

Drug Pricing Law Could Have Unintended Consequences

By **Alice Chen, Andrew Elzinga and Penka Kovacheva** (June 28, 2023)

The Inflation Reduction Act was signed into law in August 2022 with the goal of curbing inflation by, among other things, lowering prescription drug prices.

Notable prescription drug provisions of the IRA include the introduction of Medicare drug price negotiations, Medicare inflation rebates and a redesign of the Medicare Part D benefit structure.

Since the law's passage, the Centers for Medicare & Medicaid Services has issued a series of guidance memorandums on how these various provisions will be implemented.[1]

For example, in March, CMS provided initial guidance on the Medicare negotiation process, and more recently in May, CMS released guidance on how the updated benefit design for Medicare Part D will affect the statutory discounts required of pharmaceutical manufacturers.

Despite CMS providing some insights on the IRA's implementation through these guidance memorandums, the full economic impact of the IRA on the pharmaceutical industry remains uncertain.

In particular, there may be several unintended economic impacts on pricing, drug access, benefit design, innovation and competition, particularly for biologics and biosimilar drugs.

1. The IRA's Medicare drug pricing provisions may result in higher list prices at launch and suboptimal research and development.

Two provisions in the IRA are likely to significantly affect drug pricing: Medicare's drug price negotiations and inflation rebates.

First, the IRA empowers Medicare to negotiate prices for certain drugs covered under Medicare Part B, covering physician-administered drugs, and Part D, covering self-administered drugs.

The price negotiation program is limited to drugs without a generic or biosimilar competitor and those with the highest Medicare spending. In 2026, 10 drugs will be subject to price negotiations, and this number will grow in subsequent years.

The price negotiations will establish a maximum fair price at which the manufacturer is required to make the drug available to pharmacies and providers for Medicare beneficiaries.

Second, similar to the Medicaid Drug Rebate Program, the IRA requires drug companies to pay a rebate to the federal government if list prices rise faster than inflation for drugs used by Medicare beneficiaries.



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This provision applies to all single-source brand-name drugs and biologics covered under Medicare Part B and most covered drugs under Part D. The inflation rebate amount will be determined as the difference between the drug's current price and its inflation-adjusted 2021 price.

Both provisions aim to reduce the future price growth of existing drugs. But paradoxically, they may have the opposite effect on the price of new drugs. Both the price negotiations and the inflation rebates may lead to increased list prices of new drugs at launch, as manufacturers anticipate they may be subject to negotiations in the future and will be limited in their ability to raise prices after launch.

The extent of any pricing behavior change in response to the IRA will likely depend partly on whether a drug is utilized more by Medicare beneficiaries or by commercially insured patients.

Because these provisions apply only to Medicare beneficiaries, drugs with smaller Medicare market shares will be less affected. For example, for drugs with lower Medicare utilization, manufacturers may be more willing to increase list prices — potentially accompanied by higher rebates in commercial markets — even after launch, as the Medicare penalty will be smaller in relative terms.

Nonetheless, because there is a single list price for each drug product, changes in manufacturer pricing behavior could affect both Medicare and commercial sales.

Additionally, identifying price negotiation — eligible drugs based only on the size of their spending may negatively affect manufacturers' research and development decisions.

For example, high-value drugs may be associated with high total expenditures because their therapeutic value drives high utilization. Policies such as the IRA's price negotiation program that only consider drug spending and not the overall health benefits provided by the drug may lead to lowering the prices of some high-value drugs below their marginal benefits.

This, in turn, could lead to lower investment in developing high-value drugs and result in a socially inefficient outcome. This is because high-value drugs can translate into lower overall health care spending if utilization of these drugs results in less medical intervention due to improved health outcomes.

2. The IRA may lead to suboptimal prescribing and higher consumer costs for some Medicare Part B drugs.

As noted above, Part B drugs are physician-administered drugs, typically purchased by physicians and then administered to Medicare beneficiaries.

For most Part B drugs, except biosimilar drugs, Medicare reimburses physicians based on the drug's average sales price, or ASP, plus 6% of the ASP, reflecting handling, storage and other overhead costs.

This reimbursement structure is intended to compensate providers at their cost plus a small margin. However, for drugs selected for price negotiations, the IRA establishes that physicians will be reimbursed based on the negotiated maximum fair price instead of the ASP.

Since the maximum fair price is expected to be lower than the ASP, this provision may lead

to a shortfall for some providers, resulting in them shifting away from drugs subject to negotiation and toward potentially less clinically appropriate alternatives where their costs will be covered.

The IRA also increases the physician reimbursement for certain biosimilar drugs from ASP plus 6% to ASP plus 8%, where the add-on payment is set based on the ASP of the biosimilar drug's reference product.

The increased add-on payment is intended to increase competition between originator biologic and biosimilar drugs by providing an increased economic incentive for physicians to utilize less expensive biosimilar drugs rather than the originator biologic.

However, under Medicare Part B, beneficiaries typically pay a 20% coinsurance on the total cost of the drug, i.e., ASP plus the add-on payment. Therefore, the increased payment to providers for biosimilar drugs will likely result in increased costs for consumers, which may offset some of the IRA's intended goal to reduce drug prices.

3. The IRA's Medicare Part D redesign may result in reduced drug benefits or access.

The third main pharmaceutical provision of the IRA is the Medicare Part D redesign, which modifies the share of drug costs borne by Medicare Part D plan sponsors and drug manufacturers and institutes a \$2,000 cap on out-of-pocket spending for Medicare beneficiaries.

Under the IRA, Medicare Part D plan sponsors will be required to cover a significantly greater share of drug costs once a beneficiary reaches the catastrophic coverage phase (which was lowered to equal the consumer out-of-pocket cap of \$2,000).

The increased financial exposure of plan sponsors in the catastrophic coverage phase incentivizes plan sponsors to aggressively keep their beneficiaries' spending below the start of such coverage.

Plan sponsors may accomplish this through increased utilization management, including more restrictive formularies that exclude more drugs or require prior authorizations or step therapies for high-cost drugs.

Thus, while the IRA is intended to lower out-of-pocket spending for beneficiaries, it might also reduce access to certain drugs due to Part D redesigns.

In contrast to the incentives of Medicare Part D plan sponsors, by instituting a cap on Medicare beneficiaries' out-of-pocket spending, the IRA may also reduce the price sensitivity of some Medicare beneficiaries.

Before the IRA's out-of-pocket spending cap, Medicare beneficiaries in the catastrophic coverage phase were required to pay 5% of a drug's cost, sensitizing beneficiaries to differences in drug costs.

However, the IRA's spending cap removes this requirement for consumers and may result in increased drug utilization. Recent research has shown that increases in drug utilization have been an important driver of overall drug spending increases.[2]

If the IRA's spending cap results in increased utilization, it may actually lead to higher

rather than lower government drug spending in the future.

The benefit redesign also caps Part D premiums, so they cannot increase by more than 6% annually. Again, while this policy may lower beneficiary costs, it may also have similar unintended consequences on the cap on out-of-pocket spending.

Reducing the growth of premiums may lead to higher drug utilization. Without the ability to increase premiums correspondingly, plan sponsors may react in the same way as they could to the out-of-pocket cap — by reducing plan benefits offered to beneficiaries to prevent increases in their plan costs.

4. The IRA creates a potentially complicated set of economic incentives for biologic drug manufacturers.

Under the IRA, biologic drugs may become more appealing for research and development investment relative to small-molecule drugs, as biologic drugs have an additional four years relative to small-molecule drugs before becoming eligible for Medicare price negotiations.

This may result in a shift in focus similar to that of the Orphan Drug Act, which spurred research and development investment in therapies for rare diseases.

That said, many biologic drugs are among the highest-spend drugs for Medicare. As a result, the impacts of the IRA — particularly its price negotiation program — are likely to be more pronounced for biologic drugs in the long run.

Yet, it is important to note that the price negotiations do not apply to biologic drugs with biosimilar alternatives — or biologic drugs with a high likelihood that a biosimilar alternative will be licensed and marketed soon.

This exception may encourage biosimilar entry. Specifically, originator biologic manufacturers may face a trade-off between entering government price negotiations and allowing earlier biosimilar competition, for example, through patent licenses.

The former would allow originator biologic manufacturers to maintain volume but at a reduced price, while the latter would result in reduced originator biologic volume but at potentially higher prices.

This trade-off for innovator biologic manufacturers will depend on the anticipated price reduction from the Medicare price negotiations and on the expected market penetration and price competition from a new biosimilar entrant.

Historical biosimilar uptake has been slow for certain products in the U.S.[3] This could result in innovator biologic manufacturers' preference for earlier biosimilar competition over facing Medicare price negotiations.

However, biosimilar uptake has increased in recent years.[4] The arrival of interchangeable biosimilar drugs, which are eligible for pharmacy-level automatic substitution, may alter the calculus for innovator biologic manufacturers.

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[1] "Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments," Centers for Medicare & Medicaid Services, February 9, 2023; "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments," Centers for Medicare & Medicaid Services, March 15, 2023; "Medicare Part D Manufacturer Discount Program Draft Guidance and Request for Comment," Centers for Medicare & Medicaid Services, May 12, 2023.

[2] Tichy, Eric M., et al., "National trends in prescription drug expenditures and projections for 2022," American Journal of Health-System Pharmacy 79, no. 14 (2022): 1158-1172; Fein, Adam, "Latest CMS Data Reveal the Truth About U.S. Drug Spending," DrugChannels.net, January 20, 2021.

[3] See, e.g., Chen, Alice J., et al., "Uptake of infliximab biosimilars among the Medicare population," JAMA Internal Medicine 180, no. 9 (2020): 1255-1256.

[4] See, e.g., Chen, Alice J., et al., "Cancer Drug Trastuzumab And Its Biosimilars Compete On Price For Market Share," Health Affairs, vol. 42, no. 6 (2023): 779-784.