

Battle Lines Drawn with Release of Speaker's Drug Pricing Plan

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Key Points

- On September 19, Speaker Pelosi released a drug pricing plan that includes proposals for Medicare direct price negotiation and international reference pricing.
- The Speaker's plan overlaps with policies contained in the Senate Finance Committee's drug pricing package and the administration's proposed International Pricing Index (IPI) Model, all of which highlight key divides among lawmakers.
- There is a narrow path forward for a year-end deal on drug pricing, and some expect negotiations on the issue could carry into 2020.

House Speaker Nancy Pelosi (D-CA) released her long-awaited prescription drug pricing plan on September 19, the Lower Drug Costs Now Act (**H.R. 3**). The legislation combines Medicare drug price negotiation, international reference pricing, inflationary rebates and several Medicare Part D reforms in a bid to lower prices in the public and commercial insurance markets.

Summary

The centerpiece of the proposal is the establishment of a "Fair Price Negotiation Program" that would require the Secretary of Health and Human Services (HHS) to negotiate prices for at least 25 drugs annually that are among the 250 most costly single-source drugs in Medicare and the U.S. health system in general. Insulin products would also be included in the negotiation program. HHS would negotiate directly with drug manufacturers to establish a "maximum fair price" that is no more than 120 percent of the "Average International Market" (AIM) price, the volume-weighted average of the price in six countries: Australia, Canada, France, Germany, Japan and the United Kingdom. For certain drugs with no international price available, the bill stipulates that the maximum fair price shall not exceed 85 percent of the average manufacturer price. Once selected for inclusion, a drug would remain in the negotiation program at least until a generic or biosimilar competitor comes to market.

The maximum fair price would be applied to Medicare; manufacturers would also be required to offer that price to group and individual health plans in the commercial market. Given the existing Medicaid "best price" law, the maximum fair price would

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also be applicable to Medicaid programs. Manufacturers who overcharge Medicare or fail to offer the negotiated price to other payers would be subject to a steep civil monetary penalty. If a manufacturer refuses to negotiate with HHS, the company will be assessed an escalating excise tax on annual gross sales of the product, starting at 65 percent and increasing by 10 percent each quarter of noncompliance, up to a maximum of 95 percent.

The international pricing provisions of the Lower Drug Costs Now Act bear some similarity to the administration's International Pricing Index (IPI) Model, which was outlined in an Advanced Notice of Proposed Rulemaking (ANPRM) in October 2018. A key distinction is that the IPI Model would apply only to Part B drugs and would rely on private sector vendors to negotiate the internationally indexed payment amounts. While the proposed model would initially focus on single-source products, the ANPRM raises the possibility that it could be expanded to multiple-source drugs in later years of the model. More details on the IPI Model are forthcoming pending the release of a formal proposed rule currently under review at the Office of Management and Budget.

The Lower Drug Costs Now Act also includes several proposals similar to those found in the Senate Finance Committee's Prescription Drug Pricing Reduction Act (S. 2543). The Speaker's plan, for instance, includes inflationary rebates in Medicare Part B and Part D that would require manufacturers to lower their prices or pay a rebate to the government if they have increased the price of a drug above inflation. In contrast to the Senate Finance proposal, which would be indexed to July 2019 Consumer Price Index for All Urban Consumers (CPI-U), the inflationary rebates in the Lower Drug Costs Now Act would be retroactive to 2016, in an effort to reverse significant price increases from recent years. The Speaker's plan makes other significant changes to Part D as well. The legislation would set a \$2,000 out-of-pocket cap on beneficiaries' prescription drug costs, lower than the \$3,100 limit outlined in the Finance Committee's package. The bill also lowers federal reinsurance during the Part D catastrophic coverage phase and replaces the current coverage gap discount program with a new design in which manufacturers would pay a portion of drug costs in both the initial and catastrophic phases.

Notably, the bill would exclude drugs selected for price negotiation from being considered as covered outpatient drugs under the 340B Drug Pricing Program, a provision that raises questions about the impact on hospitals.

Finally, while summary documents state that savings from the plan will be used to expand Medicare benefits for vision, hearing and dental coverage, the legislative language does not include such provisions.

Analysis

In developing the Lower Drug Costs Now Act, Speaker Pelosi sought to strike a middle ground that would satisfy both progressives and more moderate Democrats. H.R. 3 was introduced formally in the House by Energy and Commerce Committee Chairman Frank Pallone (D-NJ), Ways and Means Committee Chairman Richard Neal (D-MA) and Education and Labor Committee Chairman Bobby Scott (D-VA). All three committees plan to mark up the bill, with a floor vote possible as early as late October. If it passes the House, the bill is not expected to advance in the GOP-controlled Senate. However, even House passage alone would allow Democrats to tout some

success on the issue of drug pricing, which the Speaker identified as a priority for the caucus at the start of the 116th Congress.

Meanwhile, Senate Finance Committee Chairman Chuck Grassley (R-IA) has been pressing for his fellow Republicans to support the Prescription Drug Pricing Reduction Act (S. 2543), arguing that any delay will shift the debate toward the more extreme proposals found in Speaker Pelosi's plan. Proponents of the bill planned to combine it with the Lower Health Care Costs Act (S. 1895) reported by the Senate Health, Education, Labor and Pensions (HELP) Committee and several bills advanced by the Senate Judiciary Committee prior to consideration on the Senate floor. The Senate Finance Committee recently released legislative text of the Prescription Drug Pricing Reduction Act, and a revised score from the Congressional Budget Office may follow soon. Despite the notable overlap between the Administration's IPI proposal and H.R. 3, the President has signaled his support for the Finance package and HHS Secretary Alex Azar has applauded the plan as he urges Congressional Republicans to seek a bipartisan agreement on drug prices.

However, many in the GOP remain opposed to the inflationary price caps outlined in the Senate bill, which was reported out of Committee with a majority of Republicans on the panel voting against it. In addition, every Republican on the Senate Finance Committee except Chairman Grassley and Sen. Richard Burr (R-NC) supported an amendment from Sen. Pat Toomey (R-PA) to block implementation of the IPI Model.

Further revisions will be necessary to garner Senate GOP support including modifying the Medicare Parts B and D inflationary rebates, limiting the adoption of the administration's IPI Model and refining manufacturer disclosure requirements. Senate Democrats will also insist on floor votes on controversial issues such as repealing the Medicare Part D non-interference clause, further complicating the path forward.

In short, it will be difficult to wrap up a year-end deal on drug pricing with bipartisan and bicameral support, but not impossible. As Chairman Grassley has acknowledged, negotiations around prescription drug pricing could carry into 2020.

