kalderos

Whitepaper

Operational complexity and evolving challenges

What drug manufacturers need to know now about drug discount programs, the Inflation Reduction Act and 340B

05 2023

Executive Summary

When the Inflation Reduction Act (IRA) was signed into law in August 2022, the U.S. government sought to reduce government spending and lower healthcare costs for millions of people. The sweeping legislation introduced multiple major pricing reforms, including three new mandated drug pricing and discount programs that will bring even more operational complexity to already-intricate drug discount programs. Previous attempts to identify and resolve discount program noncompliance have been unsuccessful, and drug manufacturers now face an even more challenging task with a new source (and greater volume) of duplicate or even triplicate discount risks.

In light of these changes, manufacturers without effective Drug Discount Management programs in place will face higher revenue leakage, increased impact on gross to net and greater uncertainty in financial forecasting.

Through our collaborative work with thousands of covered entities and many of the country's largest drug manufacturers, Kalderos has gained extensive subject matter expertise on the successful implementation of drug discount programs. Our goal is to educate stakeholders about the impact these new pricing programs could have on existing and future compliance workflows.

As the IRA's drug pricing provisions compound the as-yet unresolved problem of duplicate discounts between the Medicaid Drug Rebate Program (MDRP) and the 340B Drug Pricing Program, drug manufacturers will continue to face the challenge of identifying, disputing and resolving noncompliant discounts.

Meanwhile, covered entities, state Medicaid agencies and other stakeholders will face steadily higher administrative hurdles as they attempt to remain in compliance. With many changes already underway additional implementation of the IRA's healthcare provisions through 2031, drug manufacturers must take urgent action to understand these new government-mandated pricing concessions and ensure their Drug Discount Management programs are modernized and effective.

New government-mandated pricing concessions

The new Drug Price Negotiation Program will establish a Maximum Fair Price for certain high-cost drugs covered by Medicare

The IRA introduced a new Drug Price Negotiation Program within the Department of Health and Human Services (HHS) that allows its secretary to negotiate the prices of certain high-cost drugs covered by Medicare, establishing a Maximum Fair Price. Products subject to negotiation include certain single-source, high-cost drugs or biologics without competition from small-molecule generics or biosimilars that have been on the market for a period of time.

According to its most recent timeline projections, the Centers for Medicare & Medicaid Services (CMS) will publish a list of 10 Part D drugs to be negotiated in September 2023, with new pricing scheduled to be fully negotiated by 2024 and take effect in 2026. An additional 15 Part D drugs will be announced in 2027, followed by 15 more Part B or Part D drugs in 2028 and 20 Part B or Part D drugs in 2029 (and beyond). As each year builds upon the previous one, 100 total drugs may be impacted by 2031.

Medicare Part D restructuring includes manufacturer discounts on brand-name drugs

The IRA also restructures Medicare's Part D benefit section, requiring manufacturers to provide 10% discounts on brand-name drugs during the initial coverage period and 20% discounts after beneficiaries reach the hard cap; limiting monthly cost sharing for insulin products to a monthly $35 co-payment for people with Medicare; and expanding eligibility for low-income subsidy benefits.

Starting in 2024, out-of-pocket costs will be capped at approximately $3,250 by eliminating the 5% beneficiary coinsurance requirement above the catastrophic coverage threshold.

$3,250
Out-of-pocket costs cap in 2024

$2,000
Out-of-pocket spending cap in 2025

Instead, after the patient cap is met, manufacturers of brand-name drugs, biologics and biosimilars will be required to pay 20% of costs. The remainder will be split between the beneficiary's health plan and Medicare. Out-of-pocket spending will be capped at $2,000 in 2025, with caps in future years linked to the rate of Part D cost increases.

Manufacturers will be required to pay rebates under Part B and Part D when drug prices rise faster than inflation

The IRA penalizes manufacturers for raising prices for single-source drugs and biologics faster than the rate of inflation by requiring them to pay rebates under Part B or Part D. Part D inflation rebates began to accrue in October 2022, while accrual of Part B inflation rebates began in January 2023.

It's important to note that while accrual is already in effect, HHS has not yet begun invoicing for those rebates. (Feedback received from stakeholders during an open comment period between February and March 2023 will be factored into revised guidance expected from CMS by the end of the year.)

Operational complexity and evolving challenges

Layered over existing rules and procedures, these new government-mandated pricing concessions are sure to create more operational challenges for Drug Discount Management.

In a recent report, the HHS' Office of the Inspector General (OIG) stated:

> "Unless [CMS] takes action to remedy several administrative issues, the agency will face the following challenges in implementing...rebates; [one of which is] excluding claims from Part B rebate calculations that were already subject to rebates under the Medicaid Drug Rebate Program, and discounts under the 340B Drug Discount Program."

At the same time, new administrative challenges will make it even harder for both covered entities and state Medicaid agencies to maintain lawful and compliant programs. Both parties are required by law to prevent duplicate discounts. But in the absence of a single legal authority overseeing drug discount programs — and without clarity about who is ultimately responsible for preventing and remediating duplicate discounts — the industry's highly fragmented system of controls has been ineffective.

The operational complexities involved will likely increase the volume of duplicate discounts while creating opportunities for triplicate discounts.

Strategies and solutions

As more IRA provisions are implemented in 2023 and beyond, it is critical for drug manufacturers to educate themselves on the many risks of noncompliant discounts, including revenue leakage and increasing gross-to-net, and to act urgently to build effective Drug Discount Management programs.

In this report, we'll explore how the IRA's new drug pricing provisions impact stakeholders. We'll also investigate how these new programs interact and overlap with existing drug discount programs (like MDRP and 340B Drug Pricing Program).

Finally, we'll present the most comprehensive solutions available today and examine what drug manufacturers can expect and plan for in the future.

Unpacking the impacts of operationalizing discount programs

Operational impacts of Drug Price Negotiation

Under the new Drug Price Negotiation Program, the HHS secretary has the power to negotiate a Maximum Fair Price that manufacturers must offer to applicable Medicare beneficiaries. Once a drug is named to CMS' list of drugs to be negotiated, HHS will consider factors like research and development costs, production costs, federal financial support for drug discovery, patent information and company revenue before providing an initial offer.

Based on CMS' initial guidance applicable to Part D products for the first implementation year, drug manufacturers have 30 days from receipt of the written initial offer to either accept the proposed Maximum Fair Price or submit a counteroffer. HHS has the option to renegotiate but is under no obligation to accept the counteroffer, and the manufacturer will be required to accept a price based on the minimum discount set forth in the statute. Once a Maximum Fair Price is agreed upon between CMS and the manufacturer, it will remain in place until either the drug is no longer included in the Drug Price Negotiation Program or an indication of material changes occurs (i.e., the approval and marketing of an authorized generic).

Once negotiations are complete and new pricing is in effect, there will be consequences for noncompliance. Manufacturers that don't adhere to the established Maximum Fair Price could face civil penalties equal to 10 times the amount equal to the product of the number of units of the drug or biologic dispensed or administered during the year and the difference between the price the manufacturer offered and the price that was negotiated.

The highly specific selection criteria for inclusion in the Drug Price Negotiation Program make opting out essentially non-negotiable. Medicare and Medicaid are two of the largest purchasers of prescription drugs in the United States, and failing to participate in the negotiation process would likely make all of a manufacturer's products ineligible for Medicare or Medicaid purchase.

Operational impacts of inflation rebates

Inflation rebates also impact manufacturers at the drug pricing level by limiting their ability to raise prices beyond the annual rate of inflation without facing penalties. Rebates are calculated by multiplying the volume of sales by the difference between a drug's published price and the inflation-adjusted benchmark price.

Added complexities at the intersection of IRA and 340B

The Maximum Fair Price established under the Drug Price Negotiation Program will also set the best price available under Medicaid, which in turn impacts Medicaid rebates and the 340B ceiling pricing. Manufacturers must offer covered entities the ability to purchase whichever is lower: the 340B ceiling price or the Medicare-negotiated Maximum Fair Price.

One concern being flagged by industry experts is the potential for duplicate discounts — when a covered entity or contract pharmacy receives both a Maximum Fair Price rebate and a 340B chargeback on the same dispense. While the statute is clear that this is not how the system should work, it is currently less clear on who will be responsible for preventing this outcome, and how.

Current inventory management systems and accumulator software used by covered entities are designed to tally the number of drugs dispensed to 340B-eligible patients. The process will need to be modified to account for situations in which a 340B-eligible patient was dispensed a Maximum Fair Price drug, which would not be eligible to accumulate toward 340B replenishment.

Thousands of covered entities using hundreds of vendors to support their 340B programs must consider how to implement Maximum Fair Prices and 340B programs in a manner that complies with government rules (which are still being developed).

Without clear and accurate processes for adjusting how these inventory management systems are used, the risk of noncompliance is high.

Lessons from ongoing challenges with 340B

Starting in January 2024, CMS will require all covered entities that submit claims for Part B drugs to use modifiers that indicate when those drugs were acquired through the 340B Drug Pricing Program. The modifier system seeks to both address the Part B inflation rebate and avoid any overlap between Part B rebates and 340B discounts.

There is already an established system of using modifiers to share information about pharmacy and medical claims between stakeholders, but there has been much debate about whether 340B modifiers in particular can either solve the duplication problem or address the overlap between 340B and Part D or between Parts B and D.

<1% **of claims at contract pharmacies used 340B modifiers**

Because these modifiers have been in use since before the IRA, there is already data to suggest their ineffectiveness. This linked report from IQVIA indicates that even when the use of 340B modifiers was required by law, reporting wasn't at 100%. When reporting was mandatory, modifier usage reached 90%. When it was optional, modifier usage fell below 20%. In the study, less than 1% of claims at contract pharmacies used 340B modifiers, but CMS' February 2023 guidance mandates that pharmacy claims should use 340B modifiers to identify 340B drugs.

Our experience at Kalderos echoes the conclusions drawn by this study. In our extensive work with the 340B program, we have found the use of 340B modifiers to be inadequate to consistently identify claims.

$150M

Kalderos-identified duplicate discounts in states using modifiers

We have discovered that even if a 340B covered entity correctly identifies a claim as a 340B claim, which does not occur consistently, that modifier may be removed at some point, given the many touchpoints: pharmacy, third-party administrator or pharmacy benefit manager, among others. Currently, 38 states require 340B claims modifiers from covered entities when submitting claims to Medicaid for reimbursement. Kalderos has identified approximately $150 million in 340B duplicate discounts in these states over the past six years.

This points to a massive gap between current usage and what will soon be required if the infrastructure or education necessary to support widespread implementation of the 340B modifier system is not made available.

Evolving policy and known hurdles to effective implementation

Without clear regulatory guidance forging a path forward for the industry, stakeholders have already pointed out a number of critical challenges.

Insights from the Office of the Inspector General

In February 2023, the OIG released a technical assistance brief about potential challenges in implementing Part B inflation rebates. The brief draws on past work by the OIG to identify significant administrative challenges that CMS could face as it operationalizes this program and to suggest potential fixes.

The brief notes at a high level that, as mentioned, CMS is likely to face challenges in identifying products subject to Part B inflation rebates as well as in excluding claims from other rebates that were already subject to other discounts. The brief's conclusions are further summarized below, as well as in this write-up from Sidley Austin.

Challenge 1

Identifying which drugs are subject to Part B inflation rebates

The IRA requires that only single-source drugs and biologics (typically brand-name products with no generic versions) are subject to Part B rebates. These rebates are calculated based on Part B payment increases that are set by the Healthcare Common Procedure Coding System (HCPCS). The issue is that a single HCPCS code may represent several single-source drugs from different manufacturers, making it difficult to determine which manufacturers to invoice, how many units they should be invoiced for and in what amount. CMS has proposed a solution, but it may not be sufficient to address the challenges.

Challenge 2

Identifying Part B rebate drugs that are also subject to Medicaid rebates

The IRA requires CMS to exclude from Part B rebate calculations any units that are subject to Medicaid rebates. This is particularly relevant for dual eligible enrollees (individuals enrolled in both Medicare and Medicaid) because Medicaid might pay for a portion of the units included on a Part B claim. There is no way currently to indicate on a Part B claim whether or not Medicaid will pay a portion of the claim (thereby reporting that those units are subject to Medicaid rebates and excluding them from Part B rebate calculations).

Challenge 3

Identifying Part B rebate drugs that were purchased at 340B discount prices

The IRA states that CMS must exclude from Part B rebate calculations any units that were already subject to discounts through the 340B Drug Pricing Program. Hospitals participating in the 340B program have been required to include modifiers on Part B claims since 2018, and CMS recently released guidance requiring the continued use of modifiers for hospitals beyond 2023.

However, as OIG's brief states, "certain Part B claims for 340B-purchased drugs may not be readily identifiable in 2023." While CMS recently announced a requirement for all 340B covered entities to use modifiers on Part B claims, this requirement is new for non-hospital-type covered entities, and it will take time for them to update their billing systems accordingly. Further, as discussed above, the use of modifiers is not consistent and can be complicated, as claims pass through multiple stakeholders.

Staying informed as changes occur

With a road map planning the full implementation of the IRA over several years, there is still time for regulators and government leaders to build the infrastructure and systems required to make the legislation a success for all involved — provided every stakeholder is willing to come to the table in a transparent and collaborative way. It's imperative for drug manufacturers to understand the ongoing impacts as the changes continue to roll out over the coming years.

Looking ahead

Since the MDRP and the 340B Drug Pricing Program were established in the early 1990s, stakeholders have struggled to resolve confusion surrounding duplicate discounts. Expanding these programs under the Affordable Care Act in 2010 exacerbated the issue, and further complexity will be added through the IRA.

As CMS moves forward in implementing these provisions, initial guidance, public feedback and subsequent revisions are sure to increase confusion. As each reform is implemented, HHS and CMS will need to adapt rapidly to issue guidance and build the support systems necessary for well-intentioned stakeholders to comply with the law.

Many drug manufacturers are expressing concern, not just over the obstacles still standing in the way of compliance but also over the sheer cost of these sweeping changes.

Litigation is already underway in some states, and the arguably short timeline for rolling out the rest of the IRA's healthcare and drug pricing provisions is expected to inspire even more legal pushback in the coming months and years.

The landscape is constantly shifting in light of these changes and challenges, so we recommend that all stakeholders invest in staying informed and up-to-date with the official implementation news coming out of HHS and CMS.

Scaling your Drug Discount Management program to meet the challenges ahead

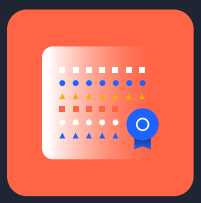
Addressing operational complexity requires comprehensive and thoughtful solutions that are built to scale. The Kalderos platform brings together dozens of disparate data sources to power Drug Discount Management solutions for drug manufacturers, covered entities and payers.

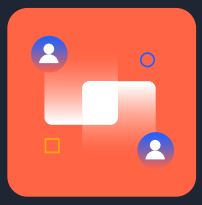
Tech-enabled solutions in the cloud

Kalderos' advanced tech stack powers a dynamic and constantly improving product suite, with solutions hosted in the cloud for seamless upgrades. We've built our product and our team to respond quickly and nimbly to evolving policy and legal guidance, so our stakeholders have the most up-to-date solutions to enable compliance with laws.

A single source of verified data

Instead of data that's siloed by program — or by stakeholder — the platform provides a holistic, unified view across programs and stakeholders for clearer insights. With the IRA's additional government-mandated pricing concessions cutting across new programs, this big-picture approach is more important than ever when it comes to identifying and resolving noncompliance.





Transparency, trust and collaboration

The Kalderos platform is designed to bring all stakeholders to the table for more equitable relationships and collaborative problem-solving. Because manufacturers, covered entities, Medicaid and Medicare must work together to ensure compliance across the new discount programs, we are driving an ethos of productive collaboration for the good of patients.

A team dedicated to your success

Our expert customer success teams are segmented by manufacturer, covered entity and payer to deliver specialized insights based on your use case. While a number of questions remain about how new discount programs will be implemented, our Kalderos subject matter experts are rapidly gaining and applying lessons from all our partners across the ecosystem.

The Kalderos platform for Drug Discount Management is powered by a world-class data engine built for enterprise customers.

Acquisition and ingestion

We take fragmented, complex and incomplete data sources and bring them together for one source of truth.

Transformation and validation

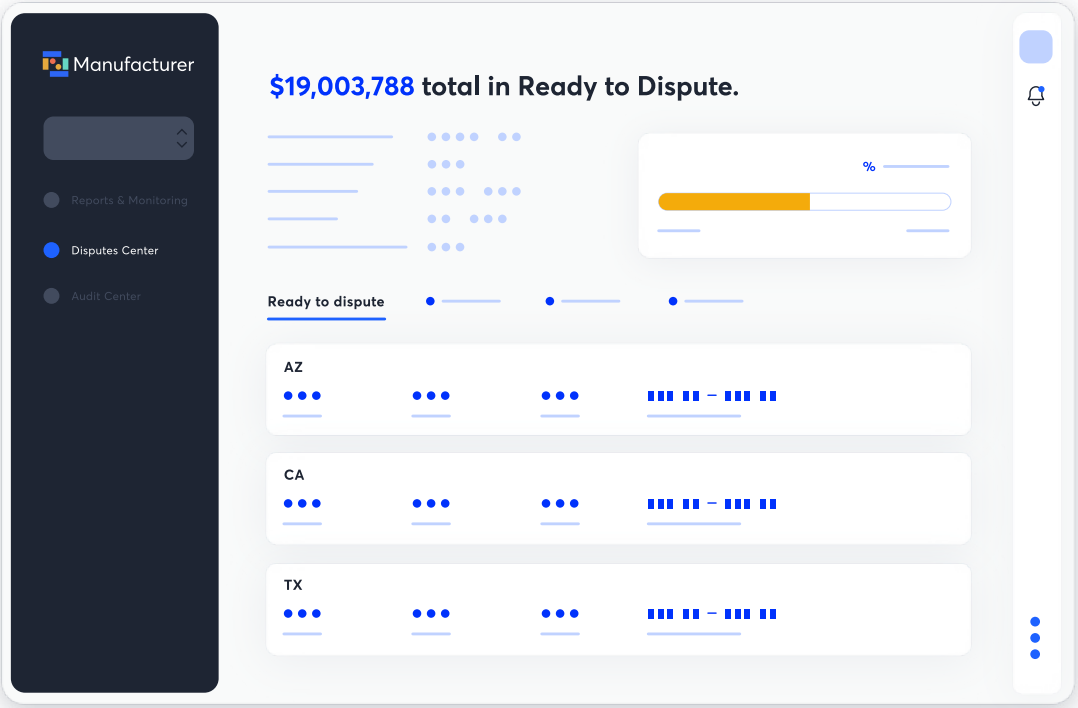
Data has little value if it isn't easy to understand. Once data is in the platform, we standardize, transform and validate these files and formats into actionable insights.

Downstream actioning and reporting

Utilizing our solutions, our customers can act on disputes over potential noncompliance and report on dispute success.

Solutions

Kalderos for Manufacturers is a purpose-built product suite that draws on the power of our tech-enabled, data-driven platform for Drug Discount Management. We partner with drug manufacturers to identify and resolve noncompliant discounts and rebates, improving gross-to-net forecasting and lifting net revenues.



MDRP Discount Monitoring

Kalderos' MDRP Discount Monitoring solution offers a transparent view of your Medicaid claims data, the gold-standard data to for disputing noncompliant claims with confidence and a collaborative platform that enables manufacturers to dispute directly with states.

- Stop wasting time on outdated, incomplete solutions
- Eliminate the need to cross-check spreadsheets or internal systems for noncompliance
- Secure improved engagement from states on disputes and dispute resolution
- Reduce revenue leakage

Commercial Discount Monitoring

Kalderos' Commercial Discount Monitoring solution brings consistency and predictability to validating commercial claims. This gives you greater confidence about which claims to exclude and arms you with clear and accurate data to enforce contractual terms.

- Benefit from Kalderos' knowledge of process improvement
- Expand up-to-date expertise around the impacts of 340B
- Rely on accurate data reporting to support effective contract negotiations

340B Pay

340B Pay is a solution for manufacturers and covered entities to gain instant visibility into 340B drug discounts, preventing duplicate discounts before they occur and simplifying the process for all stakeholders.

- Collaborate directly with covered entities
- Implement real-time disputing and reconciliation
- Pay rebates directly to covered entities, improving covered entity cash flow
- Reduce revenue leakage

Ready to learn more?

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

Kalderos combines industry expertise, design thinking and technology to target waste and improve efficiency as the category leader in healthcare financial network management. Its initial SaaS product is the world's first Drug Discount Management solution, which identifies, checks and resolves noncompliance. Using sophisticated models and machine learning processes, Kalderos detects inconsistencies overlooked by current methods, providing material benefits by eliminating waste. Based in Chicago, Kalderos was founded in 2016 by a team firmly rooted in the belief that it is essential to fix this problem in order to help patients and reduce inefficiencies.

Contact us at **kalderos.com**.