HIV + HEP

POLICY INSTITUTE

July 20, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C., 20201

Re: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-P)

Dear Secretary Azar:

The **HIV + Hepatitis Policy Institute,** a national, non-profit organization whose mission is to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, is pleased to submit comments on a proposed Medicaid Drug Rebate rule. If finalized, parts of the rule would have serious negative ramifications for patient access to prescription drugs in the private market and jeopardize future drug development. Our comments pertain to two sections of the proposed rule: 1) Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs ("PBM Accumulator Programs") from Determination of Best Price (§ 447.505) and Average Manufacturer Price (AMP) (§ 447.504); and 2) Definition of Line Extension, New Formulation, and Oral Solid Dosage Form for Alternative Unit Rebate Amount (§ 447.502).

Both proposals would have impacts on patients that perhaps HHS has not fully considered, and through the comment process **HIV + Hep** hopes HHS will decide not to move forward with them and not finalize these sections.

Exclusion of Certain Manufacturer Copay Assistance from Best Price Determination

HIV + Hep has been closely monitoring the growth of copay accumulator programs and their impact on patient access to and affordability of prescription medications. HHS has correctly stated in the preamble of the proposed rule that an increased number of insurers and their

pharmacy benefit managers (PBMs) are instituting these programs that are harmful to patients. By not counting copay assistance towards beneficiaries' out-of-pocket costs and deductibles, as you have described in the preamble, "The manufacturer assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug." As you further describe in your patient scenarios, "This results in the health plan delaying the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan." In the end, the consumer ends up paying substantially more for their drug and the manufacturer spends more, while the insurer receives more money, which you define as "generating savings." The plan is collecting more money per drug just because the patient is using a copay coupon and the plan has instituted a copay accumulator. Therefore, the patient, along with the manufacturer, is being punished for using a copay coupon and the insurer rewarded.

While the patient scenarios described in the preamble appear accurate, **HIV + Hep** would like to point out one error in your description of copay accumulator programs. Insures and their PBMs do not only apply them "for a brand name drug not on a plan's formulary." They apply them to all drugs that the patient accesses through their insurance plan that have copay assistance. When insurers institute copay accumulators, they are described usually by one sentence buried in the plan documents. For example, Ambetter in Georgia includes the following language in their plan document: "Cost sharing paid on your behalf for any prescription drugs obtained by you through the use of a drug discount, coupon, or copay card provided by a prescription drug manufacturer will not apply toward your plan deductible or your maximum out of pocket."[1] It is applied to all drugs, not just those off formulary.

HIV + Hep has commented on numerous occasions on the importance of copay assistance so that patients can afford and adhere to their prescription drugs. Due to insurance benefit design, patients are faced with high deductibles and high cost sharing, often in the form of co-insurance. We have also commented on the *2021 Notice of Benefit and Payment Parameters* rule that reverses the 2020 rule and now allows insurers to implement copay accumulator programs on all drugs regardless if the coupon is for a brand name drug with or without a generic equivalent. The *2021 Notice of Benefit and Payment Parameters* rule, finalized during the COVID-19 pandemic when patients are struggling to afford the basics of life, including their prescription medications, was a significant loss for patients and their use of copay assistance

[1] The AIDS Institute," Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients, June 2020," http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf, 30.

programs. Now, HHS has proposed yet another rule that will further endanger the use of copay assistance for patients, this time in a roundabout fashion through a Medicaid rule.

Best Price Calculation

HIV + Hep usually does not involve itself in drug pricing calculations, such as the determination of "best price" in Medicaid; however, since the proposed rule will have significant ramifications for the future use of copay assistance in the private market, which patients with HIV, hepatitis and other serious and chronic conditions rely on, we are compelled to comment at this time. HHS is proposing that companies can no longer exclude the value of the coupons in determining best price because they cannot ensure the value of the coupons are going to patients due to copay accumulators. While HHS has correctly stated that the discounts offered through coupons are not always directly benefiting patients, it is wrong to conclude the drug companies can determine which patients are subject to copay accumulator programs and which ones are not in order to comply with the proposal. HHS is proposing to require drug companies to do something that they cannot do and penalize patients in the process.

Copay accumulator programs are a benefit design controlled by the insurers and the PBMs, a policy frequently imposed without the beneficiary's knowledge and certainly not to the knowledge of drug manufacturers. While a manufacturer may be able to retrospectively analyze claim data and guess which beneficiaries *might have been* subject to copay accumulators, it is not a reliable data point. This is made more difficult by the fact that all beneficiaries do not fill their prescription at the beginning of the year but at all different times of the year, including in the last months. Only the insurer and PBM would know If a copay accumulator was in effect.

One major vendor in the copay coupon market, TrialCard, recently stated:

> "There is no reasonable method for manufacturers to ensure the benefit of assistance programs goes exclusively to consumers.
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> "Placing responsibility on pharmaceutical manufacturers to ensure that the benefit of copay assistance goes only to patients is an unrealistic standard.
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> "Determination of how manufacturer support funds are accounted for is made by the health plan sponsor, fully independent of the pharmaceutical manufacturer. In nearly all cases, the manufacturer is unaware of whether the patient's health plan has an accumulator adjustment policy in place. Many health plans do not openly publish their policy on accounting for manufacturer support funds.

> "In addition, self-funded plan sponsors have significant flexibility to change benefit designs as they choose. A plan could implement an accumulator adjustment policy at any time within the plan year. The same patient in the same manufacturer program could receive the full benefit of the copay support offer on one use, but not on a subsequent use, entirely outside of the control of the manufacturer." and beneficiary started a drug in the beginning of the year and had her full deductible met by prescription drug spending have been." [2]

HIV + Hep has long wanted to obtain accurate data on which beneficiaries are being subject to copay accumulator policies, particularly for those who are being prescribed HIV and hepatitis medications but have been unable to obtain such information. Drug manufactures have been unable to provide it. To complicate matters, while the copay accumulator policy language could be contained in the policy documents, plans do not always implement them for one reason or another. Therefore, you cannot rely on the plan documents to determine if a beneficiary is subject to one or not.

Impact of Proposed Rule

While there is no question drug manufacturers offer copay assistance to beneficiaries to help patients access and afford their drugs so they can improve their health or be cured of a deadly virus, manufactures also benefit because their medication will be paid for by the insurer. The insurer collects premiums, rebates, and risk adjustment to provide these drugs. However, due to the growing use of copay accumulator programs, as demonstrated in your patient scenarios, manufactures are paying an increased amount. The recent *2021 Notice of Benefit and Payment Parameters Rule* provides permission to insurers and PBMs to implement copay accumulators, which clearly harm patients and increase drug company costs, as the proposed rule describes. **HIV + HEP** continues to be disappointed that the administration reversed course from the 2020 rule to allow copay accumulators.

The implementation of this Medicaid rule, if it were to be finalized, would financially penalize manufactures again, all for their desire to help patients afford their medications. As an organization that represents the interests of patients, we are concerned that due to the multiple financial penalties being levied against manufacturers, they will be less willing to offer

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[2] Rick Fry and Jason Zemcik, "CMS Best Price Proposal and Copay Assistance: How New Rule Could Change the Access Landscape," Drug Channels, July 10, 2020, https://www.drugchannels.net/2020/07/cms-best-price-proposal-and-copay.html.

patient assistance programs. In the end, it is the patients who cannot afford high deductibles and high copays who will be harmed. **HIV + Hep** urges HHS to withdraw this section of the proposed rule. Manufactures cannot comply with it and in the end it will harm patients.

Definition of Line-Extension & New Formulations

HHS is also proposing to change the definition of "line-extension" and "new formulations" that will have significant ramifications in the development of HIV, hepatitis, and other medications. Based on a misinterpretation of the law, HHS is proposing that combination drugs, which includes all HIV and most hepatitis drugs, along with "new routes of administration" for an existing drug, to be a "line-extension." This means that drug manufactures would have to use existing rebates from the original drug that could be years old and not start the calculation of mandatory rebates over with the new innovative combination drug.

Combination Drugs

While there are cases in which new drugs and formulations are pure line-extensions, what HHS is proposing goes far beyond what Congress intended when they defined a "line-extension." HIV, hepatitis, and some other illnesses are treated through combination drugs. For HIV and hepatitis, combination drugs bring two or more drugs together to successfully attack the virus through different mechanisms. One drug on its own would not be successful but combining it with one or more additional innovative drugs will be. This has been the remarkable success story of HIV antiretroviral therapy and hepatitis C curative drugs. Without these combination drugs, we would not be where we are in treating and preventing HIV or curing hepatitis C. These new and highly effective drugs are not mere line-extensions, but new innovative combination therapies.

Many of the most effective and widely used HIV and hepatitis drugs today are the result of a combination of a significantly older back bone drug. That one older HIV drug, which would never have been prescribed on its own, could have been combined with another drug in the past. Then manufacturers may take that same older drug and combine it with a new and innovative drug to produce a more tolerated, more effective, combination drug that results in fewer side effects and less resistance to the virus. The same occurred with the hepatitis C drugs. Through different combinations they were able to treat more genotypes all through just one combination drug, combined with an older drug.

If the proposal were to be finalized, to get around the new regulation, drug manufacturers would be less likely to produce combination antiretrovirals which would lead to increased pill burden for patients, possibly reducing adherence and leading to poorer health outcomes.

Routes of Administration

HIV + Hep is also concerned that HHS is proposing that if a route of administration for a particular drug is changed it would also be classified as a "new formulation" and a "line-extension" of an existing drug. **HIV + Hep** is concerned that if this were to be finalized there would be fewer financial incentives to develop new and improved drugs, including highly anticipated, long-acting HIV medications for both prevention and treatment. Pharmaceutical manufacturers are currently investigating long-acting agents that could be injected or implanted for both prevention and treatment. These long acting agents could include an existing solid oral drug or drugs that would be delivered through a different route of administration. Instead of taking medications for treatment or prevention daily, people could take them once every two months, twice a year, or even once a year. Having these new drugs available should increase patient adherence to their medications, improve health outcomes, and reduce the number of new HIV infections not only due to new and better prevention options but also to increased adherence to treatment, which leads to increased viral suppression.

Economic Impact Analysis

HIV + Hep notes that HHS has concluded in the proposed rule that the economic impact of its proposal is less than $100 million per year and therefore they do not have to perform a Regulatory Impact Analysis and the rule is not considered to be major. We strongly disagree with this conclusion. While there are many aspects of the proposed rule, just focusing on the two issues **HIV + Hep** addressed above each will have a significant economic impact.

The value of copay assistance from drug manufacturers in the private insurance market totaled $13 billion in 2018 according to the IQVIA National Prescription Audit, Formulary Impact Analyzer (January 2019).[3] If manufacturers had to include large portions of the value of copay assistance in calculating best price there certainly would be a significant economic impact on the drug manufacturers. If manufactures were to reduce their level of copay assistance it would also have a severe impact on consumers who would have to increase their level of cost-sharing. Medicaid programs would equally benefit from a reduction in the amount of spending they would pay for prescription drugs.

Changing the definition of a "line-extension" will also significantly impact drug manufactures each year in the reduced revenue they will receive for their medications and impact patients as well in the form of less adherence to medications and poorer health outcomes due to taking

[3] The IQVIA Institute, "Medicine Use and Spending in the U.S.", May 9, 2019, https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023.

multiple drugs instead of combination therapy along with multiple copays instead of a single one.

While **HIV + Hep** urges HHS to withdraw these two proposed changes, if you do move forward with them, a thorough Regulatory Impact Analysis must be conducted.

HIV + Hep thanks you for the opportunity to provide these comments. Should you have any questions, please feel free to contact me at cschmid@hivhep.org or (202) 462-3042.

Sincerely,

Carl E Schmid II
Executive Director

cc: Seema Verma, CMS
Calder Lynch, CMCS