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March 3, 2016

The Honorable Ron Wyden
Ranking Member
U.S. Senate Finance Committee

The Honorable Charles E. Grassley
U.S. Senate Finance Committee

RE: Comments to Report on “The Price of Sovaldi and its Impact on the U.S. Health Care System”

Dear Ranking Member Wyden and Senator Grassley:

The Center on Budget and Policy Priorities is a nonpartisan research and policy organization based in Washington, D.C. Founded in 1981, the Center conducts research and analysis to inform public debates and policymakers about a range of budget, tax and programmatic issues affecting individuals and families with low or moderate incomes.

We thank you for your comprehensive report investigating how Gilead Sciences, Inc., developed, priced, marketed and sold the hepatitis C drug Sovaldi and its follow-on drug Harvoni. The report provides welcome transparency on how high drug prices for breakthrough innovator drugs can adversely affect public payers like Medicare and Medicaid and particularly in the case of Medicaid, restrict patient access to needed care. As our comments below explain, we believe that rebates are one effective policy tool for both Medicaid and Medicare to address the impact of high-cost drugs and corresponding access restrictions.

1. Medicaid

As the report points out, in order to have their prescription drugs covered by Medicaid, brand-name manufacturers provide mandatory drug rebates to the federal government and the states equal to the higher of a minimum rebate (23.1 percent of the Average Manufacturer Price or AMP) and the “best price” or discount available to other private and public purchasers.¹ In addition, manufacturers of both brand-name and generic drugs must pay an additional rebate if their drug prices rise faster than inflation. According to the Medicaid and CHIP Payment and Access

¹ The minimum drug rebate for generic drugs is equal to 13 percent of the AMP.

Commission (MACPAC), these rebates successfully reduced total gross federal and state Medicaid prescription drug spending by about 46 percent in fiscal year 2014.²

The report finds, however, that states like Oregon are concerned that existing rebates provide only limited help in mitigating the financial impact of breakthrough high-cost drugs like Sovaldi. We therefore recommend that you consider increasing the mandatory minimum drug rebate for certain high-cost specialty or biological brand-name drugs where there is no competing entity or only one additional entity in the same therapeutic sub-class. That could provide additional fiscal relief to state Medicaid programs and better ensure that low-income Medicaid beneficiaries have appropriate access to needed, breakthrough treatments.

Alternatively, the Administration has also proposed to establish a federal-state Medicaid negotiating pool to obtain supplemental rebates for certain high-cost prescription drugs. It has also proposed other sound improvements to improve the Medicaid drug rebate program. The Administration estimates that together such proposals would produce \$11.4 billion in federal savings over 10 years (with states accruing additional savings as well).³

2. Medicare

Unlike in Medicaid, there are no federally-required minimum drug rebates for manufacturers as a condition of Medicare Part D coverage of prescription drugs. Rather, the private plans that deliver the Medicare Part D drug benefit must negotiate their own rebates from manufacturers. The report, however, highlights that in the case of breakthrough drugs like Sovaldi, manufacturers have minimal incentive to offer price discounts to Part D plans if there is little or no competition in the same therapeutic class and if manufacturers are confident that drugs will be included in Part D plan formularies.

Moreover, research indicates that overall, private plans have done a comparatively poor job of negotiating rebates from drug manufacturers. Prior to the creation of Part D, “dual eligibles” (people enrolled in both Medicare and Medicaid) received drug coverage through Medicaid. When Congress enacted the Medicare drug benefit, it assumed that the private insurance companies participating in Part D would negotiate larger discounts from drug manufacturers than those that Medicaid requires.⁴

In reality, the private insurers offering Part D coverage get significantly smaller rebates than Medicaid does for the same drugs. For example, in 2009, for the top 100 brand-name drugs with the highest total Part D costs, Medicaid drug rebates were *three times* larger on a per-unit basis than

² Medicaid and CHIP Payment and Access Commission, “MACStats: Medicaid and CHIP Data Book,” December 2015, <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2015.pdf>.

³ U.S. Department of Health and Human Services, “Fiscal Year 2017: Budget in Brief,” February 2016, <http://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf>.

⁴ Under the “best price” provision, drug manufacturers must provide state Medicaid programs the same level of rebates that they provide most other public and private purchasers for the retail class of trade if the rebates that they provide to other purchasers exceed certain minimum amounts. As part of the Medicare drug law, Congress specifically excluded Medicare Part D rebates from the calculation of best price because of concerns that the best price provision could interfere with the expected ability of private plans to negotiate larger rebates than those required under Medicaid.

the median rebate negotiated by private Part D plans, according to the HHS Office of Inspector General. As a result, the Medicaid cost per drug (net of rebates) was lower than the net Medicare cost for all but seven of these 100 drugs. Overall, the rebates that Medicaid obtained in 2009 reduced Medicaid spending for these drugs by 45 percent, while the rebates obtained by Medicare Part D plans reduced Medicare costs by just 19 percent.⁵ Medicare thus pays substantially more than Medicaid does for the same drugs, which results not only in higher program costs but also in higher Part D premiums for beneficiaries (and larger profits for drug manufacturers).

Requiring that Part D get the same rebates as Medicaid does just for drugs that Part D covers for low-income Medicare beneficiaries (the large majority of whom are dual eligibles), as both Senator Nelson (S. 1083) and the Obama Administration has proposed, would reduce Part D costs by \$121 billion over the next ten years, according to a 2015 Congressional Budget Office estimate of the Administration's proposal from last year.⁶ Requiring Medicaid-level rebates for *all* Part D beneficiaries, as well as increasing the minimum Medicaid drug rebate for certain breakthrough high-cost brand-name specialty and biological drugs as we recommend above, would produce even greater Medicare savings.

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Thank you again for this opportunity to provide comments to the Sovaldi report. Please let us know if you have questions or if we can be of any further assistance.

Sincerely,



Edwin Park
Vice President for Health Policy
Center on Budget and Policy Priorities

⁵ The gap between Medicaid and Medicare rebates is likely larger today because the Affordable Care Act significantly increased Medicaid drug rebates starting in 2010. See HHS Office of Inspector General, "Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D," August 2011.

⁶ Congressional Budget Office, "Proposals for Health Care Programs — CBO's Estimate of the President's Fiscal Year 2016 Budget," March 12, 2015, https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/dataandtechnicalinformation/50013-HealthPolicy_0.pdf.