



**Embracing value-based pricing
in pharmaceuticals: A path to
sustainable success**

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Navigating the current challenges and demands of the pharmaceutical industry

With the ever-increasing healthcare delivery costs, pharmaceutical companies are facing mounting pressure to demonstrate the impact of their products in treating illness and enhancing patients' overall health and quality of life. Unfortunately, drug prices continue to rise. From 2015 to 2020, North America accounted for more than half of the global sales of pharmaceutical products during the same period.

The drug prices in the United States are significantly higher than those of peer nations. According to a 2021 study by the RAND Corporation, the prices of prescription drugs in the USA are 156% higher compared to 32 other countries (including the UK, Germany, and Australia).¹ In addition to having higher base prices, the prices of prescription drugs have increased at a higher rate than inflation.

Over time, traditional pricing models of pharmaceuticals, which consider production costs and market competition, are being questioned. These models often fail to reflect the real-world value of drugs to patients and healthcare systems.

The landscape is changing rapidly, and patients, payers, and regulators demand more transparency and accountability from pharmaceutical products.



Perspectives on pharmaceutical pricing: Payers, regulators, and patients

Payers' perspective

Payers in the United States express challenges and concerns in achieving better value in the healthcare system. For instance, as a part of a study conducted on Understanding Payer Perspectives on Value of the Use of Pharmaceuticals in the United States, during interviews with various payers, it was revealed that they feel compelled to cover treatments that have been approved by the FDA, even if they come at a high cost and provide little value.²

Many payers expressed concern regarding the little or no control over pharmaceutical pricing. As patients in the United States take on more of the financial burden related to their healthcare, patient-reported and other outcomes are becoming increasingly important to U.S. payers.



Regulators' perspective

At a national level, there has always been a long-standing debate on the non-sustainable increase in healthcare spending. American healthcare reform has long been a key political agenda, which includes the Patient Protection and Affordable Care Act of 2010, the American Health Care Act of 2017, and Executive orders in the 2017 administration, which modified the execution of the Affordable Care Act.

The Inflation Reduction Act (IRA), introduced recently and signed into law by President Joe Biden in August 2022, has significantly altered the pharmaceutical market. The IRA has three main components to reform Medicare's drug pricing policy:

- 1. Cap on price rise:** IRA limits the price increase on prescription drugs to not more than the inflation rate and requires inflationary rebates if the prices rise above inflation from 2023.
- 2. Price negotiation:** Starting in 2026, IRA will authorize Health and Human Services to negotiate prices for expensive prescription drugs within the Medicare program.

To start with, ten drugs would be under the purview in the year 2026, and the number of drugs would increase to 60 by the year 2029. The negotiations with participating drug companies will occur in 2023-2024, and the negotiated prices will be effective from January 2026.

- 3. Cap on out-of-pocket expenditure:** Beginning in 2025, Medicare Part D out-of-pocket spending will be capped at \$2,000 by the IRA. The cap will be adjusted for inflation in the following years.

The IRA and the others mentioned are some of the many measures taken to regulate the price of care delivery in the USA. While the measures taken differ across the administration, the central objective has always been to reduce the price of care delivery and improve overall transparency.

Patients' perspective

In a 2023 poll, 3 out of 10 American adults reported not taking their medications at some point in the past year because of the cost. These include adults who have not filled out a prescription, took an Over-the-counter drug, have cut their recommended dose to half, or skipped a dose. While 65% of the adults reported that affording prescription drugs is 'somewhat easy,' over 80% of the adults still feel that the prices are unreasonable, and a majority of the consumers attribute the high prices to profits earned by the pharmaceutical companies (~80%).

Among the consumers polled, ~80% showed strong support for the recently introduced IRA, with 84% showing strong support for capping out-of-pocket expenses for insulin.

Agnostic of the political alliances in the U.S., the public has shown and continues to show strong support for lowering drug prices and allowing Medicare to negotiate drug prices for Medicare recipients.

While the impact of controlling prices and its unintended consequences on research and development and patient access to drugs is still being argued, pharmaceutical manufacturers persistently face questions regarding the value and impact of their products on patients' health.



Price transparency impact and recent trends

As healthcare costs continue to rise, there is a growing demand for transparency in pricing. Starting January 2021, all hospitals and group health plans in the U.S. are required to provide transparent pricing information for the goods and services they cover. The healthcare industry is dedicated to empowering patients with the information they need to effectively manage their health and treat illnesses.

Until recently, pharmaceutical manufacturers did not have to disclose the details of their products' pricing (list price). However, some states have implemented regulations that mandate pharmaceutical manufacturers to share data for a select set of products. For instance, in California, pharmaceutical companies must provide information on drugs with a Wholesale Acquisition Cost (WAC) of over USD 40 (during treatment) that have seen a price increase of more than 16%.⁴ This information must be provided to local health authorities and include pricing trends over time and an explanation for any changes or improvements that led to the price increase. However, the data to be shared is limited to regulatory authorities and unavailable to end consumers.

Recent trends in price transparency indicate that the end consumer likes to be empowered with more data to make the necessary decisions from a medical and financial perspective.

The Biden-Harris Administration has made lowering prescription drug costs in the United States a key priority. CMS proposed a rule in May 2023 that would allow Medicaid to hold drug manufacturers more accountable for the cost of their drugs. The rule would give CMS greater insight into the manufacturing and distribution costs of today's most expensive drugs. The proposed regulation would also provide CMS and states with new tools, like a drug price verification survey, to increase transparency about manufacturers' drug prices. This survey would verify drug prices, helping states to negotiate the cost of high-priced drugs better and understand why they are expensive for Medicaid.

Multiple factors, which include the patient/payer perspective and the emerging political landscape, are pointing towards a significant change in how pharmaceutical manufacturers in the U.S. can price their drugs. Pharmaceutical companies must create models to effectively demonstrate the product's value and safeguard their prices to the greatest extent.

Rationalizing pharmaceutical drugs pricing: The role of value-based pricing

Across the U.S. healthcare spectrum, there is a growing need to rationalize the pricing of pharmaceutical drugs. Both regulatory and market pressures are driving pharmaceutical manufacturers to create a framework that demonstrates the clinical impact of their products on patients' health and how they can contribute to a long-term positive social and economic impact. The authorities are now asking these manufacturers to tag their drug prices based on the potential or historical performance of the drug.

Value-based pricing is a strategy of setting prices based on consumers' perceived value. When applied to the pharmaceutical industry, it refers to how a drug can be priced to optimize the balance between maximizing a patient's health outcomes and minimizing the cost incurred to improve the health outcomes.

Although value-based pricing concepts have been around in the U.S. pharmaceutical industry for a while, we must question whether it is genuinely 'Value-based Pricing'—'Pricing' being the keyword.



Over the years, various agreements have been made between pharmaceutical manufacturers, Payers, and PBMs to modify payments based on health outcomes. For example, a Payer can choose to withhold reimbursements if a drug fails to deliver the health outcomes as per the agreement. These are more of a pay-for-performance model and have little to no impact on the drug's actual price.

Most engagements involve providing discounts and rebates from pharmaceutical manufacturers based on potential health outcomes. However, only a few engagements consider pricing a pharmaceutical product based on retrospective real-world health outcomes and clinical trial data.

Let's take the example of Lecanemab (Leqembi), an anti-amyloid monoclonal antibody for managing Alzheimer's disease. The FDA approved the drug in January 2023 under the accelerated pathway based on its ability to remove amyloid plaques. Lecanemab underwent Phase III RCT evaluation, with the primary clinical outcome of measuring the change in the mean score of the Clinical Dementia Rating Scale. At 18 months, the drug showed a statistically significant slow down in cognitive decline.

Analysis of secondary end points, including other cognitive measures and patient and caregiver quality of life, consistently favored the lecanemab-treated group. However, the patients also exhibited amyloid related imaging abnormalities and/or haemorrhage.

The drug demonstrated a net-positive impact and was rated as promising but inconclusive by an ICER Report. From the healthcare sector perspective and a modified societal perspective, based on the lifetime cost-effectiveness of lecanemab in addition to supportive care compared to supportive care alone, ICER estimated the Health Benefits Price Benchmark for lecanemab to be between USD 8,900 to USD 21,500. However, lecanemab is priced annually at USD 26,500, requiring a discount of -66% to 19% to align with the benchmark estimated by ICER.⁵

To implement a pricing model that benefits patients, care givers, and society, pharmaceutical companies should offer direct discounts on their wholesale acquisition cost and set prices based on the value their drugs provide. This does not imply that all drugs should be discounted. Recently, drugs like **belimumab** and **voclosporin** have been approved for treating lupus and significantly improving kidney function. These drugs are priced at around \$43,000 and \$92,000 per year, respectively, which reflects the value they provide to patients. These prices are also within the acceptable range estimated by ICER.

While the above studies are based on a single valuation body (ICER), pharmaceutical companies would need to design frameworks that would allow them to estimate and price drugs based on benefits delivered to patients, the healthcare industry, and society as a whole. With IRA becoming a law, pharmaceutical companies would have to negotiate a Maximum Fair Price (MFP) for the drugs being considered. They would need to offer the drugs at MFP.

Discounts and rebates on the list price have driven the existing value-based pricing programs in the U.S. However, negotiations based on the IRA would lead to a change in the product's list price. These negotiations would primarily depend on the value demonstrated by the product retrospectively. CMS would consider three primary factors when determining MFP for a drug :

1. Comparative effectiveness of the drug, including if the drug represents a therapeutic advance or satisfies an unmet need in the market.
2. The costs of developing, manufacturing, and distributing the drug, including any prior federal funding.
3. Current price of drug and sales, including generic competition.

The negotiated price will be in effect from Jan 2026 and applicable to eligible members under Medicare. However, pharmaceutical companies must know that new prices may be extended to other commercial payers and federal programs. To begin with, prices for ten drugs will be negotiated in 2023–2024. However, it is essential to see how a negotiated price may also have a ripple effect on other players in a competitive market.

Considering the impact of direct negotiations under the IRA, pharmaceutical manufacturers need to develop a robust mechanism to gather evidence on the value of the drug. CMS will request a range of evidence from companies to establish a suitable negotiated price, such as cost-effectiveness, R&D expenses, and unit costs. This allows companies to gather more evidence to support their desired price, including aspects like scientific quality, diversity and inclusion, health outcomes, and financial consequences.

Drug makers need to double down on their real-world evidence-generation programs and ensure they can demonstrate clinical value, cost-effectiveness, and impact on the overall care delivery and management of a clinical condition.

Data-driven negotiations

As a pharmaceutical manufacturer, one thing is certain: 'The negotiations are coming.' If not directly through the IRA, sooner or later, other federal/state agencies and private insurance organizations will want to get pricing (not just for the drug class but potentially at the therapy level) closer to the Maximum Fair Price.

Pharmaceutical manufacturers have been engaging in value-based contracts with payers for a while. A survey done in 2019 revealed the key reasons for the success or failure of an agreement over value-based negotiations between manufacturers and payers.

Top 3 reasons for negotiations to succeed:	Top 3 reasons for negotiations to fail:
<ol style="list-style-type: none">1. Availability of measurable outcomes clearly tied to product use2. Target patient population that is easily identified in claims3. Reasonable administrative burden	<ol style="list-style-type: none">1. Challenges related to data collection and evidence development2. Availability of appropriate outcome measures3. Implementation costs

Value-based drug pricing focus areas

The pharmaceutical industry would need to focus on generating insights on their drug performance to enable data-driven negotiations. Below are some focus areas for a pharmaceutical organization to create a repeatable, sustainable process to be prepared for the next phase of value-based pricing:

1. Tighter integration with payers, Providers, and other data collection bodies:

Procuring data would be critical to the new phase of value-based pricing. Pharmaceutical manufacturers would need to identify payers and Providers whose patients are active consumers of their products and be able to develop and integrate systems that can procure deidentified patient data.

2. Grounding pricing to principles of Population Health:

Pharmaceutical manufacturers need to define data & analytics framework to help demonstrate the long-term impact of products at a population level. The effect would need to be quantified across various factors like health outcomes, cost of care, and long-term socio-economic implications.

3. Defining measurable outcomes: Pharmaceutical companies need to identify or curate two markers that can show value.

a. Clinical Marker: Markers that demonstrate the positive impact on a patient's health, could range from lab reports and hospitalization rates and can also include patient reported outcomes that potentially demonstrate the effects of the product on a patient's day-to-day life.

b. Financial Marker: Pharmaceutical manufacturers must use data to demonstrate the financial impact on the healthcare system. Pharmaceutical companies need to show scenarios of how their products reduce the financial burden on payer programs.

4. Creating a platform/framework for scenario testing for MFP and counter offers: Pharmaceutical organizations should consider strategically looking at the upcoming negotiations by performing data-driven simulations and scenario planning.

Organizations need to conduct scenario planning through:

- a. Price – Patient access – Cost of care models:** demonstrate the impact of change in price on patient access (affordability) and its consequent impact on the cost of delivering care at a population level.
 - b. Price – Revenue – Profitability:** Impact of price change on overall organizational/therapeutic revenue and its impact profitability. Understand how the financial implications would influence other strategic initiatives and outcomes.
- 5. Plan for drugs that can be under the IRA purview:**
Leaders need to prepare for drugs that would be exposed to direct negotiations under the IRA in the coming years. Organizations need to identify drugs from their portfolio with high baseline prices and a higher medical necessity across the Medicare patient population.



Conclusion

The U.S. Pharmaceutical market is undergoing a paradigm shift as end consumers become more involved in their healthcare journey. There is a growing demand across the board, from individual consumers to healthcare payers, to demonstrate the value of health care services rendered. This has led to governments and regulators taking measures to improve transparency and reduce costs.

To succeed in this new dynamic market, executives in the pharmaceutical markets operating in the U.S. would need to pivot their strategies around patient access, marketing, and pricing. Although a pharmaceutical product's end impact or value may remain constant (subject to the product), pharmaceutical organizations must implement data-centric approaches to demonstrate their products' short and long-term value in a more consumer-centric format.

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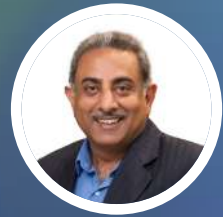
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