April 8, 2019

Mr. Aaron Zajic
Office of Inspector General
U.S. Department of Health and Human Services
Attention: OIG-0936-P
Room 5527, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via email to http://www.regulations.gov

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 Mr. Zajic:

The Medicaid Health Plans of America (MHPA) appreciates the opportunity to comment on the Department of Health and Human Services (Department)/Office of Inspector General (OIG) proposed rule to amend the safe harbor regulation concerning discounts. MHPA is the national trade association representing 94 private-sector health plans that contract with state Medicaid agencies in 37 states plus DC to provide comprehensive, high-quality health care to more than 23 million Medicaid enrollees in a coordinated and cost-effective way. Our member plans offer comprehensive, coordinated care that supports the health care needs of Medicaid beneficiaries while also managing costs for our state and federal partners.

While the proposed rule would apply to Medicare Part D plan sponsors, Medicaid managed care organizations (MMCOs) and the pharmacy benefit managers (PBMs) under contract with MMCOs, we are focusing our comments on the impact of the proposal on the Medicaid program, Medicaid health plans, and Medicaid beneficiaries.

We appreciate the efforts of the Department to address rising prescription drug prices and to work with the OIG to ensure that safe harbor protections extend only to arrangements at low risk of harm to federal health care programs and beneficiaries. We also support the overall goals of the proposed rule to align incentives among parties that participate in the current rebate framework for federal health programs to address systemic barriers to lowering drug costs to the Medicare Part D and Medicaid programs.

However, we have serious concerns about the proposed rule's inclusion of and application to the Medicaid program. We believe the proposed exclusion of rebates paid by pharmaceutical manufacturers to MMCOs and to PBMs under contract with MMCOs from the discount safe harbor contravenes the proposed rule's aforementioned goals, does not support the financial sustainability of the Medicaid program, discourages integrated health care delivery, and is not in the best interests of Medicaid beneficiaries.

We also believe the proposal could have an unintended chilling effect on efforts to create additional value to the Medicaid program, including value-based payment arrangements. Furthermore, the proposed rule raises several legal questions related to the proposal's characterization of rebates, its applicability to Medicaid managed care plans, and potential liability issues.

Given these concerns, we strongly recommend that the Department exclude Medicaid from this proposal, thereby keeping intact the existing safe harbor for rebates negotiated between drug manufacturers and MMCOs and PBMs contracting on their behalf. Alternatively, we recommend that the implementation date be delayed until a comprehensive analysis of the impact on Medicaid program can be completed and properly assessed.

Our specific concerns with the inclusion of Medicaid in this proposal are as follows:

I. The proposed rule's focus on reducing beneficiary cost-sharing is inapplicable to Medicaid.

The proposed rule would substantially restructure and regulate pharmaceutical contractual arrangements for Medicare Part D plan sponsors, MMCOs, and PBMs acting on their behalf. Its primary focus is to change a rebate-based system to a more transparent one that provides point-of-sale (POS) discounts to minimize cost-sharing burdens for beneficiaries at the pharmacy counter. As noted in the preamble, this proposed rule is an outgrowth of the Administration's effort to lower prescription drug costs in federal health care programs. While we support the Administration's intent to address drug pricing, particularly when drug prices can act as a barrier to appropriate patient care, we do not believe the proposed changes and their intended effect are applicable to the Medicaid program.

Medicaid beneficiaries generally do not incur cost-sharing or have nominal copays for prescription drugs and therefore the conversion of rebates into point of sale discounts, or rebates, is unnecessary. This is supported in the proposed rule's accompanying analysis conducted by the Office of the Actuary (OACT), referenced in the Regulatory Impact Statement and posted as supplementary materials, that expects no impact on Medicaid beneficiaries' out-of-pocket costs under the proposed rule. Similarly, the Milliman analysis, that also accompanied the proposed rule, found 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.

We also note that the preamble focuses almost exclusively on the application of the changes to Medicare Part D. While the Department commissioned actuarial analyses from the OACT, Milliman, and Wakely Consulting Group, only OACT estimated the effect on Medicaid spending. We contend there was insufficient consideration given to the impact of the removal of

the safe harbor discount on the Medicaid program and that including Medicaid in this proposal, particularly without further analyses, would cause considerable uncertainty and put this vital program at financial risk.

II. The proposal would not necessarily reduce prescription drug prices.

The proposed removal of the discount safe harbor protection does not require pharmaceutical manufacturers to lower the list prices of their prescription drugs, but rather relies upon an *expectation* that pharmaceutical manufacturers would decrease their list prices with the removal of rebates for Medicare Part D plan sponsors, MMCOs, and PBMs acting on behalf of plans. We believe this expectation is misplaced. Should pharmaceutical manufacturers lower list prices - whether for individual national drug codes (NDCs), specific therapeutic categories, or universally across product lines – the decreased prices would not necessarily produce the same level of cost savings to state Medicaid programs that are achieved under the current rebate arrangements between manufacturers and MMCOs or between manufacturers and PBMs working on behalf of health plans. This is reflected in the additional costs to the states of $0.2 billion over ten years as estimated in the OACT analysis.[1]

Moreover, for the Medicaid program, the largest portion of rebates paid by pharmaceutical manufacturers are mandated under the Medicaid Drug Rebate Program (MDRP). The required federal rebates are comprised of the base rebate (23.1 percent for brand drugs and 13 percent for generic drugs) and the inflationary rate rebate that is indexed to the consumer price index. The Medicaid rebate amount, including both the base rebate and the inflation rebate, are capped at the drug's average manufacturer price (AMP). According to the Medicaid and CHIP Payment and Access Commission (MACPAC), in federal fiscal year 2017, drug manufacturers paid $34.9 billion in rebates to the federal government and the states, lowering Medicaid prescription drug costs by 54.5 percent.[2] Given the significant rebate amounts required under the MDRP, and that the current proposal does not change the mandated rebate requirements, pharmaceutical manufacturers are likely to maintain their prices at a high enough level to account for the cost of these federal Medicaid rebates.

While pharmaceutical manufacturers *could* lower the list prices, as anticipated by the proposed rule, this seems unlikely absent a mandate or significant incentive, neither of which exist in the proposed rule. As a result, the proposed rule, at a minimum, introduces uncertainty into the Medicaid marketplace and, in our view, would most likely result not in lower prices, but rather in increased drug costs for state Medicaid programs.

III. The proposal would likely increase government expenditures.

While explicitly exempting the MDRP from its proposed changes, the proposed rule would still impact key components of the MDRP, particularly "best price", and have detrimental

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[1] CMS Office of the Actuary. "Proposed Safe Harbor Regulation." August 2018 (84 FR 2351).

[2] MACPAC, "MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2017," https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/.

effects on supplemental rebates and Medicaid managed care capitation rates. As referenced in the proposed rule's Regulatory Impact Statement, the Department's own actuary estimates that including Medicaid in this proposal will result in increased costs for both states and the federal government with a net cost to Federal Medicaid of $1.7 billion between 2020 and 2029 and $0.2 billion of net state Medicaid costs over the same period.[3]

A. Medicaid Best Price

The proposed rule would not alter the statutory provisions for manufacturers to pay Medicaid prescription drug rebates to state Medicaid agencies for drugs that are dispensed by MMCOs, including the requirements regarding "best price" and the additional "inflation penalty" rebate amounts.

Interestingly, however, as part of the rationale in favor of the proposed rule, the preamble explicitly references two issues related to Medicaid "best price" that would be impacted by the proposed changes. First, the preamble notes that some rebates now provided by drug manufacturers to PBMs may be excluded from the determination of best price under the MDRP. Second, it notes 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. We agree that both of these issues result in lower rebates and higher net Medicaid drug costs.

However, we believe the proposed rule's changes to the discount safe harbor to address these specific issues are misplaced and over-reaching. We believe there are more specific and narrowly-focused avenues for clarifying that the definition of best price includes all rebates negotiated between manufacturers and PBMs contracting with private insurance plans such as through amendments to Medicaid rebate regulations or for eliminating the statutory rebate cap through Congressional action.

We also note that the proposed POS discounts could affect Medicaid rebates due to the uncertainty of how pharmacy chargebacks would be handled in the calculation of average manufacturer price and recommend clarification on that point.

B. Supplemental Rebates

The preamble distinguishes supplemental rebates between a manufacturer and MMCOs, and PBMs acting on behalf of MMCOs, and supplemental rebates between a manufacturer and the state, asserting that the latter arrangement has less potential for fraud and is less likely to be in violation of anti-kickback statute. Most states who contract with MMCOs currently rely on the plans to negotiate voluntary supplemental rebates, in addition to those required under federal law and it is important to note that these rebates count toward Medicaid best price. We recognize and support the Department's interest in fraud prevention. However, we do not agree with the Department's assertion and, even if the assertion were true, we believe there are more direct pathways to protect against fraud that do not have a detrimental impact on the Medicaid program. Specifically, we are concerned that removing the protection for those rebates and

[3] CMS Office of the Actuary. "Proposed Safe Harbor Regulation." August 2018 (84 FR 2351).

moving toward POS discounts would raise best price and lessen the amount manufacturers pay in rebates under the MDRP.

We also have concerns that this proposal creates an incentive for states to move away from an integrated approach to health care delivery that could encourage the implementation of a state-mandated single preferred drug list (PDL) or a carve-out of the drug benefit from managed care. We believe that an integrated approach to health care delivery that includes the management of the Medicaid prescription drug benefit by MMCOs facilitates the delivery of better, high quality, and comprehensive care that is in the best interests of Medicaid beneficiaries, particularly given their vulnerabilities and their often medically complex needs.

Additionally, the preamble notes that the Department does not "presently believe" that supplemental rebate agreements that states negotiate with drug manufacturers will be affected by the proposal. We question the intent of this tentative language related to state negotiated rebates with pharmaceutical manufacturers and seek clarification.

C. Medicaid Managed Care Plan Capitation Rates

For states that rely on MMCOs to negotiate voluntary supplemental rebates, in addition to those required under federal law, the supplemental rebates are generally passed on to states in the form of lower managed care capitation payments or are collected by states themselves. Individual MMCO arrangements will likely vary. While supplemental rebates are modest relative to the size of the federally-required rebates under the MDRP, the supplemental rebates obtained by Medicaid health plans (and the PBMs with which they contract) are important contributors to lowering 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 proposed rule suggests that the additional cost to MMCOs could be mitigated in part through negotiated, upfront or point-of-sale discounts with the manufacturers in lieu of the rebates once received. The incentive for pharmaceutical manufacturers to provide discounts at a level equal to or similar to the savings leveraged through the current rebate framework are simply lacking in the discount-focused approach.

The proposed rule also notes that states could offset some capitation rate increases by including the managed care enrollees in their own supplemental rebate negotiations or carve out the prescription drug benefit from managed care contracts. We believe that many states recognize the benefits for patient care and financial predictability when keeping plans at risk.

We urge the Department to continue to support the existing Medicaid managed care rebate framework that leverages the expertise of Medicaid health plans in lowering prescription drug costs. We believe the continuation of this partnership will support financial sustainability and facilitate better beneficiary outcomes for the Medicaid program.

D. State Medicaid Programs.

Prescription drugs are a critical component of health care delivery and pharmaceutical manufacturer rebates – both statutorily required and supplemental rebates - are used by MMCOs

to lower overall drug costs for the State Medicaid programs. As of March 2018, 39 states, including DC, have comprehensive, risk-based contracts with MMCOs[4]. Risk-based arrangements between states and MMCOs optimize the quality of care delivered to the often medically complex and underserved Medicaid population and help states limit financial risk and uncertainty.

The proposal to remove rebates from the discount safe harbor is an unnecessary action that will have a negative impact on State Medicaid programs. For fiscal year 2017, states spent over $220,000,000,000 in Medicaid expenses (not including administrative costs).[5] Medicaid accounts for nearly 30 percent of total state spending,[6] and Medicaid costs are projected to continue to increase faster than economic growth overall.[7] In 2016, over 80 percent all Medicaid enrollees received their care through managed care as an increasing number of states turn to the expertise of managed care plans to provide health care for a growing number of Medicaid enrollees with diverse needs.[8]

Under the proposal, the preamble recognizes that "for Medicaid managed care organizations (MCOs), the loss of rebate revenue would lead to higher spending for these contracts." For states, this would result in fewer dollars overall given the uncertainty, and unlikelihood, that lost rebates will be offset by lower prescription drug prices. As the Milliman supplementary report for the Department stated: "States and MCOs are already motivated to manage to the lowest POS costs, but also have limited tools to influence member behavior, both of which mean there is much less potential to reduce total Medicaid pharmacy spending to offset the loss of rebates."[9]

We also point out that the increasing trend among states to require MCOs to pass supplemental rebates directly to Medicaid programs will also mean lost revenue to the state under the current proposal. If costs to states increase, costs to the federal government—as states' partner in Medicaid—are likely to increase as well.

IV. The proposal is not in the best interests of Medicaid beneficiaries.

Serving over 23 million Medicaid enrollees, MHPA has serious concerns with the impact of these proposals on the Medicaid program, its benefits, and its beneficiaries. A primary focus of the proposed rule is to move away from the current rebate framework for Medicare Part D and

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[4] https://www.kff.org/other/state-indicator/total-medicaid-mco-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[5] https://www.kff.org/medicaid/state-indicator/federalstate-share-of-spending/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[6] National Association of State Budget Officers, 2018 State Expenditure Report, p.52.

[7] National Association of State Budget Officers, 2018 State Expenditure Report, p.53.

[8] Centers for Medicare & Medicaid Services, 2016 Managed Care Enrollment Survey, https://data.medicaid.gov/Enrollment/2016-Managed-Care-Enrollment-Summary/x3sw-xby3.

[9] Milliman, Impact of Potential Changes to the Treatment of Manufacturers Rebates, p. 24.

Medicaid managed care toward a point-of-sale discount structure. The Department cited concerns that currently rebates are often not applied at the point of sale to offset the beneficiary's deductible or coinsurance or otherwise reduce the price paid at the pharmacy counter. However, we note that most Medicaid beneficiaries pay flat, low-co-pays, or no co-pays, and therefore will not benefit from this proposal.

In fact, if rebates are removed from the safe harbor, we believe beneficiaries may be harmed. Medicaid requires coverage of certain mandatory benefits, but many others—including prescription drugs, physical, occupational and speech therapy, optometry and dental services—are optional. If rebates are no longer paid to MMCOs as a result of this rule, and overall costs increase for Medicaid programs, states may choose to change or cut benefits, rather than increase funding for care.

Additional guidance is also needed for how the proposed changes would impact certain subsets of Medicaid beneficiaries. For example, Medicaid regulations allow for certain, higher income Medicaid beneficiaries (i.e., an income greater than 150% of the FPL) to pay copays on non-preferred drugs up to 20% of the drug cost paid by the state. How would a point-of-sale discount work for such a beneficiary under managed care versus fee-for-service (FFS)?

Another concern is for Medicaid beneficiaries who "spend down" to become Medicaid eligible. Given that most "spend down" members are in FFS and are not necessarily considered "Medicaid enrollees" until they spend down a portion of their monthly income, we question if POS rebates would further delay members from reaching the spend down threshold and if there is a difference depending on if the members are in managed care versus FFS?

Finally, the proposed rule may negatively impact Medicaid beneficiaries' health and the quality of care they receive. By treating state supplemental rebates differently than managed care-negotiated rebates, the proposed regulation creates an unintended consequence that states that elect managed care may look to carve out those benefits solely based on financial reasons. The proposed regulation indicates that state-negotiated supplemental rebates through established PDLs should be unaffected while MMCO-negotiated rebates will no longer be protected by the discount safe harbor. Since overall rebate levels under the proposal are estimated to be lower, states opting for a managed care plan may be inclined to carve-out drug benefits and move to a FFS approach or state-controlled PDL to realize greater rebates.

A full pharmacy carve-out could mean that Medicaid beneficiaries will not receive the same integrated and quality care as they do today. The MMCOs' ability to monitor adherence and appropriately manage the medication regimen for beneficiaries who often suffer from complex medical conditions is greatly limited under a carve-out. Adherence to drug therapy reduces the risk of complications, avoids costly hospital stays, and leads to better outcomes for beneficiaries.

To the extent the proposal prompts states to carve the prescription drug benefit out of Medicaid managed care contracts, MMCOs will lose timely visibility into their members' prescription drug utilization and adherence, including monitoring the use of opioids. This fragmentation of care would deprive MMCOs of the ability to effectively manage and coordinate a critical component of their members' healthcare, such as by identifying at-risk members'

failure to timely fill prescriptions necessary for the management of chronic or life-threatening conditions.

We respectfully request additional consideration be given to the impact of the proposed changes on Medicaid beneficiaries.

V. The proposal discourages value-based payment arrangements.

States are increasingly using MMCO contracts as vehicles to change how providers are paid for delivering health services and to accelerate the adoption of value-based payment arrangements. These value-based payment arrangements include a range of state-defined models, such as performance incentives or penalties, shared savings and/or risk based on quality and cost targets, episode or bundled payments, or global payment programs. We believe such arrangements are innovative approaches that can bring value to the Medicaid program.

However, without an explicit safe harbor protecting such arrangements, contractual agreements that include elements that may be characterized as "performance requirements" are not definitively allowable under the proposed rule. As such, we believe the proposed rule creates significant uncertainty for value-based payment arrangements between pharmaceutical manufacturers and MMCOs or PBMS acting on their behalf and recommend the adoption of explicit protections, such a specific safe harbor, for value-based agreements.

We also would like to raise that under current policy (that is unchanged by this proposal), supplemental rebates given to state programs do not count towards MBP while supplemental rebates provided through MMCOs count toward MBP; this creates a loophole for value-based care provided in FFS that does not exist for managed care. We recommend that this issue be considered for future guidance.

VI. Efforts to promoting transparency and innovative approaches in Medicaid should be applicable, appropriate, and in the best interests of the program.

We appreciate the efforts to support transparency in the healthcare system. However, it is important to recognize that the transparency of certain types of information, such as negotiated prices, can have the undesirable effect of discouraging competition and potentially minimizing downward pressure on pricing. As mentioned earlier, we do not believe the proposed rule, including its effort to promote transparency through point of sale discounts, are applicable to the Medicaid program.

However, we would like to recommend one approach to promote transparency that we believe is specific to and in the best interests of the Medicaid program. Under the current rebate framework, MMCOs may negotiate supplemental rebates directly with pharmaceutical manufacturers to minimize costs based on the net cost to the MMCO. However, the lowest net cost product for the MMCO may not always align with the lowest net cost product for the Medicaid program. We believe that mandating transparency of the unit rebate amount (URA) and unit rebate offset amount (UROA) to MMCOs would help MMCOs drive toward the lowest net costs to the system. We suggest that states release the URA and UROA to MMCOs on a quarterly basis.

We also support the Administration's goals to encourage state flexibility and foster innovative solutions in Medicaid. However, the proposed rule could restrict state choices when it comes to developing innovative ways to improve access and lower all-around costs. States currently have many tools to address the challenges of rising drug costs and are taking steps to lower drug costs and increase price transparency. States, over the past few years, have taken steps to increase drug price transparency in a way that is tailored to the state and brings down, rather than increases, state costs. By treating state supplemental rebates differently than MMCO-negotiated rebates, the proposed regulation creates an unintended consequence that states that elect managed care may look to carve out those benefits solely based on financial reasons.

VII. The proposal raises significant legal questions.

We believe the proposed rule raises a number of legal issues and seek clarification or further guidance.

First, the Secretary's characterization of "[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price" as prohibited remuneration is inconsistent with the agency's approach requiring reporting of rebates as price *concessions* under Medicaid. We request clarification on how to reconcile the conflicting approaches and seek additional guidance.

Second, the preamble seeks comment as to whether the amendment "also should apply to prescription pharmaceutical products" payable under "other HHS programs" such as "section 1915(b)." Currently, a MMCO can operate under any one of several authorities, including a Section 1915(b) program waiver, state plan amendment (SPA), or a Section 1115 research and demonstration waiver. As proposed, the rule would already appear to apply to a MMCO operating under Section 1915(b) authority. We recommend that the Department clarify to whom the proposed amendment applies, under what authority, and provide any rationale for its determinations, including justifications for differential treatment between programs or entities, if any.

And, finally, the Department's proposed removal of the *regulatory* discount safe harbor could potentially present legal exposure for parties to ongoing or past rebate-based contracts, most notably via *qui tam* lawsuits. We seek clarity about this potential impact.

VIII. The Department should consider allowing states to decide how best to administer supplemental rebates within the context of each state's unique Medicaid program.

To the extent the Department declines to carve Medicaid out of the proposed rule altogether, the Department should give states a choice of whether to adopt the new chargeback model or keep the existing system instead of implementing a one-size-fits-all approach that would preclude all MMCOs from negotiating and receiving supplemental rebates. This would give states and various affected stakeholders the opportunity to determine the most effective approach to managing their drug costs based on local conditions.

There is wide variation across states in terms of how they structure and administer Medicaid pharmacy benefits, and this variation likely will result in differences among states in

terms of how they would prefer to handle supplemental rebates. For example, states that directly negotiate and collect supplemental rebates may prefer a safe harbor that allows them to continue receiving supplemental rebates while disallowing MMCOs from doing so, whereas states that have delegated to MMCOs responsibility for negotiating and collecting supplemental rebates likely would prefer a safe harbor that allows MMCOs to continue receiving supplemental rebates. Because states will differ in this way, a one-size-fits-all approach for Medicaid supplemental rebates is not the most effective way to address rebates within the Medicaid program. Instead, the Department should allow states the flexibility to choose the approach that works best for them.

IX. The implementation date for all aspects of the proposed rule should be delayed pending a complete analysis of the impact on all affected federal health care programs.

The proposed new safe harbor for point of sale discounts would take effect 60 days after publication of a final rule, but the Secretary seeks comments on removing safe harbor protection for current rebate structures effective January 1, 2020. The proposed rule would significantly disrupt current arrangements among manufacturers, PBMs, MMCOs, and pharmacies. The potential for such an imminent effective date raises major questions about contractual obligations and liabilities if the change goes into effect and presents challenges to negotiate and implement replacement point-of-sale discounts (to the extent those are offered) and to modify existing plan reporting processes to reflect the new system.

We also point to the very wide range of positive and negative economic impacts set out by the actuarial analyses commissioned by the Department that, in our view, seem indicative of a high level of uncertainty about the likely impact of this proposed rule.

Accordingly, we recommend, at a minimum, that the implementation date be delayed until a full analysis of the impact on the Medicaid program and its beneficiaries is completed and assessed. Preferably, for the reasons discussed in this submission, we recommend that the Medicaid program be entirely removed from this proposed rule.

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Thank you for the opportunity to provide comments on this proposed rule. Our member plans are committed to serving Medicaid beneficiaries and working with our state and provider partners; we are available to assist you as you consider the applicability of this rule to the Medicaid program. Should you need any additional information or seek further clarification on our comments or recommendations, please feel free to contact me at sattanasio@mhpa.org.

Sincerely,

Shannon Attanasio

Shannon Attanasio
Vice President, Government Relations and Advocacy