Medicaid Services (CMS), there's not always perfect clarity about how each federal agency intends the programs to work together, or who ultimately has purview over the issue of duplicate discounts. As a result, stakeholders can feel they are operating in the dark.

As attorney Nicholas Fisher states in an article in the *Journal of Health Care Law and Policy,* "Issues with the 340B Program stem from the lack of guidance. The law is inundated with vagueness and ambiguities."[37]

According to a 2020 report from the Government Office of Accountability, even HRSA and CMS feel they're operating without the data they need to run these drug discount programs effectively.[38] Some highlights from the report:

> "HHS's Centers for Medicare & Medicaid Services (CMS) conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts. CMS does not track or review states' policies or procedures for preventing duplicate discounts, and GAO found that the procedures states used to exclude 340B drugs are not always documented or effective at identifying these drugs. As a result, CMS does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests. CMS also does not have a reasonable assurance that states are seeking rebates for all eligible drugs, potentially increasing costs to state and federal governments due to forgone rebates.

> "HHS's Health Resources and Services Administration's (HRSA) audits of covered entities do not include reviews of states' policies and procedures forthe use and identification of 340B drugs. As a result, the audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply with the prohibition on subjecting manufacturers to duplicate discounts."

Manufacturers face a compliance abyss in drug discount programs

The data gaps around drug discount programs impact all stakeholders, creating an administrative burden that takes a toll on teams. But the financial impact falls primarily on manufacturers, who face revenue losses due to noncompliant discounts.

According to global professional services firm ZS, pharmaceutical companies "collectively lose more than $15 billion in bottom-line revenue" due to a variety of factors, including noncompliant discounts.[39] This revenue leakage can impact operations, reduce the R&D budgets that allow innovation on life-saving new therapies, and, for emerging and growth-stage companies, pose a serious threat to the survival of the organization.

Even for large and well-established drug companies, data gaps around drug discount noncompliance can have a damaging effect on the organization's financial reporting and performance.

Duplicate discounts between 340B and Medicaid are prohibited by law, but noncompliant commercial discounts, defined by private contracts, pose a serious financial risk to drug manufacturers, too.

The impact of duplicate discounts isn't just felt by manufacturers: unknown levels of noncompliance harm the integrity of these vital drug discount programs. Making it easier to identify duplicate discounts helps ensure these programs run more smoothly and sustainably so they can continue to aid vulnerable patients and the safety net healthcare providers that serve them.

Kalderos' tech-enabled platform vs. conventional methods

↑ **450%** more value in noncompliant Medicaid claims uniquely flagged by Kalderos (beyond what was initially flagged by prospects using their existing methods)

↑ **972%** more value in all payer-based rebate claims uniquely flagged by Kalderos (beyond what was initially flagged by prospects using their existing methods)

Source: Kalderos Internal Data

Through Kalderos' rapid growth in 2021, we greatly expanded our work with drug discount stakeholders, enabling us to gain more insights into the extent of noncompliant discounts. The data platform is growing more robust than ever.

As we've worked with manufacturers to assess their drug discount data, we've made some startling discoveries. When we load a potential client's drug discount transaction data into our first of its kind, A.I.-powered compliance engine, the platform's smart algorithms often flag exponentially more noncompliance than the conventional methods used by the manufacturers themselves.

On average, these advanced assessments have identified 972% more noncompliance than the manufacturer's existing methods. For Medicaid, Kalderos identified an average of 450% more noncompliance.

In one case, Kalderos identified nearly 187 high-risk claims for each 1 identified by the manufacturer.

What drives this immense difference? Simply put, it's the difference between a human-analyst driven approach and a machine-learning, tech-enabled one. No matter how great the human team, they simply can't rival an A.I. platform when it comes to detecting patterns in the data.

The contrast in results is also due to Kalderos taking an industry-level systemic approach. Existing legacy technology, even when quite advanced, remains narrow in focus—simply scanning invoices or relying too heavily on consultants. Custom software builds can also quickly lose relevance when the scope of the problem shifts.

Despite their years of work with skilled in-house teams, experienced service providers and legacy technology solutions, manufacturers have only been able to illuminate the very outer edges of the Great Unknown when it comes to noncompliance in drug discount programs.

Policy impacts: the weight of not knowing

Each stakeholder is grappling with a challenge tied to one or more data gaps that hinder their operational efficiency. Collectively, these data gaps impact the price of prescription drugs and the level of care available throughout the system.

Complicating the search for systemic solutions are broad public perceptions of what might actually be the root cause of high costs for prescription drugs. Media outlets are often eager to focus on list or wholesale prices, which are well-documented as a shaky-at-best insight into the true cost of prescription drugs.

Assertions that high prices are solely caused by manufacturer price hikes[40] or market forces[41] give the public and policymakers an inaccurate view of the deeper problems that must be addressed. They also can lead to legislative proposals that care provider groups say are "leaving patients behind."[42]

There are consequences of prescribing blunt solutions to problems that have yet to be fully studied or understood. Analysts have shared[42] that policy changes to generate federal or state savings could trigger a butterfly effect of repercussions, from how PBMs and managed care organizations negotiate, to how pharmacies operate, to the balance sheets of 340B covered entities.[43]

Policy goals to reduce the price of prescription drugs will always come with a caveat of uncertainty as long as the system is rife with the data gaps of the Great Unknown. How can drug discount programs become more efficient if we don't know how they are currently working? How can states better serve their patients if they aren't able to unify data records? How can we lower drug prices if we don't know what they really are — or where the money is going?

With each stakeholder doing their best to solve a problem of which they may only have a one-dimensional view, any effort to make holistic changes will be weighed down by doubt and uncertainty. This is the fundamental challenge of the Great Unknown—and it is a challenge that we believe can be solved with ubiquitous data and transparency.

Part 3:

New Frontier

Arriving at true north

When it comes to healthcare, the focal point for all parties should be patients. Pharmaceutical manufacturers, providers, contract pharmacies, states, policymakers, PBMs and more are all supposed to operate with the patient at the center of every decision.

Unfortunately, the current system does not always function that way. The data gaps of the Great Unknown drive all stakeholders into defensive positions—forcing plenty of stakeholders who might otherwise communicate into bunkers of silence.

If the data gaps continue to widen, they will also create an alarming gulf between patients and system stakeholders. With so much left unknown, it will be harder to track how stakeholder actions end up directly impacting the populations they serve.

Prescription drug stakeholders need to locate their own North Star in order to find their way out of the unknown. Without some focal point of agreement, data gaps will grow larger and the goal of widespread treatment access and affordability will become even more elusive.

Finding a North Star in the Great Unknown will require a buy-in from all stakeholders and a level of consensus across a diverse range of individuals, from CEOs to senators to hospital associations and corner drug store pharmacists.

Such widespread accord is a challenge of both technology and willpower. But it will be necessary to bring about meaningful and positive change for patients and the system as a whole.

Scaling systemic obstacles

The first step in eliminating the data gaps that create waste and dysfunction within the system begins with an understanding of how it got to this point. There is not a single stakeholder, or action, that allowed the data gaps of the Great Unknown to emerge and widen. Instead, it is the result of a mix of systemic motivations, political decisions and operational impediments.

In the drug distribution system there is an understandable desire to balance transparency with proprietary information. But the result is an industry suffocating under the weight of its own compulsion for secrecy.

In many cases, the law itself is what has created this system—the way manufacturers establish drug prices is protected by federal antitrust laws[44], but that secrecy extends to the contractual terms between manufacturers, payers, PBMs and more. Some insiders claim these laws are necessary for competition in the marketplace.[45] But the reality has yet to produce benefits for patients.

When legislative solutions for transparency have been enacted, they overwhelmingly fall short of the broader goal of industry-wide clarity, as a USC study[45] concluded after reviewing 166 prescription drug pricing laws[46]:

"We find that most bills in the recent flurry of state price transparency activity are of limited impact and none provide complete transparency throughout the distribution system, despite the enormous legislative resources spent to enact them."

The shortcomings of these legislative solutions typify the struggle to cultivate more systemic transparency. For example, when the Affordable Care Act was passed, the law did much to require price disclosures for insurers while not imposing the same requirements on other stakeholders.[47] Professional lobbying from stakeholders skeptical of more information sharing has also proven effective over the years.[48]

Another key obstacle to data sharing: outmoded technology. This is a major challenge in drug discount programs. Even when stakeholders want to work together—or are legally compelled to do so—transferring relevant data between parties can be a hassle or even impossible.

In fact, the difficulty of sharing data appears to be one of the major drivers of misapplied discounts. Calculating discounts accurately requires complex coordination between healthcare providers, pharmacies and state Medicaid agencies. But with each organization relying on stand-alone tech systems that weren't built to communicate with each other, wires get crossed. Key data is lost in translation. The impact is billions of dollars in waste in the system and thousands of human hours spent trying to track it down.

Drug discount and pricing data is incredibly complex. Many stakeholders attempt to manage this massive volume of data using spreadsheets. Others understand the value of a tech-enabled approach, but rely on legacy solutions that are actually a patchwork of third-party applications originally created for other purposes and stitched together by the labor of human teams.

There are plenty of challenges when it comes to conquering the Great Unknown. Perspectives will need to change; stakeholders will need to embrace the value of transparency. Policies may need to change. But first and foremost, the system is badly in need of a technical upgrade.

The good news is the technological solutions we need to embrace ubiquitous data and conquer the Great Unknown are imminently attainable. Kalderos is building them today.

Technology unleashed

To help conquer the Great Unknown, Kalderos built the world's first platform for Drug Discount Management, powered by a modern data warehouse that can process more than 100 million drug discount claims per hour. This is also the world's highest-throughput pipeline for pharmaceutical claims; a powerful data engine that brings together data collection, data ingestion and data consumption.

What's the source of the data on Kalderos' platform for Drug Discount Management? The data comes from stakeholders, and is validated by multiple parties to ensure a "gold standard" of accuracy. Sticking to firm guidelines of independent verification creates a cleaner, more precise data set than is available anywhere else in Drug Discount Management.

By bringing stakeholders together, and building tools that add value to multiple parties' workflows, Kalderos isn't just supporting the successful collaboration that ultimately benefits patients—we're also ensuring data accuracy by making drug transaction data open and transparent to the stakeholders who need it.

Using this gold standard data set, the Kalderos platform uses advanced technologies in artificial intelligence and machine learning to further analyze and apply the data, driving actionable insights for all stakeholders. Through machine learning, the platform continues to refine its checks and validations, identifying ever more useful and accurate patterns in the data.

The result is a powerful data ledger that can follow a single transaction through its entire lifecycle, giving every party involved in the drug discount ecosystem—the provider, the pharmacy, the payer and the manufacturer—a complete picture to file the discount accurately, pay correctly and resolve disputes promptly.

This technology offers an unparalleled view into the system. Suddenly communication breakdowns and infrastructure pain points become much easier to identify and solve in a way that benefits everyone.

Resolving the data gaps

Today, Kalderos' most widely adopted product is Discount Monitoring, the only modern, cloud-based solution that applies intelligent algorithms to claims level data, identifying noncompliant discounts that other approaches miss.

Since its launch in 2016, Kalderos Discount Monitoring has achieved:

3,500
- covered entities on the Kalderos platform

50
- U.S. states in which covered entities have responded to inquiries

$85m
- in 340B/MDRP duplicate discounts verified by covered entities

850k+
- claims reviewed across Medicaid

$640m
- in overall noncompliance identified

How does Kalderos Discount Monitoring work?

1 Data ingestion
The Kalderos platform ingests a steady flow of data from public, subscription and proprietary sources.

2 Pattern recognition
AI uses pattern recognition to identify anomalies within the data that indicate a high risk of noncompliance.

3 Covered entity verification
The platform surfaces specific claims directly to the covered entity for verification through a specialized provider dashboard. This helps covered entities gain actionable data on how their compliance program is working, too.

4 Dispute report creation
The platform then routes verified noncompliant claims to the manufacturer, which can build a dispute report. Manufacturers have clear data on incorrect claims to dispute with the state.

5 Dispute report submission
Using the platform, the manufacturer submits the dispute report directly to the state with high confidence. The state has clear visibility into the history of verified noncompliant claims, easing the dispute resolution process.

No more exchanging spreadsheets, tracking down noncompliant claims over phone and email, or putting armies of human staff to work on searching for anomalies in the data.

No more Great Unknown keeping covered entities, state Medicaid agencies and drug manufacturers at odds as they work to keep drug discount programs operating compliantly and successfully.

The Kalderos platform helps every stakeholder take a giant leap toward ubiquitous data by making data gathering, data sharing and data analysis easy.

On our product roadmap
Kalderos is scaling rapidly to expand our suite of tech-enabled solutions to end drug discount dysfunction and enable even more collaboration between stakeholders in Drug Discount Management.

Coming soon:

- Invoice management and payment management across stakeholders
- More tools for healthcare providers, state payers and commercial payers
- Enhanced capabilities for the entire Drug Discount Management workflow

Conquering the Great Unknown

Since Kalderos was founded 6 years ago, our powerful data platform has opened the door of possibilities for so much more—and offers a preview of a world where the Great Unknown is no longer a threat.

With greater insight into compliance concerns, program stakeholders can be freed from the burdens of extra work, unnecessary costs and communication breakdowns. Suddenly the data gaps are less pervasive and more manageable.

As we collectively improve the system and its operations, we strengthen our ability to take on larger problems. By offering end-to-end visibility into the process of verifying discounts and resolving disputes, we are empowering everyone to spot disruptive errors or systemic challenges. Transparent practices can multiply, as more parts of the system are able to leverage platform solutions from Kalderos to resolve more data gaps, creating more efficient operations and reducing waste.

Sight lines into how these discount programs operate will be advantageous to policymakers whose repeated efforts to adjust and improve these programs have yet to bear meaningful change. Those running discount programs will have easier access to answers they need in order to respond to tough questions.

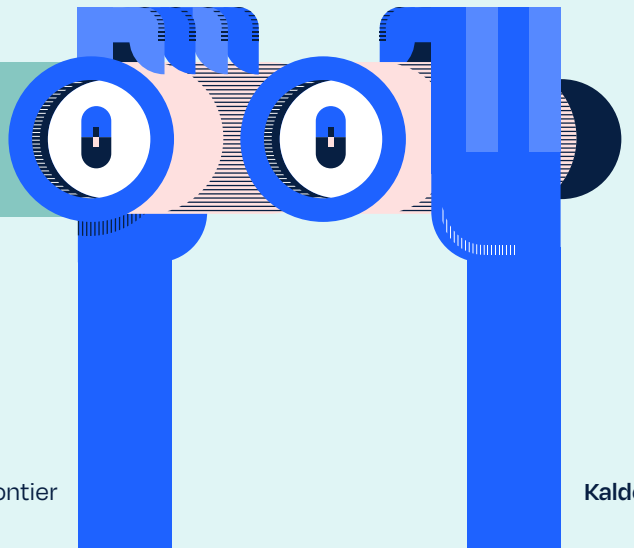
Most importantly, these benefits will reach the patient, who can finally emerge from the wilderness and become a knowledgeable participant in the system originally created to serve them.

New Frontier

Conquering the Great Unknown requires a truly collective push from all stakeholders to embrace a more transparent future.

But the effort will be worth it. Our recent reality of shared sacrifice and pandemic strife has shown both the dire consequences of a healthcare system on the brink and the incredible achievements borne out of breakthrough technology and a spirit of collaboration.

Kalderos is poised to be a connective facilitator in this world. In many ways, we already are. We are building technologies that conquer the Great Unknown, moving towards a world where the needs of patients truly come first.



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Kalderos created the world's first Drug Discount Management platform, which uses sophisticated models and machine learning to resolve noncompliance in drug discount programs. The company's solutions include Discount Monitoring, which identifies and resolves historical instances of noncompliance, and 340B Pay, which allows providers of any size to request 340B rebates and manufacturers to verify and pay them through a third party payment partner.

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