April 8, 2019

Via electronic submission: www.regulations.gov

The Honorable Alex Azar
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201


Dear Secretary Azar:

The AIDS Institute, a national nonprofit organization dedicated to supporting and protecting health care access for people living with HIV, hepatitis, and other chronic and serious health conditions, commends the Trump Administration’s commitment to lowering prescription drug and out-of-pocket costs. We appreciate the opportunity to offer our strong support for this proposed Medicare Part D rule that would eliminate rebates. We believe, when finalized and implemented, it will have a lasting, positive impact for Medicare patients by reducing out-of-pocket costs at the point of sale and reversing the perverse incentive structure that has patients with high prescription drug needs subsidizing health insurance for healthier people. However, we do have concerns about the application of the rule to Medicaid Managed Care and urge the Administration to withdraw that portion of the rule.

The AIDS Institute is pleased that in its efforts to contain the cost of prescription drugs, HHS has focused on ways in which prescription drug prices can be lowered but also addresses proposals to reduce patient out-of-pocket costs. By eliminating rebates in Medicare Part D, with this proposal HHS will actually address both high drug prices and high patient cost-sharing. If patient cost-sharing is too high, patients will not be able to afford their medications. Patients with serious and chronic health conditions, such as HIV and hepatitis, often shoulder the heaviest
cost burden and are looking forward to implementation of policies and proposals that would reduce their costs without compromising their access to the medication they need to be healthy.

Access to innovative medications for people living with HIV, hepatitis, and many other serious and chronic health conditions is critical for their health and survival. Access to medications is central to the well-being of all people living with HIV, who now can live a relatively healthy, normal life if they have access to the antiretroviral treatment prescribed to them and take them daily. When on treatment, the person’s HIV can be suppressed, which makes transmission of the virus to others effectively impossible. Access to direct acting antivirals for the treatment of hepatitis C now provides a cure to patients in as little as eight weeks for a once deadly virus. Moreover, PrEP, or Pre-Exposure Prophylaxis, is a drug that prevents HIV infection. It is because of these medications, that we can actually end both of these infectious diseases as public health threats, as the Administration has proposed with regard to HIV in its “Ending the HIV Epidemic: A Plan for America,” if people are able to gain and maintain access to them.

**Importance of Medicare Part D to HIV & Hepatitis C**

We want to stress the importance of the Medicare Part D program to people living with HIV, hepatitis, and others with serous and chronic health conditions. Over 120,000 people living with HIV rely on Medicare Part D to access their medications, and more than 600,000 will become eligible for Medicare over the next two decades, as the first-generation survivors of the HIV/AIDS crisis age into the program. Moreover, an estimated 287,000 Medicare beneficiaries are living with hepatitis C; more than 75 percent of people with hepatitis C were born between 1945-1965, the “baby boom” generation, who are now beginning to age into Medicare. 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 out of every 10 believe their drug plan is a good value. HHS must not institute any policy changes that would diminish the program’s success and the health of its beneficiaries.

**Benefits of Eliminating Rebates**

The AIDS Institute applauds HHS for addressing the significant role of rebates, collected by plan issuers and Prescription Benefit Managers (PBMs), from drug manufacturers, and their role in raising drug costs and patient out-of-pockets expenses. We applaud HHS for proposing this policy to reduce the level of rebates, which has led to increased drug prices, and instead, pass on savings directly to the patients in the form of discounts.

As a patient group, The AIDS Institute is most concerned about the impact of the growing use of rebates 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 manufacturers to offer discounts at the point of sale in lieu of rebates. Doing so will decrease patient cost-sharing, reduce the incentive for plans to choose high priced, highly rebated drugs, while increasing patient adherence to medications.

HHS reports that the average difference between the list price of a drug and the post-rebate price ranges from 26 to 30 percent, and, according to the Drug Channels Institute, this “gross to net bubble” has reached a value of $166 billion in 2018.\(^1\) This amount is double the value in 2013, and although annual increases in overall rebates have slowed in recent years, the trend continues to be upward.\(^2\) 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 stated, beneficiaries “end up paying a larger share of the actual cost of the drug.” This is because coinsurance paid by beneficiaries is based on list price rather than net price, which means that as rebates push list prices up, beneficiaries pay more.

While we acknowledge that the proposed rule will likely result in minor increases in premiums for all beneficiaries, these increases will be offset by lower out-of-pocket costs for prescription drugs. HHS estimates that 30 percent of beneficiaries – such as those living with HIV and Hepatitis C, who rely on higher-priced prescriptions, will see reductions in out-of-pocket costs for prescription drugs that will be far greater than any premium increases. Since nearly all plans require coinsurance (based on list price) for at least some drugs on their formularies, the elimination of plan and PBM rebates will result in savings for a large share of beneficiaries. According to the Kaiser Family Foundation, the median coinsurance among all Part D plans for non-preferred drug is 40 percent, and 25-33 percent for specialty drugs.\(^3\)

Moreover, many of the prescriptions our patients rely on are specialty drugs often placed on the highest tier, and for which there are no generic alternatives. High out-of-pocket costs have a detrimental impact on patient adherence and increase medication abandonment, which is harmful to patients’ wellbeing and the overall healthcare system. Results from a 2017 survey by Consumer Reports Best Buy Drugs revealed that 14 percent of patients stated that an increase in out-of-pocket costs was the cause for not filling a prescription; 47 percent were deterred by as little as a $20 increase.\(^4\) Improved adherence to prescription drug regimens will likely result in reduced non-prescription Medicare health costs.

---

\(^1\) [https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf](https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf); [https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html#more](https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html#more)

\(^2\) [https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html#more](https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html#more)


Incentives for Medicare Plans to Prioritize High Cost, High Rebated Drugs

For some time, The AIDS Institute has been concerned with the embedded misaligned incentives in the structure of the Part D program that favor high cost drugs with high rebates. In November 2016 we commissioned Milliman to conduct a study to highlight 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. The report concluded that because benefit designs have shifted more to co-insurance 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.

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

In The AIDS Institute Milliman study, we analyzed the point-of-sale (POS) costs and benefits for payers in the Medicare Part D system based on differing drug costs and rebate levels. The report compares the situation for a person who is taking a drug that costs $50,000 and has no rebates with one 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 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 elimination of negotiated rebates for Part D plans and PBMs can begin to correct the perverse incentives within the Part D program and help reduce patient cost-sharing and improve their access to medications. Although it will significantly change the way plans, PBMs, and manufacturers do business, it should not unfairly disadvantage any of them. Plans would still have the ability to negotiate with the drug companies by offering discounts for beneficiaries. PBMs would be able to earn a fixed payment for their services instead of a percentage of the artificially high list price of the drug.

Ensure Savings are Passed to Patients & Plans do not Restrict Formularies

While we strongly support this important policy change, we urge HHS to ensure that savings are passed on to beneficiaries. Drug manufacturers must actually lower their list prices and plans and PBMs must negotiate substantial discounts to ensure cost savings are passed on to

beneficiaries). We also want to ensure that indirect costs to plans and PBMs are not passed along to patients to offset any losses accrued to them from this change.

Further, we want to ensure this policy change will not provide issuers added incentives to restrict formularies or implement other mechanisms, such as enhanced utilization management tools (i.e., step therapy and prior authorization), to restrict beneficiary access to specialty-tier medications. This policy, in conjunction with the previously-proposed changes to allow greater utilization management for the six protected classes of drugs within Medicare Part D, could result in harmful restrictions that would interrupt care regimens for people with HIV and hepatitis C, and others. The AIDS Institute has previously commented against proposed changes to the six protected classes, and we urge CMS once again to withdraw that proposal. We also urge HHS to closely monitor Part D plans to ensure that patients’ access to prescription drugs is not hampered by the implementation of the proposed rebate rule.

**Medicaid Managed Care**

While we are supportive of eliminating rebates in the Medicare program, we oppose applying this rule to Medicaid Managed Care programs. Medicaid is an important source of coverage for people living with HIV and hepatitis C, with 41 percent of patients living with HIV in treatment relying on Medicaid for access to care.

Since Medicaid copayments are limited by federal law to nominal amounts, rebate arrangements do not have the same impact on Medicaid beneficiaries as they do for Medicare beneficiaries. The change to the safe harbor for Medicaid would reduce funds available to states to operate their Medicaid programs, which could result in harmful cuts to the benefits available to beneficiaries.

We 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.

Finally, our support for this proposed rule and the elimination of rebates only pertains to the Medicare Part D Program. Statutory and additional rebates in other programs, including 340B rebates, are extremely critical to lowering patient costs for people living with HIV and hepatitis C, and to the funding of the health infrastructure for the treatment and prevention of HIV and the treatment of hepatitis C. Support for eliminating Medicare Part D rebates in no way should be equated to our support for changing the rebate system in other programs.
Should you have any questions or comments, please do not hesitate to contact Carl Schmid, Deputy Executive Director, at cschmid@theaidsinstitute.org or by phone at 202-835-8373.

Sincerely,

Michael Ruppal
Executive Director

cc: Aaron Zajic, Office of Inspector General