



January 16, 2018

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
US Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

Re: Comments on Medicare Part D Proposed Rule for 2019 (CMS-4182-P)

Dear Administrator Verma:

The AIDS Institute, a national nonprofit organization dedicated to supporting and protecting health care access for people living with HIV/AIDS, hepatitis, and other chronic and serious health conditions is pleased to submit comments to the Center for Medicare and Medicaid Services (CMS) on the proposed policy changes to the Medicare Prescription Drug Benefit Program for Contract Year 2019 (the proposed rule).

Before commenting on the proposed rule, we want to stress the importance of the Medicare Part D program to people living with HIV, hepatitis and others with serious and chronic health conditions. The program is working well, performing under budget and with the vast majority of Medicare beneficiaries reporting they are satisfied with Part D. A 2016 national survey of 2,000 seniors conducted by *Morning Consult* found that an astounding 88 percent are satisfied with their Part D coverage and eight of every 10 believe their drug plan is a good value. CMS must not to institute any policy changes that would diminish the program's success and the health of its beneficiaries.

We are pleased that many of the proposals contained within the proposed rule will improve beneficiary access to Part D medications, but have some concerns with certain elements. The AIDS Institute has signed onto comments submitted by the MAPRx Coalition and the HIV Healthcare Access Working Group, and our concerns are expressed in those comment letters. **The AIDS Institute would like to focus its comments on the Request for Information regarding the application of manufacturer rebates to drug prices at the point of sale.** (Please note that The AIDS Institute signed onto a separate patient group letter in support of applying all

pharmacy price concessions to be reflected in the negotiated price that is made available at the time a medication is dispensed.)

**Need for Changes:** Much attention has been paid in recent years to increasing drug prices and the corresponding increase in manufacturer rebates. As a patient group, we are most concerned about the impact of this situation on beneficiary cost sharing and access to medications. In addition, due to the design of the Medicare Part D program, high priced drugs have also had a significant impact on the federal government's cost, particularly in the reinsurance stage of the program. **In order to address this growing concern, The AIDS Institute is highly supportive of requiring plan sponsors to pass on at least a certain percentage of manufacturer rebates at the point-of-sale (POS) to the beneficiary.** Doing so will decrease patient cost-sharing, reduce the incentive for plans to choose high priced, high rebates drugs, and increase patient adherence to medications.

As CMS stated in the proposed rule, between 2010 and 2015, price concessions received by Part D sponsors and their pharmacy benefit managers (PBMs) grew by 24 percent per year, or about twice as fast as gross drug costs. These price concessions by manufacturers were mostly in the form of drug rebates to the plan sponsors. And as CMS further states, "the data also show that manufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010." Unfortunately, these plan savings, which have helped maintain lower premiums, have not resulted in lower drug pricing and patient cost-sharing at the point of sale. As CMS states, beneficiaries "end up paying a larger share of the actual cost of the drug." **The practice of plans not passing on savings to beneficiaries must end, and we encourage CMS to pursue efforts to require plan sponsors to do so as was originally intended in the Medicare Part D program.**

**The AIDS Institute Milliman Study:** For some time, The AIDS Institute has been concerned with these trends that result from embedded, misaligned incentives in the structure of the Part D program. **In fact, The AIDS Institute commissioned Milliman to conduct a study in November 2016 which highlighted that Part D plans have a financial incentive to cover drugs with higher list prices and higher rebates as a means of driving down the premium, compared to lower price drugs with lower rebates<sup>1</sup>.** Moreover, the report concluded that because benefit designs have shifted more to coinsurance for brand drugs (based on the list price), patients who take medications with high rebates are not benefitting financially from those higher rebates. Thus, these embedded incentives result in increased costs to both the government and beneficiaries.

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<sup>1</sup> "Financial Incentives in Medicare Part D" commissioned by The AIDS Institute and prepared by Adam J. Barnhart and Jason Gomberg of Milliman, Inc. November 3, 2016.  
<http://theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf>

In January 2017, CMS also released a study examining direct and indirect remuneration (DIR) in Part D, which reached the same conclusion.

In The AIDS Institute Milliman study, we analyzed the point-of-sale costs and benefits for payers in the Medicare Part D system based on differing drug costs and rebate levels. The report compares two scenarios; a person who is taking a drug that costs \$50,000 and has no rebates, compared with a drug for the same condition that costs \$100,000 but offers significant rebates. While the pharmaceutical company receives the same revenue in both cases, the cost to the federal government through the federal reinsurance subsidy would be over \$20,000 more for the higher priced drug. The beneficiary would pay an additional \$2,500 at POS for the higher priced drug. The plan sponsor would actually pay nearly \$23,000 less due to the rebates received. In fact, the plan sponsor would receive more than \$14,000 above what they pay for the medicine.

**We believe changes such as the ones CMS is proposing can begin to correct the perverse incentives within the Part D program, and help reduce patient cost-sharing and improve their access to medications.**

**CMS Proposal:** While The AIDS Institute is highly supportive of the type of recommendation CMS is proposing, we have some comments on how it can be devised. In response to your request for comments on specific aspects, The AIDS Institute offers the following:

- 1) **Percentage of rebates that should be passed on:** We do not offer a specific percentage, but do not believe 100 percent of all manufacturer rebates should be reflected at the point-of-sale. As CMS has stated, rebates have caused Medicare Part D beneficiary premiums to remain low. However, by not passing rebates onto the beneficiaries, it forces patients who have chronic and serious conditions, including people living with HIV and hepatitis who depend on high priced medications, to pay higher cost-sharing by moving through the donut hole faster and paying high co-insurance. While we realize the benefits of lower premiums across the board, CMS must recognize the impact on the health and financial impact of beneficiaries who rely on higher priced drugs, who greatly suffer from the current situation. Allowing plans and PBMs to maintain a small portion of rebates will allow premiums to remain stable, while better serving beneficiaries with serious and chronic illnesses who rely on higher priced medications.
- 2) **Applying rebates by drug class or specific drug:** We do not believe that CMS should consider implementing such an arrangement by drug class or category. Manufacturers who produce medications within the same drug class or category may approach drug pricing and rebates in very different ways. One manufacturer may price a drug at a lower price and offer smaller rebates, while another may offer a drug for the same condition at a high list price with high rebates. If CMS applies the rebates across the

entire drug class, it would penalize those companies that have lower list prices. We realize that CMS is concerned about confidentiality but hope you can overcome this through other methods.

- 3) **Applying rebates based on a weighted average of sales:** Similar to our comments above, applying the rebates based on a weighted average of sales penalizes those drug manufacturers who may have lower drug prices and rebates, but do not result in corresponding sales. Again, we hope CMS can devise a different system.

**Economic Analysis:** We note that according to the analysis CMS included in the proposed rule, overall, consumers will widely benefit from applying a large percentage of manufacturer rebates at the point-of-sale. Since CMS has stated that it is not considering requiring plans and PMBs to pass on 100 percent of the rebates, we will highlight the scenario in which 90 percent of the rebates are passed on. While premiums would increase by \$26 billion over 10 years across the board, beneficiary cost-sharing would decrease by \$79 billion, for a total overall savings for consumers of \$53 billion. If the costs and savings are examined at a member per month basis, premiums would increase by \$40 but cost sharing would drop by \$122. **It is clear that passing a large percentage of rebates on to beneficiaries will result in significantly lower costs for patients.**

In the same 90 percent scenario, CMS estimates that the federal government will spend \$62 billion less in reinsurance and \$48 billion less in low income cost sharing subsidies over ten years. However, CMS estimates that these significant costs savings will be offset by increased spending in the form of direct subsidies. As our Milliman report concluded, higher rebates for higher priced drugs, results in significant higher expenditures for the federal government in the reinsurance phase, so we clearly understand the CMS conclusion of those savings. However, while we do not possess the expertise to specifically counter CMS claims about the increased direct subsidy costs, we note that CMS is not considering behavior changes and would hope that by changing the current system would result in overall cost savings to the federal government.

We thank you for the opportunity to submit these comments and **urge CMS to move forward as soon as feasible with some type of system that will require that a high percentage of manufacturer drug rebates be passed on to Medicare Part D beneficiaries. In doing so, CMS will correct the perverse incentives within the Part D program, reduce patient cost-sharing, improve access to medications and the health of beneficiaries.**

Sincerely,

A handwritten signature in blue ink, reading "Carl E. Schmid II". The signature is fluid and cursive, with the first name "Carl" and last name "Schmid" being more legible than the middle initial "E".

Carl E. Schmid II  
Deputy Executive Director