



August 4, 2022

Honorable Jason Smith  
Ranking Member  
Committee on the Budget  
U.S. House of Representatives  
Washington, DC 20515

*Re: Additional Information About Prescription Drug Legislation*

Dear Congressman:

This letter provides additional information that you and your colleagues requested about subtitle I of the reconciliation recommendations of the Senate Committee on Finance regarding prescription drug legislation.<sup>1</sup> You asked about how provisions involving inflation rebates and the negotiation of drug prices would affect launch prices for new drugs and the introduction of new generic drugs.<sup>2</sup> You also asked how a provision to

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<sup>1</sup> See Congressional Budget Office, estimated budgetary effects of subtitle I of reconciliation recommendations for prescription drug legislation (July 8, 2022), [www.cbo.gov/publication/58290](http://www.cbo.gov/publication/58290).

<sup>2</sup> Section 129101, “Medicare Part B Rebate by Manufacturers,” would require manufacturers to pay a rebate on all non-Medicaid sales for drugs covered by Medicare Part B whose average sales price (ASP) in a given year is greater than its ASP in 2021, adjusted for inflation as measured by the consumer price index for all urban consumers. Section 129102, “Medicare Part D Rebate by Manufacturers,” would require manufacturers to pay a rebate on all non-Medicaid sales for drugs covered by Medicare Part D whose average manufacturer price (AMP) in a given year is greater than its AMP in 2021, adjusted for inflation as measured by the consumer price index for all urban consumers.

Section 129001, “Providing for Lower Prices for Certain High-Priced Single Source Drugs,” would require the Secretary of Health and Human Services to negotiate prices for a set number of drugs that account for the largest amount of spending in Medicare Parts B and D and have been on the market for specified lengths of time: at least 7 years for small-molecule drugs and 11 years for biologic drugs. Those negotiated prices would serve as upper limits for prices in the Medicare program.

stabilize premiums as a part of the redesign of Medicare's benefits would affect the federal budget and premiums.<sup>3</sup>

### **Effect of the Inflation-Rebate and Negotiation Provisions on Launch Prices**

The Congressional Budget Office projects that 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 (sections 129101 and 129102), which would begin to apply to prices within 12 months of a given drug's entering the market. Under those provisions, manufacturers would have an incentive to launch new drugs at a higher price to offset slower growth in prices over time. The negotiation provision (section 129001) would have less of an impact on launch prices, CBO expects: Although the ceiling for a drug's negotiated price is based on its price from a prior year, negotiation could not occur until drugs were on the market for a number of years—at least 7 for small-molecule drugs and 11 for biologics.

Higher launch prices would primarily affect spending for drugs in the Medicaid program, CBO projects, because an increase in that program's basic rebate brought about by the higher launch prices would only partly offset those prices.<sup>4</sup> Higher launch prices would also tend to affect spending for drugs covered by Part B of the Medicare program because that program's payments for those drugs are based on the average sales prices. Over time, slower price growth would attenuate the effect of higher launch prices.

In the commercial and Medicare Part D segments of the market, spending would be less affected by higher launch prices, CBO estimates, because

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<sup>3</sup> Section 129201, "Medicare Part D Benefit Redesign," would limit the growth of base premiums for Medicare Part D to no more than 6 percent per year over the 2024–2029 period. Overall, the section would eliminate the coverage gap phase of the prescription drug benefit under current law, cap out-of-pocket spending at the catastrophic threshold, and change the calculation of discounts for manufacturers. The section would also align the design of the standard benefit for enrollees who receive the low-income subsidy with that for enrollees who do not receive it.

<sup>4</sup> Medicaid's basic rebate for most brand-name drugs is equal to 23.1 percent of the average manufacturer price (AMP) or to the largest rebate granted to a private payer (excluding Medicare Part D plans), whichever is greater. In many cases, CBO expects that the basic rebate for newly launched drugs would equal 23.1 percent of the AMP; with a higher launch price, the basic rebate would be larger than before but less than the increase in the launch price.

manufacturers would have more flexibility to manage rebates to maximize their revenues in those sectors.

### **Effect of the Negotiation Provision on the Introduction of New Generic Drugs**

CBO has not analyzed the effects of the negotiation provision on the introduction of new generic drugs. In projecting the effects of the negotiation provision, CBO estimated the share of spending that would be subject to negotiation each year and the average reduction in prices that would stem from the negotiations. But the agency did not analyze how the provision would affect prices or spending on specific drugs, nor did it quantify any impact on the introduction of new generic drugs.

### **Effects of the Premium-Stabilization Provision**

Under the premium-stabilization provision (section 129201), the federal government would subsidize any growth in beneficiaries' base premiums for Medicare Part D exceeding 6 percent from one year to the next over the 2024–2029 period. The provision subsequently would lower the base premium percentage (the percentage of the average cost of standard Part D coverage that is used to calculate beneficiaries' premiums) to ensure that premiums did not grow by more than 6 percent between 2029 and 2030.<sup>5</sup> That subsidy and subsequent reduction in premiums would increase federal spending by roughly \$40 billion over the 2024–2031 period, CBO estimates. Beneficiaries' spending on premiums would be lower under the premium-stabilization provision than it would be without it.

That estimate is an average effect among the possible paths of premiums that CBO considered when modeling the uncertainty of future outcomes. Under some of those paths, premiums would grow by less than 6 percent a year, and the provision would have no cost; under others, premiums would grow faster, and the provision would generate costs.

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<sup>5</sup> That reduction in the base premium percentage is capped so that it cannot fall below 20 percent of the average cost of standard Part D coverage. If restraining premium growth to 6 percent would require reducing that percentage below 20 percent, then the percentage would be set at 20 percent, and base premiums would grow somewhat more than 6 percent from 2029 to 2030.

Honorable Jason Smith

Page 4

I hope this information is useful to you and your colleagues. Please contact me if you have further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Phillip L. Swagel", with a long, sweeping flourish extending to the right.

Phillip L. Swagel  
Director

cc: Honorable Kevin Brady  
Ranking Member  
House Committee on Ways and Means

Honorable Cathy McMorris Rodgers  
Ranking Member  
House Committee on Energy and Commerce

Honorable John Yarmuth  
Chairman  
House Committee on the Budget

Honorable Richard Neal  
Chairman  
House Committee on Ways and Means

Honorable Frank Pallone, Jr.  
Chairman  
House Committee on Energy and Commerce