Issue No. 3

Sightlines

FUTURE-FOCUSED PERSPECTIVES ON DRUG PRICING NEWS

Hello Reader,

The brisk fall weather has Sightlines filling our mug with spiced apple cider and settling in for what many like to call "Spooky Season." We're embracing the spirit(s) of the season by exploring the trends that are most likely to keep drug pricing stakeholders up at night.

While a changing landscape of drug pricing concessions and other market trends are putting some in an uncomfortable fog of uncertainty, we also see bright spots in tech breakthroughs and collaboration that suggest a less frightening future.

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Who you gonna call?

"Stranger Things" in 2024?

Season 5 of the hit Netflix show may be delayed until 2025, but drug pricing is going to start looking different — and perhaps a bit stranger? — in 2024 as the landscape continues to transform.

- In 2024, CMS will publish the maximum fair prices resulting from Medicare Part D negotiations from the Inflation Reduction Act (IRA),

the first of many IRA drug pricing provisions to take effect. The Congressional Budget Office estimated that the IRA's price negotiation provisions will reduce the federal budget deficit by $25 billion by 2031. Other studies have sought to explore the reverberations of the IRA, including a University of Chicago study that forecasts a 31.3% drop in pharmaceutical revenue through 2039. The study also forecasts 135 fewer new drug approvals over that same time period. While the real-world impacts of the IRA price negotiations remain to be seen, manufacturers certainly have every incentive to get a jump on financial planning for when new prices take effect in 2026.

- The beginning of an evolution for pharmacy benefit managers (PBMs) could be coming in 2024. Blue Shield of CA announced it will end its 15-year relationship with PBM CVS Caremark as part of the state's new approach to managing pharmacy benefits. Lawmakers in Washington have also raised the specter of federal PBM legislation. Even with bills advancing in House and Senate committees, it is still anyone's guess if we will see any new PBM laws on the books in 2024.

- An economic slowdown in 2024 would have far-reaching impacts, and major players in healthcare and biopharmaceuticals would not be immune. Though many analysts still see healthcare and pharmaceutical companies as "defensive" places to invest in should there be a recession, companies could still face challenges if cash is in short supply. In the case of fiscal tightening next year, companies may see technology as a "lifesaver and a game-changer," according to an analysis from BioSpace.

MDRP Summit talks hopes and fears

From September 18-20, drug pricing experts and key stakeholders gathered in Chicago for Informa Connect's Medicaid Drug Rebate Program (MDRP) Summit for a robust dialogue on the government pricing space — sharing perspectives, insights and some fears for the future.

With our focus on collaborative and data-driven drug pricing solutions, Kalderos was an eager participant and associate sponsor at the MDRP Summit, which gave many Kalderonians the opportunity to engage one-on-one with attendees and speakers.

Here is a quick rundown of what we observed:

- **Spotlight on IRA:** As expected, the IRA featured prominently in many discussions. In the Summit's opening remarks, Chairperson Odalys Caprisecca, Vice President, Managed Markets Finance at Novartis, observed that "three little letters" have "changed so much" for the industry. In one session on the downstream effects of the IRA, speaker Clay Willis, Director at Berkeley Research Group, noted that operationalizing the IRA has also led to increased attention on the duplicate challenges from the 340B program. Many other speakers offered perspectives and careful predictions on the impact of the IRA's drug pricing provisions and how manufacturers could navigate the dynamic regulatory landscape.

- **Eye to the future:** Many panels did their best to look down the road at imminent challenges and long-term trends. The proposed rule changes for drug pricing from HHS and CMS could come as early as 2024, leading panelist Alice Valder Curran, Partner at Hogan Lovells, to remark that manufacturers need to "stop being reactive" and start "proactively engaging." A session centered on PBMs had Rahul Rao, Deputy Director of the Federal Trade Commission (FTC)'s Bureau of Competition, noting that "business is rushing to new ground" in reference to ongoing studies on PBMs from the FTC.

- **Meeting the moment:** The persistent threat of revenue leakage caused by duplicate discounts was discussed in a session featuring Kalderos' Micah Litow and Vishali Amin. The session zeroed in on specific challenges caused by using modifiers to prevent duplicate discounts. Litow and Amin revealed "the truth about modifiers," highlighting their inadequacy in identifying duplicate claims, showing how reliance on modifiers could lead to triplicate or even quadruplicate discounts from commercial discounts and implementation of the IRA's maximum fair price.

Double, double, toil and trouble with commercial contracts

Wondering what keeps the gross-to-net gap so large for manufacturers? It's not witchcraft — it's partially the persistent challenges of commercial contracts.

The cost of commercial price concessions that have been paid over the last decade has risen dramatically: In 2012, there was $39.7 billion in commercial discounts; by 2022, manufacturers paid $115 billion.

According to an internal analysis of drug discount data currently available on our platform, Kalderos estimates at least 5% of commercial rebates paid by manufacturers are likely duplicates with the 340B Drug Pricing Program — meaning a total of roughly $6 billion annually.

Duplicate discounts that arise from a commercial contract with a payer create a layer of complexity for manufacturers because contracts and contract exclusion terms for discount programs can vary significantly. Actionable data that manufacturers can use to get a clearer view of their commercial contracts is extraordinarily difficult to come by, making it challenging for stakeholders in the commercial space to effectively manage these contracts.

If the commercial sphere all feels like a bit of hocus-pocus, Kalderos invites you to a live webinar event on Wednesday, November 1, that promises to explore the challenges in this space and the value of accurate, actionable data in managing commercial contracts — **"Sharpening focus: How data analytics transforms commercial contracting strategies."**

Sign up for the webinar

Trick-or-treat: Kalderos edition!

Treat: If you're looking to learn more about the challenges of commercial contracts, check out Kalderos President and COO Micah Litow's guest post on Drug Channels: "**'More Than a Feeling:' Five Key Challenges When Walking Away From Commercial/340B Duplicate Payments**."

Treat: Delve deeper into commercial contracts with a webinar from BioPharma Dive and Kalderos on Wednesday, October 18, with Kalderos Founder and Chief Strategy Officer Jeremy Docken: "**The Impact of 340B on Commercial Contracts and Using Data to Close the Gross to Net Gap**."

Trick: No tricks from us! Just a "Happy Halloween!" from Sightlines and a link to everyone's **favorite spooky song**!

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