

H.R. 3

[Members of Congress](#) are considering including certain drug pricing reforms in the infrastructure legislation, despite President Biden not including such reforms in his [American Families Plan](#). These reforms will likely incorporate some, if not all, components of [H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act](#), which was reintroduced on April 22, 2021. This Fact Sheet summarizes some of H.R. 3's strengths and weaknesses.

PRO: Out-of-Pocket Cap for Medicare Beneficiaries

H.R. 3 would cap the out-of-pocket limit on prescription drugs for Medicare beneficiaries at \$2,000. Currently, there is no out-of-pocket cap for the Medicare program. This requirement would [undo previous years' price increases](#) that have risen above inflation and across thousands of drugs. This change would [reduce exposure](#) to high drug costs for nearly 39 million Part D beneficiaries who are not currently receiving low-income subsidies. Aimed Alliance supports this provision because these changes make prescription medications more affordable, and therefore, accessible, for Medicare beneficiaries.

CON: Medicare Negotiation

H.R. 3 would provide the U.S. Department of Health and Human Services (HHS) with the authority to negotiate directly with the manufacturers of 250 Part B and Part D brand medications with no generic or biosimilar alternative. Of those drugs, HHS would negotiate the price for at least 25 drugs beginning in 2024 and 50 drugs in years that follow. Drug manufacturers would also be required to offer the negotiated prices in the private market.

H.R. 3 would allow for Medicare negotiation by repealing a law that currently prohibits negotiations. According to a Congressional Budget Office (CBO) [report](#), this change alone is not likely to lead to any meaningful cost savings. However, H.R. 3 would also levy a steep excise tax of 65 percent to 95 percent on drug makers' gross sales if they refuse to negotiate or agree to a maximum fair price, as determined by HHS. As such, the Medicare negotiation provision is akin to anti-competitive government price controls than true negotiations. And while this excise tax would generate more cost savings, the CBO also found that the tax is likely to lead to a stifling of innovation. In particular, eight to 15 fewer drugs, such as those that could treat cancer or Alzheimer's disease, could

come to market over the next 10 years. While Aimed Alliance supports reducing drug prices, we do not support efforts that result in fewer innovative medications coming to market.

PRO: Spreading Out Cost-Sharing

H.R. 3 would allow Part D and Medicare Advantage enrollees who do not qualify for low-income subsidies to spread out their cost-sharing responsibilities under certain circumstances. More specifically, Medicare beneficiaries could make several payments over the course of a year rather than paying the entire \$2,000 cap upfront. This provision applies to Medicare beneficiaries who would meet the \$2,000 cap when filling their first prescription alone. As with an out-of-pocket cap, Aimed Alliance supports this provision because such changes make prescription medications more affordable, and therefore, accessible, for Medicare beneficiaries.

CON: International Pricing Index

The International Pricing Index (IPI) imposes price controls on certain Part B and Part D prescription drugs similar to those imposed by foreign countries. In particular, the proposal would create a cap for negotiated drug prices equal to 120 percent of the Average International Market (AIM) price paid by Australia, Canada, France, Germany, Japan, and the United Kingdom. It is important to note that patients in countries that have aggressively restricted drug prices have seen reduced access to medications because fewer drugs come to market as compared with the U.S.

Additionally, price caps stifle innovation. As noted, CBO found that eight to 15 fewer new drugs would come to market from 2020-2029, and 30 fewer new drugs in subsequent decades. Another [study](#) by the California Life Sciences Association found that the IPI would reduce the number of drugs brought to market by small and emerging drug makers in California by 88 percent and eliminate over 80,000 biotech research and development jobs nationwide.

PRO: Reinvest in Innovation

Some of the savings garnered from H.R. 3 would be allocated to the National Institutes of Health to fund research for new breakthrough treatments and cures. Funding would support research related to rare diseases and antibiotic resistant bacteria, among other things. It would also support clinical trials for new cures, medical products, and therapies. As such, it could improve patient accesses by resulting in new medications coming to market.

CON: Inflation Rebates

If the price of certain Part B and Part D prescription medications increase faster than inflation, then the drug manufacturer must rebate the revenue difference back, thereby setting government price controls. The base year is set at 2016, so drug companies that have increased their prices since then would have to lower those prices or pay a rebate to the government retroactively. This means that the government is requiring payments for previously settled transactions. Again, this is another provision that could result in a reduction of patient access to certain medications and less funding available for research and development of new medications. It could also result in cost-shifting that may raise prices of other medications, and drug manufacturers could respond by increasing the launch price of new drugs.

PRO: Study on High-Risk, High-Reward Drugs

The bill would require HHS to conduct a study to identify serious, life-threatening, or rare diseases or conditions that lack an FDA-approved treatment and could fill an unmet medical need. It also requires HHS to recommend appropriate incentives that would lead to the development, approval, and marketing of such treatments. As such, it could improve patient accesses by resulting in new medications that meet unmet needs coming to market.

WHERE CAN YOU GET MORE INFORMATION?

For more information, contact Aimerd Alliance:

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