Health Policy Institute
CENTER FOR CHILDREN AND FAMILIES

**VIA ELECTRONIC SUBMISSION**

June 29, 2018

Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW, Room 600E
Washington D.C 20201

Re: RIN 0991-ZA49 Comments to HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Sir or Madam:

As part of the McCourt School of Public Policy, the Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center that conducts research, develops strategies and offers policy solutions to improve the health of America's children and families, particularly those with low- and moderate-incomes.

We appreciate the opportunity to make the following comments to the HHS Blueprint. Our general and specific comments focus on the Medicaid program. Prescription drugs are essential for the health of tens of millions of low-income children enrolled in Medicaid, including not only routine care but also treatment and maintenance for chronic conditions such as asthma or attention deficit hyperactivity disorder, illnesses like childhood cancers and serious behavioral health issues, and rarer conditions such as cystic fibrosis, Gaucher's disease and spinal muscular atrophy.[1] The Medicaid Drug Rebate Program (MDRP) is highly successful in significantly reducing state Medicaid prescription drug costs, while ensuring access to needed prescription drugs for low-income individuals and families who rely on Medicaid today. It is thus achieving the intent of the Drug Rebate Program, when it was enacted in 1990, to make prescription drugs much more affordable for state Medicaid programs and low-income beneficiaries by ensuring that Medicaid gets among the largest discounts, and thus among the lowest effective prices, available to any payer. Medicaid obtains rebates that are far larger than those in Medicare Part D and in private insurance.

As a result, to better help state Medicaid programs address rising drug costs and ensure continued access to needed prescription drugs for low-income Medicaid beneficiaries such as children and families, the top priority for HHS should be to improve and strengthen the Medicaid Drug Rebate Program, not weaken or undermine it.

[1] Jack Hoadley and Joan Alker, "How Medicaid and CHIP Shield Children from the Rising Costs of Prescription Drugs," Georgetown University Center for Children and Families, July 2017, https://ccf.georgetown.edu/wp-content/uploads/2017/07/Prescription-drugs-v3-link-fix.pdf.

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## 1. General Comments: Medicaid Drug Rebate Program Is Highly Effective

Under the Medicaid Drug Rebate Program (MDRP) today, drug manufacturers must provide rebates to the federal government and states as a condition of having their drugs covered by Medicaid. (They must also agree to participate in the 340B program and provide discounts to the Veterans Administration, among others.) For example, in the case of brand-name drugs, manufacturers must pay rebates equal to 23.1 percent of the Average Manufacturer Price (AMP) or the AMP minus the "best price" provided to most other purchasers, whichever is greater. (The AMP is generally the average price paid by wholesalers for drugs distributed to retail community pharmacies.) For generic drugs, rebates equal 13 percent of the AMP. Manufacturers must also pay additional rebates for both brand-name and generic drugs if their prices rise faster than general inflation.[2] Nearly all states also directly negotiate with manufacturers (or negotiate together as part of a multi-state purchasing pool) for voluntary supplemental rebates on top of these federally required rebates.[3]

These rebates are substantial, demonstrating the effectiveness of the Medicaid Drug Rebate Program in lowering prescription drug costs for state Medicaid programs, which was the intent of the Rebate Program when it was enacted in 1990. According to the Medicaid and CHIP Payment and Access Commission (MACPAC), in federal fiscal year 2016, drug manufacturers paid $31.2 billion in rebates to the federal government and the states, lowering Medicaid prescription drug costs by 51.3 percent.[4] In contrast, data from the 2018 Medicare Trustees report shows that the rebates negotiated between private insurers and drug manufacturers lowered Medicare Part D costs by only 19.9 percent in 2016.[5]

Other analysis has similarly found that the drug rebates manufacturers pay in Medicaid are far larger than what Medicare Part D plans receive. For example, among select brand-name drugs with the highest Part D expenditures, the HHS Office of Inspector General previously

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[2] Medicaid and CHIP Payment and Access Commission, "Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress" June 2018, https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf.

[3] National Conference of State Legislatures, "Pharmaceutical Bulk Purchasing: Multi-State and Inter-Agency Plans," May 31, 2018, http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx and Medicaid and CHIP Payment Access Commission, "Medicaid Payment for Outpatient Prescription Drugs," May 2018, https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.

[4] Medicaid and CHIP Payment and Access Commission, "MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2016," December 2017, https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/.

[5] "2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," June 2018 (see Table IV.B8), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf

determined that the median "unit rebate amount" rebate was about three times larger than under Part D in 2012 and ten times or more for many drugs.[6] Altarum recently estimated that relative to the full retail or "point of purchase" price for brand-name drugs, Medicaid receives rebates of about 61 percent, while Medicare Part D plans obtain rebates of about 31 percent and private insurance plans negotiate rebates of only about 16 percent.[7] In addition, preliminary results from an analysis conducted by the Congressional Budget Office finds that for the 50 top-selling brand-name specialty drugs in Medicare Part D in 2015, the weighted average Medicaid rebate for these specialty drugs in 2015 were more than three times larger than rebates in Medicare Part D. Medicaid rebates reduced the weighted average price per specialty drug prescription (net of rebates and discounts) by nearly 56 percent, compared to nearly 18 percent in Medicare Part D.[8]

In exchange for these rebates, except for a very limited set of drug classes, state Medicaid programs cannot outright deny coverage of drugs produced by manufacturers participating in the drug rebate program. In addition, children enrolled in Medicaid receive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit which ensures that children can obtain any drugs their practitioners determine they need as the result of a screening and diagnosis. Medicaid also limits co-payments that may be charged on each prescription to nominal amounts, and for most children on Medicaid, co-payments and other cost-sharing are prohibited entirely. Together, these protections help ensure that low-income Medicaid beneficiaries including children and families have access to the prescription drugs they need.[9]

State Medicaid programs, however, have other considerable tools to lower drug costs and manage drug utilization. For example, nearly all states use preferred drug lists and require prior authorization for certain prescription drugs, often in conjunction with supplemental rebate negotiations. They can require "step therapy" under which a beneficiary must first try other drugs within the same drug class. States also can require generic substitution when a generic version of a drug is available, and deny coverage for drugs that are not used for a medically accepted indication. In addition, state Medicaid programs also must operate drug utilization review (DUR) programs. This includes screening prospectively for duplication, contraindications, interactions with other drugs, incorrect dosage and abuse and misuse as well as retrospectively reviewing claims and other data for overuse, inappropriate or medically unnecessary care, appropriate use of generics and fraud and

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[6] Office of Inspector General, U.S. Department of Health and Human Services, "Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin," April 2015, https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf.

[7] Charles Roehring, "The Impact of Prescription Drug Rebates on Health Plans and Consumers," Altarum, April 2018, https://altarum.org/publications/the-impact-of-prescription-drug-rebates-on-health-plans-and-consumers.

[8] Anna Anderson-Cook, Jared Maeda and Lyle Nelson, "Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid," Congressional Budget Office, June 11, 2018, https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/53929presentation.pdf.

[9] Hoadley and Alker, *op cit*.

abuse. Many states also conduct provider education to ensure appropriate prescribing patterns on the part of physicians and other health professionals.[10]

While the Medicaid Drug Rebate Program is already highly effective, state Medicaid programs need additional tools and assistance in addressing the twin drug pricing problems of high launch prices and excessive annual price increases, such as those we recommend below. That being said, it is critical that HHS should only consider Medicaid policy proposals that build on, improve and strengthen the Rebate Program. Conversely, it should reject any policy proposals that would have the effect of weakening or undermining the Rebate Program, which would result in higher federal and state Medicaid drug costs. HHS should also reject Medicaid drug pricing policy proposals that could have an adverse impact on access to needed prescription drugs among low-income beneficiaries, including millions of children and families and people with disabilities. As MACPAC recently stated, policymakers must not only consider how to rein in Medicaid drug spending but "must also consider how such efforts would affect Medicaid beneficiaries' access to therapies that extend lives and improve health and functional status."[11]

**2. Specific Comments: Recommendations to Strengthen the Medicaid Drug Rebate Program**

To build on, improve and strengthen the existing Medicaid Drug Rebate Program, we recommend the following policies:

- *Require increases in the minimum base rebate for new brand-name drugs with excessive launch prices.* To help state Medicaid programs address the cost of new brand-name drugs, such as specialty drugs, with very high launch prices, the minimum percentage for the Medicaid base rebate should be increased above 23.1 percent. The percentage increase would escalate as the launch prices exceed certain tiered thresholds. This would not only allow states to better afford the cost of new brand-name drugs with launch prices of tens of thousands or hundreds of thousands of dollars but also help deter manufacturers from setting such high initial prices.

- *Uncap total Medicaid drug rebate amounts*. We agree with the Blueprint that the Affordable Care Act's limit on total Medicaid drug rebates on both brand-name and generic drugs to 100 percent of AMP undermines the effectiveness of Medicaid's inflation-related rebates in discouraging manufacturers from instituting excessive annual price increases. It is clear that when Congress enacted the 100 percent of AMP limit, it did not anticipate the very large year-to-year price increases for both

[10] As permitted under federal law, some states also set arbitrary, numerical limits on the number of prescription drugs that will be covered in any given month, even for people with multiple chronic conditions who require many prescription drugs. This can severely restrict access to needed drugs. Children, however, are not subject to these limits under EPSDT requirements.

[11] Medicaid and CHIP Payment and Access Commission, "Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress," *op cit*.

brand-name and generic drugs that have occurred in recent years. For example, assume a new brand-name drug has an initial AMP of $100 but has annual price increases that double the price. By the fourth year, state Medicaid programs would no longer be fully shielded from annual price increases because of the 100 percent of AMP limit (assuming the base rebate amount is equal to the minimum rebate percentage of 23.1 percent of AMP and general inflation of 2.4 percent). Without the 100 percent of AMP limit, the manufacturer would otherwise owe a total of $877 in rebates per unit, with inflation-related rebates constituting 80 percent of that amount. But because of the 100 percent of AMP limit, the manufacturer would only owe $800.

Eliminating the 100 percent of AMP cap, while retaining and strengthening the rest of the Medicaid Drug Rebate Program, would thus ensure that state Medicaid programs receive rebates equal to the full amount of such percentage price increases in excess of general inflation. That would have the benefit of helping state Medicaid programs better address excessive annual drug price increases while also seriously deterring manufacturers from instituting such increases.

- *Increase inflation-related rebates to discourage excessive price increases*. To further deter the increasingly common tactic of manufacturers substantially hiking the price of existing drugs, the Medicaid inflation-related rebates for both brand-name and generic drugs should be further increased if annual price increases exceed certain thresholds. Manufacturers would be subject to an escalating add-on inflation-related rebate (that is, the inflation-related rebate they would otherwise owe would be increased by certain percentages and such increases would be set on a tiered basis so that the amount of the add-on would rise with the size of the annual percentage price increase).

- *Include all Pharmacy Benefit Manager (PBM) rebates in calculation of best price.* The Blueprint notes that some rebates negotiated by pharmacy benefit managers (PBMs) in the private insurance market are excluded from best price in the Medicaid Drug Rebate Program. (Rebates that are passed on to the retail or provider level are included in best price.[12]) We believe that HHS should reconsider this exclusion and amend the best price regulations to include PBM rebates in the determination of best price. Because private insurers in both the employer-based and individual markets increasingly rely on PBMs to negotiate rebates and discounts on their behalf, it is appropriate that such rebates be included in best price. That would have the effect of increasing base Medicaid rebates for certain drugs and thus lowering overall federal and state Medicaid prescription drug costs.

- *Conduct periodic audits on drug manufacturers to ensure better rebate compliance.* Currently, the Centers of Medicare and Medicaid Services has no systematic review process to ensure the accuracy of the information reported by manufacturers under

[12] 42 C.F.R. § 447.505(c)(17)

the Medicaid Drug Rebate Program (AMP, best price, classification of drugs as brand-name or generic, etc.). We recommend a new mandatory process under which CMS would conduct periodic audits of manufacturers participating in the Drug Rebate Program. Each manufacturer would be subject to an audit on a rolling basis (i.e. once every three or five years). The audits would verify the accuracy of the pricing information submitted as well as of the methods, assumptions and underlying data manufacturers used. This would ensure better compliance with the requirements of the Drug Rebate Program and that manufacturers are fully paying the rebates they owe to state Medicaid programs.

- *Give states full access to Medicaid pricing data on a confidential basis.* AMP and best price information reported by manufacturers is confidential and not shared by the Centers for Medicare and Medicaid Services with the states. Even the Medicaid and CHIP Payment and Access Commission lacks access to specific unit rebate amounts in conducting analysis of the Drug Rebate Program.[13] This means, for example, that states do not know how the supplemental rebates they negotiate with manufacturers compare to federally required rebates. They also cannot help enforce manufacturer compliance with the Medicaid Drug Rebate Program by checking pricing information they may obtain (such as from pharmacies, wholesalers and Pharmacy Benefit Managers licensed by the state) with the information submitted to CMS. Sharing such pricing information with states would better ensure manufacturer compliance with the Medicaid Drug Rebate Program as well as help states negotiate larger supplemental rebates, among other purposes.

- *Bar manufacturer gaming using "authorized generics" to lower rebate amounts.* As the Medicaid and CHIP Payment and Access Commission has noted, manufacturers that make their own generic version of their drugs (known as "authorized generics") can artificially lower the Medicaid rebates they pay. Drug companies sometime sell the authorized generic version of their brand-name drug to another manufacturer so that it can be distributed. But if that second company has a corporate relationship with the brand-name drug company (for example, they have the same parent company), the brand-name company may intentionally charge a much lower "transfer" price than it would otherwise charge another manufacturer or wholesalers. This would have the effect of lowering the Medicaid rebates the manufacturer pays for its brand-name drug because the formula used to determine rebate amounts takes into account the price of authorized generics. In other words, manufacturers can game the rebate program through this approach and reduce the rebates they otherwise would owe to state Medicaid programs. MACPAC thus recommends eliminating these types of authorized generic transactions from the calculation of rebates.[14]

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[13] Medicaid and CHIP Payment and Access Commission, Transcript: Public Meeting, September 15, 2017, https://www.macpac.gov/wp-content/uploads/2016/10/September-2017-MACPAC-meeting-transcript.pdf.

[14] Medicaid and CHIP Payment and Access Commission, "Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress," *op cit*. See also Edwin Park, "MACPAC Report Recommends Sound Improvements to Medicaid Drug Rebate Program," Say Ahhh! Blog, Georgetown

- *Give HHS better enforcement tools to prevent manufacturers from misclassifying drugs to lower their rebate amounts.* Some manufacturers have inappropriately and inaccurately classified some of their brand-name drugs as generics in order to reduce how much they pay in rebates. For example, the minimum rebate for generic drugs is 13 percent of Average Manufacturer Price (AMP), while the minimum rebate for brand-name drugs is 23.1 percent of AMP. Moreover, generic drugs are not subject to the "best price" requirement like brand-name drugs are. According to the Medicaid and CHIP Payment and Access Commission, to address the problem of misclassification, the Secretary should be given the explicit authority to impose civil monetary penalties on manufacturers for misclassification and to directly change the classification of a drug.[15] That's because it is unclear whether the Secretary currently has the authority to impose these intermediate-level sanctions. (The Secretary can always end Medicaid coverage of all of a manufacturer's drugs but the Centers for Medicare and Medicaid Services have never used this termination authority to sanction misclassification.)

**3. Specific Comments: Recommendations to Extend Effective Medicaid Rebate Program to Lower Costs in Other Federal Health Programs**

To lower costs in other federal health programs like the Children's Health Insurance Program (CHIP) and Medicare Part D, we recommend extending Medicaid rebates to those programs:

- *Extend Medicaid rebates to separate state CHIP programs.* Unlike for CHIP-funded Medicaid coverage, the Medicaid Drug Rebate Program does not apply to separate state CHIP programs. As discussed below, it is very likely that managed care plans contracting with separate state CHIP programs are obtaining considerably smaller rebates than what is now required under Medicaid. Extending the Medicaid Drug Rebate Program to separate state CHIP programs would thus help lower CHIP prescription drug costs.[16] That would provide financial assistance to states facing a decline in the currently enhanced federal CHIP matching rate to the regular CHIP matching match after 2020.

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University Center for Children and Families, June 19, 2018, https://ccf.georgetown.edu/2018/06/19/macpac-report-recommends-sound-improvements-to-medicaid-drug-rebate-program/.

[15] Medicaid and CHIP Payment and Access Commission, "Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress," *op cit*. See also Edwin Park, "MACPAC Report Recommends Sound Improvements to Medicaid Drug Rebate Program," Say Ahhh! Blog, Georgetown University Center for Children and Families, June 19, 2018, https://ccf.georgetown.edu/2018/06/19/macpac-report-recommends-sound-improvements-to-medicaid-drug-rebate-program/.

[16] Hoadley and Alker, *op cit*.

- *Extend Medicaid-level rebates to Medicare Part D for low-income beneficiaries.* Prior to Medicare Part D, low-income individuals eligible for both Medicare and Medicaid received their drug coverage from Medicaid, which was subject to the Medicaid Drug Rebate Program. As discussed further below, when Congress enacted Medicare Part D, it assumed that Medicare Part D insurers would negotiate larger discounts from drug manufacturers than those that Medicaid required. Even before the Affordable Care Act's improvements to the Drug Rebate Program, Part D insurers obtained significantly smaller rebates than Medicaid did for the same drugs. For example, in 2009, among the top 100 brand-name drugs with the highest Part D expenditures, Medicaid drug rebates were three times higher on a per-unit basis than the median Part D rebate, according to the HHS Office of Inspector General. The Medicaid cost per drug (net of rebates) was found to be lower than the net Medicare cost for all but seven of these 100 drugs.[17]

As a result, moving drug coverage from Medicaid to Medicare for the dual eligibles thus resulted in significant financial windfalls in 2006 for manufacturers whose products were disproportionately used by dual eligibles.[18] As noted above, the gap between Medicaid and Medicare Part D rebates continues to be substantial, with Medicaid doing a far better job in lowering drug costs than Medicare. For example, a recent HHS Office of Inspector General report found that Medicare Part D spending on brand-name drugs, net of rebates, increased by 62 percent between 2011 and 2015. For nearly half of all brand-name drugs reimbursed by Part D, unit costs increased by at least 50 percent and for 12 percent of such drugs, unit costs at least doubled.[19]

Extending the effectiveness of the Medicaid Drug Rebate Program to Part D could thus significantly help address rising Medicare Part D costs. The Congressional Budget Office estimates that imposing Medicaid-level rebates for low-income beneficiaries in Medicare Part D would produce federal savings of $145 billion over ten years.[20]

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[17] HHS Office of Inspector General, "Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D," August 2011, https://oig.hhs.gov/oei/reports/oei-03-10-00320.pdf. See also Edwin Park and Matt Broaddus, "Lower-Than-Expected Medicare Drug Costs Mostly Reflect Lower Enrollment and Slowing of Overall Drug Spending, Not Reliance on Private Plans," Center on Budget and Policy Priorities, https://www.cbpp.org/research/lower-than-expected-medicare-drug-costs-mostly-reflect-lower-enrollment-and-slowing-of?fa=view&id=3775.

[18] See Richard Frank and Joseph Newhouse, "Mending the Medicare Prescription Drug Benefit: Improving Consumer Choices and Restructuring Purchasing," The Hamilton Project at the Brookings Institution, April 2007; Stephen Schondelmeyer, Statement before the Minority Office of the House Committee on Government Reform, January 2006; and House Committee on Oversight and Government Reform, "Medicare Part D: Drug Pricing and Manufacturer Windfalls," July 2008.

[19] HHS Office of Inspector General, "Increases in Reimbursement for Brand-Name Drugs in Part D," June 2018, https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp.

[20] Congressional Budget Office, "Options for Reducing the Deficit: 2017 to 2026," December 2016, https://www.cbo.gov/publication/52142.

Applying Medicaid-level rebates to all of Medicare Part D would produce even greater savings.

**4. Specific Comments: Administration Medicaid Rebate Demonstration Proposal Raises Serious Concerns for Beneficiaries, Unlikely to Reduce Costs**

The Blueprint touts the Administration's fiscal year 2019 budget proposal to allow up to five states to opt out of the Medicaid Drug Rebate Program to test whether they could negotiate directly with drug manufacturers and obtain larger rebates than what the Rebate Program provides today. The apparent, flawed assumption underlying the proposal is that states would somehow have greater leverage with manufacturers than under the current Rebate Program because they could now establish a fully closed formulary, under which certain drugs (or even entire classes of drugs) could be excluded from coverage.

However, as noted above, current Medicaid rebates are significantly larger — two to three times greater — than what are negotiated by Medicare Part D insurers who can use restricted or closed formularies (except in the case of select protected classes). Medicaid rebates are also much greater than those negotiated by private insurance plans which can have closed formularies without any protected classes. Altarum, for example, estimates Medicaid obtains rebates that are nearly four times larger than those negotiated by insurers in the private insurance markets.[21]

In addition, more than half of current Medicaid rebates comes from the inflation-related rebates — accounting for 54 percent of total rebates for selected drugs in 2012[22] — rather than the base rebate, even though the base rebate is likely to be the primary focus of negotiations between states and manufacturers and the current base rebate is already guaranteed to be at least as large as the "best price" discount provided to most payers. Finally, states participating in the demonstration would not even know how the rebates they negotiate compare to current rebate levels, as best price data reported by manufacturers and unit rebate amounts calculated by the Centers for Medicare and Medicaid Services is confidential and not shared by the federal government with the states.

Moreover, the voluntary supplemental rebates that nearly all states now negotiate for at least some drugs (either on their own or as part of multi-state purchasing pools) are relatively small — 3 to 6 percent above the federal rebate amounts — according to one study conducted by a Pharmacy Benefit Manager contracting with state Medicaid programs.[23] Those rebates are also derived from preferred drug lists, under which states require prior authorization before a drug is dispensed. While these drug lists are not true

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[21] Roehring, *op cit*.

[22] Office of Inspector General, *op cit*.

[23] Douglas Brown, "State Levers for Managing Medicaid Prescription Drug Utilization and Costs," Magellan Health, December 2017, https://www.macpac.gov/wp-content/uploads/2017/12/State-Strategies-for-Managing-Prescription-Drug-Spending.pdf.

closed formularies, they operate under a similar approach: manufacturers provide supplemental rebates in exchange for their drugs being placed on the preferred, rather than non-preferred, Medicaid drug list.

As a result, it is highly unlikely that were it to be enacted, the Administration's budget proposal for a five-state demonstration project would produce savings and it may actually increase federal Medicaid costs if the negotiated rebates turn out to be less than current rebate amounts, as is very likely. The Congressional Budget Office estimates no savings from this proposal.[24] Even HHS and the Office of Management and Budget is skeptical that the demonstration will actually yield lower costs; it estimates that the proposal would only reduce federal Medicaid spending by $35 million over five years and $85 million over ten years.[25]

It is far more likely that if the demonstration were implemented and yields any substantial reduction in Medicaid drug costs among the participating states, it would only be the result of states unduly restricting access to needed drugs. In other words, there may be a negative volume effect — from beneficiaries not getting the drugs they require — than any price effect. The Administration proposal still includes no detail on what standards or requirements would apply to participating states in setting their closed formularies. Could drugs or entire drug classes be excluded solely based on cost, rather than any clinical criteria? How would drug classes be defined? Even for on-formulary drugs, would states be able to impose stringent prior authorization requirements that are inconsistent with clinical practice standards?

The only requirement in the proposal is that there would be "an appeals process so beneficiaries can access non-covered drugs based on medical need". But it is likely that any such appeals process would be substantially weaker and more burdensome and time-consuming than what must be provided under current law. (For example, state Medicaid programs must now respond to prior authorization requests within 24 hours, and provide a 72-hour supply in emergency situations.) Low-income Medicaid beneficiaries, especially the most vulnerable like people with disabilities and chronic conditions, would thus be at risk of going without needed drug treatments if the medications they need are simply dropped from Medicaid formularies due to cost or they cannot satisfy overly restrictive clinical requirements. Initial state actions to impose unduly restrictive prior authorization and coverage criteria of very high-cost drugs that treat Hepatitis C in apparent violation of the requirements of the Medicaid Drug Rebate Program are instructive and could be an indication of what states participating in the demonstration

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[24] Congressional Budget Office, "Proposals Affecting Health Programs in Budget Function 550 — CBO's Estimate of the President's Fiscal Year 2019 Budget," Revised May 31, 2018, https://www.cbo.gov/system/files/115th-congress-2017-2018/dataandtechnicalinformation/53903-healthprograms_0.pdf.

[25] U.S. Department of Health and Human Services, "Fiscal Year 2019: Budget in Brief," February 2018, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

project may do with any new closed formulary authority.[26] (Later, starting in January 2015, more than half of the states including the District of Columbia collectively negotiated substantial supplemental rebates with manufacturers of Hepatitis C.[27])

For the above reasons, we strongly urge HHS to drop the Administration's Medicaid drug demonstration proposal as part of the Administration's ongoing drug pricing efforts.

**5. Specific Comments: Blueprint Includes Misleading Claim Tying Medicaid Rebates to Drug Price and Spending Growth, Does Not Withstand Scrutiny**

The Affordable Care Act reduced federal and state Medicaid prescription drug costs by increasing the minimum base rebate for brand-name drugs from 15.1 percent to 23.1 percent, increasing the base rebate for generic drugs from 11 percent to 13 percent, and extending the Medicaid Drug Rebate Program to Medicaid managed care plans. The Blueprint, however, argues that these improvements to the Medicaid Drug Rebate Program may have led drug manufacturers to substantially raise overall prices, implying that they have been somehow a major contributor to rising drug prices (for both new and existing drugs) and significant prescription drug spending growth in recent years.

This misleading claim does not withstand scrutiny, displaying a fundamental misunderstanding of the causal relationship between drug spending and Medicaid rebates. Because Medicaid rebates are based on drug pricing and utilization, if drug prices and/or utilization rise, Medicaid rebate amounts correspondingly increase in response in order to offset a portion of the resulting increase in state Medicaid costs. And the Affordable Care Act's improvements help state Medicaid programs better absorb higher drug costs. Instead, the Blueprint implausibly implies the opposite: Medicaid rebates cause drug prices to increase so improving the rebates, as the Affordable Care Act did, were a major contributor to the recent rise in drug prices and spending. The Blueprint offers no specific evidence to support its misleading claim, except to cite the enactment of the Medicaid rebate improvements (and other Affordable Care Act prescription drug provisions) and higher drug pricing and spending trends in recent years.

For the Blueprint's claim to be at all valid, there would have to be a clear relationship between when the Affordable Care Act's Medicaid rebate improvements took effect and

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[26] Centers for Medicare and Medicaid Services, "Letter from Alissa Mooney DeBoy to State Technical Contacts Regarding 'Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV Drugs)," November 5, 2015, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf and Brian Bruen, Erin Brantley, Victoria Thompson, Erika Steinmetz and Lorens Helmchen, "High Cost HCV Drugs in Medicaid: Final Report," January 2017, https://www.macpac.gov/wp-content/uploads/2017/03/High-Cost-HCV-Drugs-in-Medicaid-Final-Report.pdf.

[27] National Conference of State Legislatures, *op cit.* and Medicaid and CHIP Payment and Access Commission, "Medicaid Spending for Prescription Drugs," January 2016, https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf.

overall drug pricing and spending trends. A simple examination of drug pricing and spending trends shows there is not.

The Affordable Care Act's Medicaid improvements took full effect during calendar year 2010. Yet this coincided with several years when prescription drug spending growth was very modest. In fact, according to the IMS Institute for Healthcare Informatics (now the IQVIA Institute for Human Data Science), prescription drug spending growth actually declined in nominal terms in 2012.[28] The CMS Office of Actuary similarly found growth in retail prescription drug expenditures was only 0.2 percent in 2012.[29] These overall spending trends were driven by the loss of patent exclusivity for major brand-name drugs, fewer innovative new brand-name products entering the market and reduced utilization in the aftermath of the recession.

The fifth year of the Affordable Care Act's Medicaid rebate improvements — 2014 — then coincided with a rapid increase in overall prescription drug spending. It has been well-documented that the key factors driving this growth in overall spending were a significant increase in the number of new innovative brand-name drugs like those treating Hepatitis C drugs, fewer costly brand-name drugs going off-patent, and the rapidly rising share of drug spending attributable to specialty drugs.[30] Those trends have largely continued, particularly the growth in specialty drugs. Total Medicaid rebates began to increase at a faster rate in response to increased Medicaid drug spending due to these overall pricing trends, along with some increased utilization due to implementation of the Medicaid expansion in many states.

Could drug manufacturers have raised prices to some extent in response to the ACA's Medicaid rebate improvements since 2010? Of course, but the effect of the improvements was likely very modest. The Congressional Budget Office, for example, expected that the Medicaid rebate improvements could result in drug manufacturers raising list prices for new drugs in response but the increases in the average retail price for new drugs paid by pharmacies would be no more than 4 percent, relative to prior law. For existing drugs, CBO expected little or no effect on pricing from the Medicaid improvements, in part, because of the deterrent effect of the additional Medicaid rebate if prices rise faster than general

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[28] IMS Institute for Healthcare Informatics, "Declining Medicine Use and Costs: For Better or Worse," May 2013, and CBS News, "U.S. Prescription Drug Spending Drops for First Time in 58 Years," May 9, 2013, https://www.cbsnews.com/news/us-prescription-drug-spending-drops-for-first-time-in-58-years/.

[29] Micah Hartman, Anne Martin, Joseph Benson and Aaron Catlin, "National Health Spending in 2011: Overall Growth Remains Low, But Some Payers and Services Shows Signs of Acceleration," *Health Affairs*, January 2013, https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.1206 and Anne Martin, Micah Hartman, Joseph Benson and Aaron Catlin, "National Health Spending in 2014: Faster Growth Driven by Coverage Expansion and Prescription Drug Spending," *Health Affairs*, January 2016, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1194.

[30] Martin *et al*., *op cit*.; IMS Institute for Healthcare Informatics, "Medicines Use and Spending Shifts," *op cit.;* and Murray Aitken, Ernst Berndt, Michael Kleinrock and Luca Maini, "Has the Era of Slow Growth for Prescription Drug Spending Ended," *Health Affairs*, September 2016, https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1636.

inflation and the ability of states to negotiate supplemental Medicaid rebates with manufacturers.[31]

Instead, it is clear that the Affordable Care Act's Medicaid drug rebate improvements — as well as subsequent improvements enacted into law that extended inflation-related rebates to generic drugs and clarified how line extensions of brand-name drugs are treated — combined with the underlying rebate program, have helped reduced the fiscal burden on the federal government and the states resulting from rising Medicaid drug costs due to these overall prescription drug cost trends starting in 2014. Conversely, eliminating these critical improvements to the Medicaid drug rebate program (or weakening the program overall) would substantially increase federal and state Medicaid costs for prescription drugs in the face of new costly specialty drugs.

**6. Specific Comment: Eliminating or Weakening Best Price Requirement Would Increase Medicaid Drug Costs**

The Blueprint expresses concern that the Medicaid Drug Rebate Program's best price provision as part of calculation for the base rebate for brand-name drugs may pose a barrier to innovative value-based arrangements that insurers and manufacturers may be exploring. It also states that the best price requirement may be increasing prices by limiting discounts and rebates in the private insurance market.

First, while some stakeholders have made this claim, it is unclear what particular value-based arrangements may trigger best price and would not actually happen but for the existence of the Medicaid best price requirement. For example, one analysis notes that many of the value-based arrangement concepts would not necessarily trigger best price if they were designed carefully and that other concepts could be addressed through modest changes to best price regulations. In fact, it appears that drug manufacturers are citing concerns over best price as an excuse for opposing such arrangements more generally.[32] Moreover, it is important to recognize that these value-based arrangements are primarily about the private insurance market and would not benefit Medicaid in any event. As MACPAC analysts note, they would "primarily benefit payers outside of the Medicaid program."[33] (The use of value-based arrangements by state Medicaid programs would by definition not implicate best price though they could conflict with other federal requirements.) It may be reasonable to make a few well-targeted, very limited clarifications to best price to facilitate certain value-based arrangements. What is clear, however, is that any barriers posed by value-based arrangements in the private insurance

[31] Congressional Budget Office, "Letter to the Honorable Paul Ryan," November 4, 2010, https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/11-04-drug_pricing.pdf.

[32] Rachel Sachs, Nicholas Bagley and Darius Lakdawalla, "Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule," *Journal of Health Politics, Policy and Law*, February 2018, https://read.dukeupress.edu/jhppl/article-abstract/43/1/5/132803/Innovative-Contracting-for-Pharmaceuticals-and?redirectedFrom=fulltext.

[33] Medicaid and CHIP Payment and Access Commission, Transcript: Public Meeting, *op cit*.

market do not justify eliminating the best price requirement outright, because best price contributes substantially to the Medicaid Drug Rebate Program's overall effectiveness.

Second, in general, there is very little evidence that best price is the reason why private insurers are obtaining rebates (16 percent) that are so much lower than those in Medicaid (61 percent), according to Altarum estimates.[34] Rather, private insurers do a relatively poorer job in negotiating rebates and lowering prescription drug costs, even though they can now impose more restrictive, closed formularies compared to state Medicaid programs. The example of the Medicare Part D program is instructive. Rebates negotiated by private Part D plans are already exempt from best price. 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 Part D private insurers to negotiate larger rebates than those required under Medicaid. Yet as noted above, even before the Affordable Care Act increased rebates under the Medicaid Drug Rebate Program, Medicare Part D rebates were considerably smaller than those achieved in Medicaid. Moving drug coverage from Medicaid to Medicare for the dual eligibles resulted in significant financial windfalls in 2006 for manufacturers whose products were disproportionately used by low-income seniors and people with disabilities on both Medicare and Medicaid. And the gap in rebates between Medicaid and Medicare Part D continues to be substantial, as discussed above. That is why the Congressional Budget Office estimates that imposing Medicaid-level rebates for low-income beneficiaries in Medicare Part D would produce federal savings of $145 billion over ten years. Similarly, the reason that extending the Medicaid Drug Rebate Program to Medicaid managed care was estimated to produce savings prior to the Affordable Care Act (even without an increase in the minimum rebate) is because the rebates negotiated by Medicaid managed care plans were considerably less than those under the Rebate Program.

While best price may be less important overall to the Medicaid Drug Rebate Program because of the Affordable Care Act's increase in the minimum base rebate from 15.1 percent of AMP to 23.1 percent of AMP, best price almost certainly determines the base rebate amount for certain brand-name drugs, especially high-cost prescription drugs that faces competing drugs from other manufacturers. As a result, the best price provision in the Medicaid Drug Rebate Program should be preserved.

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Thank you again for the opportunity to make the following comments to the HHS Blueprint. Please contact me at Edwin.Park@georgetown.edu if you have any questions or if we can be of further assistance.

Respectfully submitted,

[34] Roehring, *op cit*.

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