

CMS 2026 IRA Price Negotiations Results Likely to Create Upstream and Downstream Effects

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On August 15, 2024, CMS [announced the results](#) of the first round of the negotiated prices between CMS and participating drug manufacturers for the 10 selected drugs under the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program (MPN or Program). In all, reactions to the MPN results varied: *Reuters* reported that [executives from four of the manufacturers selected](#) in the first round of negotiations stated that they do not expect the negotiated prices to significantly impact their businesses; meanwhile, in its press release announcing the maximum fair prices (MFPs), CMS touted an estimated \$1.5 billion in Medicare prescription drug out-of-pocket cost savings for Medicare beneficiaries when the negotiated prices go into effect in 2026.

While it may be too soon to fully understand the potential impact of the negotiated prices, one thing is certain: this historic first round of Medicare price negotiations is likely to cause ripple effects throughout the pharmaceutical supply chain.

Brief Background on IRA MPN

Signed into law in 2022, IRA contains several provisions to lower prescription drug costs for beneficiaries on Medicare. One of those mechanisms is the ability for CMS to negotiate directly with manufacturers to establish drug costs under Medicare Part D (effective in 2026) and Part B (effective in 2028). In September 2023, CMS published a list of 10 selected drugs covered under Medicare Part D for the first cycle of negotiations and engaged in voluntary negotiations with the drug companies for the selected drugs. The August 15, 2024 MPN announcement marked a seminal event in the MPN timeline, establishing government-negotiated rates for drugs with high Medicare Part D expenditures. The negotiated MFPs will be effective as of January 1, 2026.

The [Biden Administration estimates](#) that the MPN will save taxpayers \$6 billion in the first year of the Program alone.

Upstream Effects: Impacts on MPN Litigation

As we discussed in our most recent [IRA Update](#), seven manufacturers of the selected drugs and two trade associations brought lawsuits attempting to block negotiations, asserting statutory and constitutional challenges. Only two cases remain percolating at the district court level (*Merck v. Becerra* and *Novartis Pharmaceuticals Corporation v. Becerra*), while the remaining seven cases have been dismissed or are on appeal. For those cases on appeal with Fifth Amendment challenges, we anticipate the negotiated prices will likely add fuel to any Fifth Amendment Takings Clause arguments. For example, on appeal, if an appellate court was to find that a taking occurred, the next step in this inquiry could be whether the taking was for public use and whether the manufacturers received just compensation. This “just compensation” piece is a fact-specific inquiry and would likely require the court to take a closer look at CMS’ MFP calculations.

The Program’s negotiated prices may also provide more ammunition for certain Administrative Procedure Act (APA) challenges (e.g., *AstraZeneca Pharmaceuticals LP v. Becerra*; *Novo Nordisk v. Becerra*). In *AstraZeneca* and *Novo Nordisk*, the district courts in the third circuit opined that the plaintiffs lacked standing to challenge the lawfulness of CMS guidance under the APA. While the issue of standing took a slightly different shape in *Novo Nordisk* than *AstraZeneca*, the manufacturers’ arguments in both cases would benefit from a stronger showing of redressable injury. With MFPs ranging between 38% to 79% off the drugs’ list prices, appellants may have new evidence to show tangible harms from low MFPs.

The *Chevron* Difference

The impact of the recent Supreme Court case *Loper Bright Enterprises v. Raimondo*, which overturned key portions of the longstanding *Chevron* doctrine and reduced judicial deference to administrative agencies, may provide a new pathway to block negotiation and implementation of MFPs. Assuming a plaintiff could overcome the IRA’s judicial review bar, *Loper Bright* could breathe fresh life into APA challenges to the Program, which has been constructed, at least in part, upon CMS’s interpretation of IRA requirements and implemented through agency guidance and memos.

Downstream Effects: Potential New Challenges for PBMs, Payers, and Health Plans

The impacts of the first round of MPNs will likely be felt on the other end of the pharmaceutical supply chain, on pharmacy benefit managers (PBMs), payers, and plans. [According to HHS](#), these first 10 selected drugs account for about 20% of total Part D gross covered prescription drug costs between June 1, 2022 and May 31, 2023. Therefore, while “only” 10 drugs have been negotiated so far, those drugs composed a significant portion of the prescription drug plan market. When pressure exists on one end of the supply chain, there are inevitable ripple effects on the other end of the supply chain. The negotiated price announcement may push PBMs and manufacturers to recoup costs on other parts of the supply chain through new fees, rebate structures, and financial guarantees for covered drugs. These ripple effects are not limited to federal plans. For example, in response to Medicaid’s removal of average manufacturer price (AMP) cap, manufacturers eliminated rebates across all market segments [causing disruption for commercial and Medicare Advantage plans](#). Similarly, it is likely that the effects of the Negotiation Program will spill into commercial lines of business, potentially creating more contentious negotiations between plans/payors and manufacturers/PBMs.

Looking Ahead

We continue to track litigation on the first round of selected drugs and potential new claims for the

second round of negotiations (CMS will publish the next 15 drugs for negotiation in February 2025). There are certainly potential new plaintiffs watching the circuit courts' responses to these initial lawsuits. There is a strong trend of a circuit court split on other hot button health care legal issues (e.g., reproductive health); however, currently, that does not seem to be the case with IRA's Program litigation. Future plaintiffs can learn from both the apparent circuit court consensus on IRA Program litigation to date and the outcome of the first round of the Program, with the ability to reshape the legal landscape with new claims for the next round of drug negotiations. With respect to PBMs, payers, and plans, we expect to see the practical impact of the MPNs as the new MFPs hit the market in early 2026.

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National Law Review, Volume XIV, Number 233

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