# The Impact of IRA Medicare Drug Price Provisions on the Private Market

Issue Brief

The Inflation Reduction Act, which was signed into law on August 16, 2022, included several important provisions affecting drug prices. The elements receiving the most attention were the requirement for the federal government to negotiate the prices that Medicare pays for certain high-cost drugs and the cap on out-of-pocket spending for Medicare Part D beneficiaries. But another element – **the limit on Medicare drug price increases** – deserves attention as well. The focus of this issue brief is the potential impact of this element on drug prices in the private market and the need for oversight of the regulations implementing this provision of the IRA.



#### Limits on Medicare Drug Price Increases

The IRA provides an incentive for holding down drug price increases in Medicare by requiring manufacturers to pay a rebate to Medicare if prices increase faster than general inflation. This applies to certain drugs covered under Medicare Part B (single-source drugs and biosimilars) and nearly all drugs covered under Part D. The <u>effective dates</u> for the inflation rebate provisions are October 1, 2022, for Part D and January 1, 2023, for Part B. The inflation rebate provisions will take effect much sooner than the price negotiation provisions, which do not take effect until 2026.

### Potential Impact on Drug Prices in Private Market

There are mixed opinions about the impact of the Medicare inflation rebates on drug prices in the private market. According to the Congressional Budget Office, "... the inflation-rebate and negotiation provisions would increase the launch prices for drugs that are not yet on the market relative to what such prices would be otherwise. That effect would primarily be driven by the inflation-rebate provisions . . .. "Furthermore, a 2021 article in JAMA Health Forum by a group of distinguished economists expressed concern that "... pharmaceutical companies may well accelerate price increases ... " in response to limits on price increases for Medicare drugs only. Others have argued, however, that there may be positive spillover effects on drug prices in the private market, i.e., lower prices. A study conducted by the Council for Informed Drug Spending Analysis concluded that "Because drug manufacturers sell drugs to pharmacies at the same price regardless of whether a prescription is dispensed to a Medicare beneficiary or a patient with commercial insurance, the penalty on Medicare sales will put **downward pricing pressure** on all drug sales." Furthermore, since the calculation of price increases will be based on data from both Medicare and private sales (average sales price (ASP) for Part B drugs and average manufacturer price (AMP) for Part D drugs), there is potential for the spillover effect to hold down price increases in the private market. As a recent analysis in Health Affairs describes, however, "The extent of that impact will depend on the drug's utilization in the Medicare versus the commercial market. For example, manufacturers will be more likely to continue to take substantial list price increases . . . in commercial markets for drugs that have little Medicare utilization . . ."

It should be noted that much of the analysis of the potential impact on drug prices in the private market is speculative; there is little actual data on which to base forecasts. Some of the estimates rely on standard economic theory, which sometimes does not apply to skewed public-private markets. Others are based on findings from the impact of a similar rebate program in Medicaid, but there are differences in these programs and the sizes of the markets that make it difficult to be confident about the impact of the new Medicare law. Furthermore, the complex supply chain and pricing behavior of drug manufacturers makes it difficult to analyze the interaction between the Medicare and private markets. Since the drug price provisions in the IRA are the first time that broad limits on drug prices and price increases have been used in Medicare, we simply do not have much information on which to estimate the impact on drug prices in the private market.

## The Need for Oversight of IRA Regulations

The IRA's legislative language regarding inflation rebates is fairly clear, and the formulas for calculating the rebates are reasonably well-defined. It would be prudent, however, to monitor the regulatory process and provide input as CMS develops the rules to implement the inflation rebate provisions. There are lessons to be learned from the Medicaid inflation rebate regulations, since the IRA language regarding the Medicare inflation rebates is similar. According to Sean Dickson, health policy director for the West Health Policy Center (quoted in a recent Tradeoff's podcast), "There's a long track record of manufacturers taking creative strategies to avoid paying these [Medicaid] rebates." Even the process for data collection, which appears on the surface to be simple, might not be straightforward. This will require close review of the proposed rules and pushback against any industry efforts to create loopholes.

## The Need for Monitoring and Analysis

As noted above, little data or analysis exists regarding the interaction of Medicare and private markets for drugs. This calls for close monitoring of commercial prices as the Medicare inflation rebates are implemented. Employers should insist on transparency from their Pharmacy Benefit Managers (PBMs) to enable them to identify significant price increases and major price differences between Medicare and commercial markets. Employers should use this information to work with their PBMs to modify formularies or benefit designs as needed. At the same time, academic researchers, the Medicare Payment Advisory Commission (MedPAC), and federal agencies such as the General Accounting Office should launch studies to better understand the relationship between drug prices in Medicare vs. the private market. This will enable policymakers to understand the impact of the IRA provisions and make adjustments if needed.