Georgetown University
Health Policy Institute
CENTER FOR CHILDREN
AND FAMILIES

VIA ELECTRONIC SUBMISSION

March 21, 2019

Office of Inspector General
U.S. Department of Health and Human Services
Room 5527, Cohen Building
330 Independence Avenue SW
Washington D.C 20201

Re: Comments to OIG-0936-P
Proposed Rule: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Sir or Madam:

The Center for Children and Families (CCF), part of the Health Policy Institute at the McCourt School of Public Policy at Georgetown University, 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. Thank you for this opportunity to make the following comments to the HHS OIG proposed rule, which focus on the likely impact of the rule on the Medicaid program.

We welcome the Administration's overall focus on the problem of prescription drug costs and we particularly appreciate that the Administration's fiscal year 2020 budget proposes three sound improvements to the highly effective Medicaid Drug Rebate Program[1] — eliminating the cap on total Medicaid drug rebate amounts, preventing manufacturer misclassification of drugs to lower their rebate obligations, and preventing manufacturers from using authorized generics to reduce rebate amounts — which can help state Medicaid programs better address drug cost growth and ensure continued access to needed prescription drugs for low-income Medicaid beneficiaries including children and families.[2]

[1] Edwin Park, "How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs," Georgetown University Center for Children and Families, January 2019, https://ccf.georgetown.edu/wp-content/uploads/2019/01/Medicaid-Rx-Policy-Options-v4.pdf.

[2] Edwin Park, "Trump Budget Includes Harmful Medicaid Drug Rebate Proposal, Several Sound Improvements," *Say Ahhh! Blog*, Georgetown University Center for Children and Families, March 14, 2019,

As explained below, however, the proposed rule raises serious concerns because it would likely harm the Medicaid program, raise federal and state Medicaid costs and could lead to states making cuts to their Medicaid programs that adversely affect low-income beneficiaries including children and families. Moreover, the policy rationales cited in support of the proposed rule do not support the application of the proposed rule's safe harbor changes related to the federal anti-kickback law to Medicaid.

We therefore strongly recommend that OIG leave in place the existing safe harbor for rebates negotiated between drug manufacturers and pharmacy benefit managers (PBMs) contracting with Medicaid managed care plans. In addition, consistent with the proposed rule, in any final rule, OIG should reiterate that supplemental rebates directly negotiated by states with drug manufacturers and the mandatory rebates required under the Medicaid Drug Rebate Program would be wholly unaffected by any anti-kickback law safe harbor changes.

1. Medicaid Drug Rebate Program Is Highly Effective and Ensures Beneficiary Access

Under the Medicaid Drug Rebate Program (MDRP), all drug manufacturers must provide rebates to the federal government and states as a condition of having their drugs covered by Medicaid. In the case of brand-name drugs, manufacturers must pay a base rebate 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, the base rebate equals 13 percent of the AMP. Manufacturers must also pay additional inflation-related rebates for both brand-name and generic drugs if their prices rise faster than general inflation. Nearly all states also negotiate directly with manufacturers and/or have managed care plans negotiate for voluntary supplemental rebates on top of these federally required rebates, with many states directly negotiating for some supplemental rebates together as part of a multi-state purchasing pool.

These rebates are substantial. 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.[3] 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.[4] (Unlike under the MDRP, there are no

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https://ccf.georgetown.edu/2019/03/14/trump-budget-includes-harmful-medicaid-drug-rebate-proposal-several-sound-rebate-improvements/.

[3] 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/.

[4] "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),

mandatory rebates required in Medicare Part D. All rebates are the result of negotiation between manufacturers and Part D plans and the PBMs with which they contract.) In fiscal year 2017, manufacturers paid $34.9 billion in rebates, lowering Medicaid prescription drug costs by 54.5 percent.[5] Other analysis has similarly found that the drug rebates manufacturers pay in Medicaid are far larger than what Medicare Part D plans or private insurance plans receive.[6]

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.[7]

2. Safe Harbor Changes Would Likely Harm the Medicaid Program

The proposed rule would amend 42 C.F.R. § 1001.952(h) and essentially eliminate the existing "discount" safe harbor in the federal anti-kickback law for prescription drug rebates provided by drug manufacturers to Medicare Part D plans and Medicaid managed care plans. The proposed rule would then amend 42 C.F.R. § 1001.952 to add subparagraphs (cc) and (dd) to establish new safe harbors for "point-of-sale" discounts (rebates or chargebacks which are fully passed on to the retail level) and for certain fixed payment PBM service fees paid by manufacturers.[8]

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https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf

[5] Medicaid and CHIP Payment and Access Commission, "MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2017," *op cit*.

[6] See 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; Charles Roehrig, "The Impact of Prescription Drug Rebates on Health Plans and Consumers," Altarum, April 2018, https://altarum.org/sites/default/files/uploaded-publication-files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf; and 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.

[7] 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.

[8] Office of Inspector General, U.S. Department of Health and Human Services, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain

A large majority of states currently rely on Medicaid managed care plans to negotiate voluntary supplemental prescription drug rebates on behalf of their enrollees, in addition to the rebates required under the MDRP.[9] (The preamble to the proposed rule makes clear that the safe harbor changes would not affect the federally-required base rebate and inflation-related rebate under the MDRP or supplemental rebates negotiated directly by states under so-called "sidebar" agreements.) These managed care supplemental rebates are either passed on to state Medicaid programs in the form of lower managed care capitation payments or are collected by states. While these rebates are modest relative to the size of the federally-required rebates under the MDRP, the supplemental rebates obtained by Medicaid managed care plans (and the PBMs with which they contract) help lower overall federal and state Medicaid prescription drug costs. As a result, ending the existing safe harbor for these rebates could have a significant adverse effect on state Medicaid programs.

The supplemental material in the docket for the proposed rule includes an actuarial analysis from the Office of the Actuary (OACT) at the Centers for Medicare and Medicaid Services. The OACT analysis estimates that the proposed rule would increase total Medicaid spending by $1.9 billion over the next 10 years, with $1.7 billion in increased federal Medicaid spending and $200 million in increased state Medicaid spending.[10] (The supplemental docket material includes two other two actuarial studies. The study conducted by the Wakely Consulting Group did not examine the Medicaid impact. The study conducted by Milliman did not provide any specific Medicaid impact estimates but did include a limited qualitative discussion of the effects on Medicaid.) OACT expects that 85 percent of current Medicaid managed care drug rebates would no longer be negotiated between manufacturers and PBMs on behalf of Medicaid managed care plans. As a result, Medicaid managed care plans would see higher net pharmacy costs under the proposed rule and in turn, states would have to increase their capitation payments to Medicaid managed care plans to account for those higher costs. As noted, states would still be permitted to directly negotiate supplemental rebates in managed care (as 20 states currently do for certain drugs, drug classes or in a few states, the entire outpatient drug benefit in Medicaid managed care[11]). But OACT expects only half of the existing rebates that would no longer be provided to Medicaid managed care plans would be replaced by directly negotiated supplemental rebates.

Pharmacy Benefit Manager Service Fees," 84 Fed. Reg. 2340 (February 6, 2019), https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-0001&contentType=pdf.

[9] Park, *op cit*.

[10] Office of the Actuary, Centers for Medicare and Medicaid Services, "Proposed Safe Harbor Regulation," August 30, 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf. The OACT analysis notes that states would accrue savings outside of Medicaid, with reduced drug spending in their state employee health plans if list prices decline as assumed.

[11] Park, *op cit*.

The $1.9 billion estimate likely reflects states also seeing some offsetting savings in gross pharmacy costs for their beneficiaries in managed care (and thus lower capitation payments) if drug manufacturers lower their list prices due to the elimination of the existing rebate safe harbor. The actuaries assume that manufacturers would retain only 15 percent of the rebates they now provide to Medicare Part D and Medicaid managed care plans if the safe harbor is eliminated, with the remainder of the current rebates converted to lower list prices. But if manufacturers keep a greater share than 15 percent and do not lower list prices to the extent assumed by OACT, the estimated increase of $1.9 billion in total Medicaid costs could end up considerably larger. In other words, state Medicaid programs would face even higher costs related to capitation payments to managed care plans because the loss of supplemental managed care rebates would be offset to a lesser degree by reduced managed care pharmacy costs, if list prices do not decline or by as much as assumed.

Furthermore, lower list prices, including both reduced launch prices and smaller annual price increases, would also result in lower mandatory base and inflation-related rebates under the MDRP, which would offset the effect of lower list prices on overall Medicaid prescription drug costs (including in fee-for-service). OACT expects as part of its overall Medicaid estimate that Medicaid cost increases from lower rebates would exceed by $500 million over ten years the Medicaid savings from lower list prices. While Milliman did not conduct any Medicaid-specific estimates, it clearly states that the reduction in rebates provided to state Medicaid programs would more than offset any list price savings and "would result in an increase in total government costs for the Medicaid program.[12]"

In addition, the proposed effective date for the rule's safe harbor changes is January 1, 2020. Considering that the comment period to this proposed rule ends on April 8, 2019 and OIG will need sufficient time to review comments and finalize the rule, states intending to substitute directly negotiated supplemental rebates for current Medicaid managed care rebates would have little or no time to do so before the safe harbor changes are scheduled to take effect. It is very likely that at least initially, states would be able to replace much less than half of current rebates, as assumed by OACT.

Moreover, some states would face disproportionately higher increases in net Medicaid drug costs under the proposed rule. For example, the handful of states that already fully carve out the outpatient drug benefit from Medicaid managed care plans and directly negotiate their own supplemental rebates for both fee-for-service and managed care should largely be unaffected by the rule. But several states have no directly negotiated supplemental rebates at all and rely wholly on Medicaid managed care plans to obtain any supplemental rebates. Most other states only directly negotiate supplemental rebates for beneficiaries in fee-for-service and/or for a limited number of drugs or drug classes in managed care. Medicaid programs in such states would face the largest drug cost increases under the proposed rule.[13]

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[12] Milliman, "Impact of Potential Changes to the Treatment of Manufacturer Rebates," January 31, 2019, https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-0002&contentType=pdf.

[13] Park, *op cit*.

Finally, it is unclear how the proposed rule could indirectly affect Medicaid in other ways. For example, if the proposed rule eventually results in some reduction in the rebates now provided by manufacturers to private insurance (including in employer-sponsored insurance) but without a significant reduction in list prices, that could also affect the "best price" requirement in Medicaid under which the MDRP base rebate is set at the higher of 23.1 percent of the Average Manufacturer Price (AMP) or the "best price" discount provided to most other payers including in private insurance. (Rebates negotiated by Medicare Part D plans are currently exempt from best price.) That could result in smaller rebates paid to state Medicaid programs and higher net drug costs. While the OACT analysis examines the impact on private insurance from potentially lower list prices, it does not examine how possible changes in private insurance rebates could affect Medicaid.

3. Primary Policy Rationale for Safe Harbor Changes Does Not Apply to Medicaid

The proposed rule's preamble focuses almost exclusively on the merits of the rule relative to Medicare Part D. For example, the primary rationale for elimination of the existing rebate safe harbor is that the current system of negotiated rebates harms beneficiaries. The preamble devotes much of its discussion to explaining that if drug rebates do not flow through to consumers at the pharmacy counter, consumers can face higher out-of-pocket costs if their deductible and co-insurance amounts are based on list prices, rather than prices net of rebates. The preamble argues that if existing rebates were fully converted to point-of-sale rebates, the proposed rule would lower out-of-pocket costs for Medicare Part D beneficiaries.

While this may be true of Medicare Part D in the case of some beneficiaries, that is not how Medicaid works. Low-income Medicaid beneficiaries generally pay only nominal co-payments irrespective of the price of individual drugs, although those nominal co-payment amounts may vary if the drugs are brand-name or generic. In fact, the preamble separately admits that patients "with fixed co-payments may not see changes in their cost-sharing at the point of sale…" under the proposed rule. That is why the OACT analysis expects zero impact on Medicaid beneficiaries' out-of-pocket costs under the proposed rule. Similarly, Milliman states that "most of these effects do not apply in the Medicaid market" as point-of-sale rebates would not affect beneficiaries' out-of-pocket costs and would not affect beneficiary utilization patterns.

Moreover, another policy rationale cited in the preamble is that the proposed rule would help address the problem of rising list prices which harms federal health programs. But as the OACT estimate finds, the proposed rule is actually expected to increase total Medicaid costs by $1.9 billion over the next ten years, relative to current law. And as discussed above, if the proposed rule does not lower list prices as intended (and as OACT assumes) and manufacturers retain a significant share of the rebates they now provide, the net cost to Medicaid could be even larger.

The preamble cites only two Medicaid-specific arguments in favor of the proposed rule. First, the preamble notes that some rebates now provided by drug manufacturers to PBMs

(in private insurance) may be excluded from the determination of best price under the MDRP. Second, the preamble highlights the fact that the current statutory cap on total Medicaid drug rebate amounts (equal to 100 percent of AMP) limits the effectiveness of the MDRP's inflation-related rebate in discouraging excessive annual price increases. The preamble correctly states that both result in lower rebates and higher net Medicaid drug costs.

But it is hard to see how these two issues in any way necessitate the proposed rule's elimination of the current safe harbor for rebates negotiated by Medicaid managed care plans. Instead, these issues can be addressed successfully through simple, direct remedies. As we have previously written, the Centers for Medicare and Medicaid Services (CMS) could amend current Medicaid rebate regulations to clarify that the definition of best price includes all rebates negotiated between manufacturers and PBMs contracting with private insurance plans (including in employer-sponsored insurance).[14] Similarly, as we have written, Congress could also enact legislation to eliminate the 100 percent of AMP cap to ensure that state Medicaid receive rebates equal to the full amount of price increases in excess of general inflation.[15] As noted above, in a welcome move, the President's fiscal year 2020 budget proposes to eliminate the rebate cap. A proposal to eliminate the rebate cap will also likely be formally recommended by MACPAC in an upcoming report to Congress.[16]

4. Safe Harbor Changes Should Not Extend to Medicaid

We thus strongly recommend that in the final rule, OIG should not apply the proposed safe harbor changes to Medicaid managed care — that is, OIG should retain the existing safe harbor for rebates negotiated by Medicaid managed care plans — irrespective of whatever safe harbor changes are applied to Medicare Part D. (Notably, the anti-kickback law applies to all Federal health care programs. But OIG has already elected in the proposed rule to limit safe harbor changes under the proposed rule to Medicare Part D and Medicaid managed care. In the final rule, OIG could further limit the scope of any safe harbor changes by excluding application of such changes to rebates negotiated by Medicaid managed care plans. In addition, as discussed above, the supplemental rebates negotiated by managed care plans — which are in addition to mandatory rebates under the MDRP — are substantially different than the rebates negotiated by Medicare Part D plans and the policy rationales cited in support of the proposed rule do not apply to Medicaid.)

Moreover, as under the proposed rule, OIG should reiterate that any safe harbor changes in the final rule would have no effect on federally-required rebates under the MDRP or

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[14] Park, *op cit*.

[15] Park, *op cit*.

[16] U.S. Department of Health and Human Services, "Fiscal Year 2020 Budget-in-Brief," March 11, 2019, https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf and Medicaid and CHIP Payment and Access Commission, "Potential Recommendations on Coverage Grace Period and Rebate Cap," March 7, 2019, https://www.macpac.gov/wp-content/uploads/2019/03/Potential-Recommendations-on-Coverage-Grace-Period-and-Rebate-Cap.pdf.

voluntary supplemental rebates directly negotiated between states and drug manufacturers under so-called "sidebar" agreements.

Otherwise, state Medicaid programs would be at significant risk of facing higher net prescription drug costs. States, in turn, would either have to contribute more of their funding to their Medicaid programs or as is more likely, respond by instituting programmatic cuts harming low-income beneficiaries including children and families, such as cuts to Medicaid eligibility, benefits and provider payments that reduce access to needed care including to prescription drugs.

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

Respectfully submitted,

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