IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Inflation Reduction Act Implementation

THE EVOLVING ROLE OF PATIENT ORGANIZATIONS

Summary highlights from a multi-stakeholder roundtable on May 22, 2024

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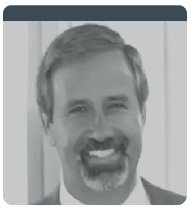

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Introduction

The Inflation Reduction Act (IRA) of 2022 includes key healthcare provisions related to negotiating lower drug prices for senior citizens, setting an inflation-based cap on prescription drug price increases, limiting out-of-pocket prescription drug costs to $2,000 per year for Medicare patients, and extending Affordable Care Act subsidies. Though clearly intended to increase treatment access and affordability, some provisions of the IRA are creating secondary and tertiary effects that could disadvantage patients in both Medicare and commercial health plans.

To discuss the IRA's potential effects and implications for patient organizations, the IQVIA Institute for Human Data Science hosted a virtual, multi-stakeholder roundtable on May 22, 2024.

The roundtable, **Inflation Reduction Act Implementation: The Evolving Role of Patient Organizations**, covered the potential positive and negative impacts of the IRA for patient organizations, including those working on behalf of individuals with rare diseases.

The discussion brought together federal government affairs, industry, and patient advocacy experts, who reviewed key healthcare provisions within the IRA, discussed how health plans and life sciences manufacturers may respond to them, and what these changes could mean to patient organizations and the individuals and families they serve.

The following summary provides highlights from the discussion.

This roundtable was convened as a public service without external funding and intended to encourage dialogue on the IRA's potential impacts on patient organizations.

Overview of the IRA

Signed into law on August 16, 2022, the IRA includes eight key healthcare-related provisions designed to address Medicare's financial outlook while improving access and affordability for patients:

1. **Drug price negotiation program**. The IRA empowers Medicare to directly negotiate prices for certain high-cost prescription drugs. As such, it marks a major departure from previous policy under the "non-interference clause" within the Medicare Modernization Act of 2003.

   The new law establishes criteria for negotiation-eligible drugs — starting with small-molecule Part D drugs and eventually expanding to cover Part B and other drugs. The roadmap calls for price negotiation on 10 Part D drugs in 2026 followed by 15 more Part D drugs in 2027. In 2028, negotiations will expand to cover 15 additional Parts B and D drugs, with another 20 to be negotiated starting in 2029.

   The IRA provides exclusions that could have significant impact for many patient organizations. These include exclusions for:

- "Orphan drugs" that treat only one rare ailment.
- Medicare drugs that are considered "low spend" (i.e., less than $200 million in annual expenditure).
- Products derived from human blood or blood plasma.
- Small biotech drugs that constitute less than 1% of total Part B/D expense and more than 80% of the company's Medicare payments.

   For negotiation-eligible drugs, the IRA directs Medicare to negotiate with manufacturers to reach a maximum fair price (MFP). It delineates specifics of the negotiation process and offer amounts, carving out negotiation eligibility delays of up to two years for certain biological products.

2. **Prescription drug inflation rebates.** The IRA requires manufacturers to provide rebates if Medicare drug prices increase faster than the rate of inflation (based on the urban Consumer Price Index). This requirement can be waived due to shortages and supply chain disruptions.

3. **Medicare Part D out-of-pocket cost cap.** The IRA grants Medicare beneficiaries an out-of-pocket cap of $2,000 starting in 2025. (The cap will increase based on annual changes in per-capital expenditure.) This eliminates the "donut hole" between initial and catastrophic coverage. After a beneficiary reaches the cap, Medicare will pay for 20% and 40% of brand-name and generic drug costs, respectively. Manufacturers and insurers absorb the balance of the costs.

4. **Medicare Part D subsidies and premium stabilization.** The IRA authorizes 10% subsidies on certain Part D drugs for beneficiaries who have not reached the out-of-pocket cap. Starting in 2025, Medicare reinsurance will be reduced, with Part D plans and manufacturers bearing greater costs. Larger life sciences companies will begin paying such rebates in 2025; small biotechs' liabilities will be phased in over time.

5. **Monthly cap on cost-sharing payments for prescription drug/Medicare Advantage prescription drug (MA-PD) plans.** The IRA requires prescription drug and MA-PD plans to include an option for cost-sharing with capped monthly payments. This provision is intended to help smooth costs for patients who may be unable to cover a $2,000 deductible in the first month of every year.

6. **Vaccine coverage.** The IRA removes deductibles and cost-sharing under Part D for vaccines recommended by the Advisory Committee on Immunization Practices. It also requires coverage with general cost-sharing limitations for adult vaccines under Medicaid and the Children's Health Insurance Program (CHIP).

7. **Part D low-income subsidies.** The IRA expands low-income subsidy eligibility from 135% to 150% of the poverty line. (Initially provided through the American Rescue Plan Act of 2021, this expansion was set to be removed at the start of 2023 without further action.)

"A number of patient groups might be concerned about [the orphan drug exclusion] because it disincentivizes, in some ways, further research on drugs with existing non-orphan indications—to say nothing of drugs with orphan indications that might be applicable to broader patient universes that wind up [with] delayed research because the manufacturer does not want to be subject to negotiation."

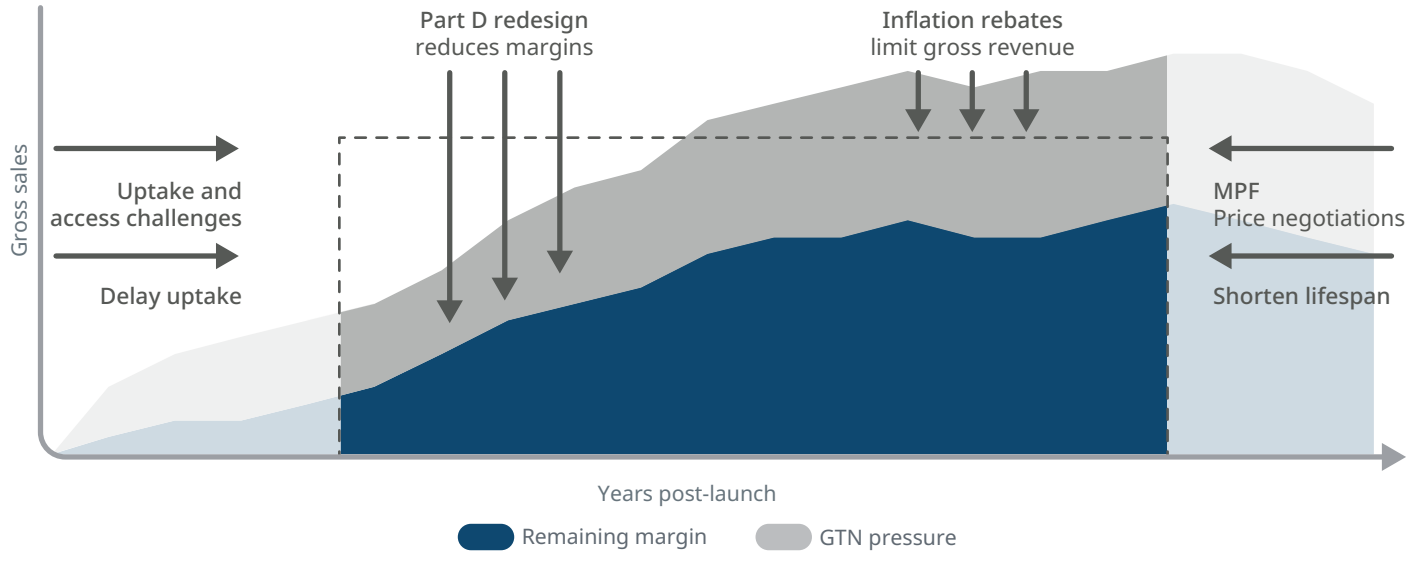
Jamie Gregorian, JD
Of Counsel, DLA Piper

Highlights from the roundtable discussion

The roundtable discussion explored potential implications of the IRA on patient organizations:

- **Patient organizations have opportunities to help patients navigate changing program designs.** By helping to lower patients' out-of-pocket costs, the IRA could reduce the burden on foundations and patient assistance programs. In addition, the law is designed to support improved patient compliance, including higher rates of adherence and lower rates of treatment abandonment. For foundations, lower per-patient costs should free up funds, enabling these organizations to support a larger number of patients.
- **Patient organizations could experience impacts specific to their therapeutic area(s).** The IRA price negotiation program exempts small-molecule drugs on the market for less than nine years and large-molecule drugs on the market for less than thirteen years. The accelerated time horizon may deter some manufacturers from making investments in small-molecule drugs. Patient organizations focused on neurological diseases and conditions could be especially affected, as such treatments generally require small molecules.
- **Patient organizations need to keep an eye on health plans.** Faced with challenging new economics — namely, an expectation that they will absorb a much larger share of costs — health plans are likely to respond in ways that could harm patients. Tactics may include raising premiums and/or changing formularies to reduce access. As one panelist shared, CMS sounded an alarm on this risk in June 2023: "CMS is concerned that Part D sponsors might be incentivized in certain circumstances to disadvantage select MFP drugs by placing these drugs on less favorable tiers compared to non-selected drugs."

Figure 1: The brand economic cycle



Source: U.S. Market Access Strategy Consulting analysis.

- **Affected manufacturers will be squeezed, too; patient organizations may want to count on less financial support from industry.** Manufacturers that face IRA-related impacts on both revenue and costs will have strained budgets at every stage of the product lifecycle. There will be less funding to support pre-launch research and development, as well as less budget to support foundations and patient assistance programs.

  Even before the IRA, manufacturers were feeling the pinch of challenging launches; the benefits redesign adds another layer of challenges in getting products to market. Again, these dynamics are likely to have a significant impact on manufacturers' calculus about whether and how to pursue new products and indications. Where IRA-related risk looms, companies may tap the brakes — or discontinue parts of their pipeline altogether.

- **Finally, patients with rare diseases may lose out on much-needed research and innovation.** An estimated 25 million to 30 million Americans (almost one in ten) have a rare disease. According to the National Institutes of Health (NIH), there are more than 10,000 rare diseases — and about 95% do not have an FDA-approved treatment. As one panelist explained, the Orphan Drug Act of 1983 created incentives for industry that have been vital to the work of patient organizations focused on rare diseases. Stakeholders fear that the IRA could have the opposite effect. Excluding one-disease "orphan drugs" from price negotiations is likely to discourage manufacturers from studying a drug's suitability for additional diseases.

"There's already a very challenging launch environment that makes drug development very risky. [The IRA] makes it even more risky. Disincentives could threaten the pursuit of multiple indications where innovation is needed the most."

James Brown
VP, Market Access Consulting and Analytics, IQVIA

Key takeaways

As this discussion illuminated, the IRA has implications beyond its intended goals of using price controls to improve patient affordability and Medicare trust solvency. As regulatory guidance and responses from both manufacturers and payers continue to take shape, patient organizations are well advised to track impacts across three mission areas:

Table 1: Tracking impacts across three mission areas

SUPPORT	ACCESS	INNOVATION
Anticipate changes or disruptions to patient support programs. Reductions/caps in patients' out-of-pocket costs create opportunities to help more people. Yet as manufacturers' budgets are increasingly strained, there may be fewer resources available to fund foundations and/or patient assistance programs.	Across payer channels, prepare for lean formularies. In this new environment, patients may need even more help navigating prior authorization processes and other access challenges. Further, access impacts on utilization and prescribing could exacerbate other disparities.	Keep advocating to support drug development and innovation. For manufacturers, a challenging launch environment makes drug development risker than ever. Ironically, the IRA creates disincentives that could threaten the pursuit of multiple indications—especially for rare diseases where innovation is most needed.

To learn more on this important topic, please see Key Context for CMS Prescription Drug Negotiations.

"Insurance is both very complicated and very important for our patients. We want to make sure that with the changes that are brought about by the Inflation Reduction Act, patients can choose the best plan for them."

Karin Hoelzer, DVM, Ph.D.
Senior Director, Policy and Regulatory Affairs, National Organization for Rare Disorders (NORD)

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

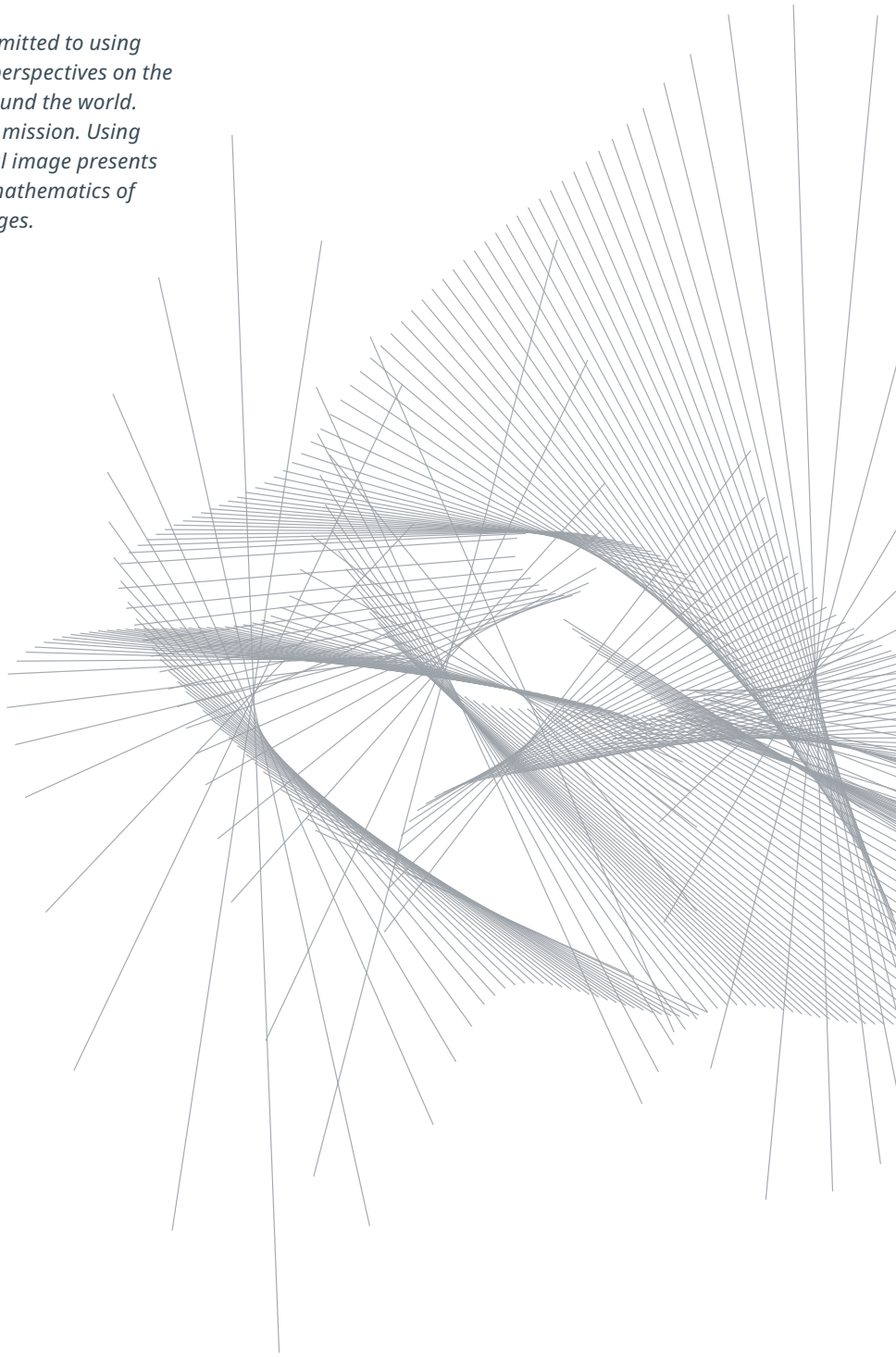
- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.



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