HIV+HEP
POLICY INSTITUTE

January 21, 2022

Christina Whitefield
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Comments on Drug Pricing Transparency Interim Final Rule [CMS-9905-IFC]

Dear Ms. Whitefield:

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 the Interim Final Rule regarding **Transparency in Prescription Drug and Health Care Spending.**

The patients we represent rely on prescription drugs to treat their health conditions and prevent others. We are pleased that the Biden administration is moving forward with the requirement that insurance plans must report on various data points associated with prescription drug spending. We believe with this greater understanding and transparency of prescription drug costs, you can better implement policies and measures that increase competition, improve prescription drug affordability and access for the American people.

Patients today face significant prescription drug affordability challenges that have only grown worse due to the cost of medications along with insurance benefit design, including high deductibles and high patient cost-sharing often in the form of co-insurance. This negatively impacts patient adherence and leads to worse health outcomes and increased costs across the healthcare system.

As you implement the prescription drug cost reporting requirements for health plans, we offer the following comments:

1. **Require Plans to be Transparent on the Treatment of Copay Assistance.** Many health plans are instituting policies that do not count drug manufacturer copay assistance towards a patient's annual deductible or out-of-pocket maximum. In doing so, issuers are collecting the value of the assistance, which often exceeds the out-of-pocket maximum, and then, after it runs out, collecting additional payments by the patient until the out-of-pocket maximum is reached again. In another scheme, plans designate certain medicines as "non-essential" and then raise the cost-sharing to ensure that they collect all of the patient assistance offered by the manufacturer. Under this scheme, the plans often collect payments far exceeding the out-of-pocket maximum. While we continue to urge you to prohibit both of these practices, in the

meantime, these double and excess payments to the insurer must be made public and considered a violation of the Affordable Care Act (ACA) out-of-pocket limit.

We are pleased that when issuers and PBMs collect copay assistance that reduces their spending, you will require those amounts to be collected separately. We look forward to those reports and analysis.

2. **Cost-sharing Assistance from Manufacturers Not Included in Definition of Rebates:** We agree with the departments that drug manufacturer cost-sharing assistance to beneficiaries should not be included in the definition of prescription drug rebates because, as you correctly state, "these amounts are not credited to the plan or coverage or its administrators or service providers."

3. **Accounting of Rebates and Pharmacy Benefit Managers.** We are very pleased that you are moving forward with the data collection on the amount of rebates, fees, and other remuneration paid by drug manufacturers to the plan and how these rebates reduce premiums and out-of-pocket costs for patients. While there has been some delay in its implementation, we strongly urge you to move forward with this requirement without any further delays.

   The high level of rebates influences the list price of drugs. Since more and more health plans carry high deductibles and utilize co-insurance to determine patient cost-sharing, patients are unfairly being overly burdened with higher out-of-pocket costs. Additionally, while the portion of rebates plans receive may be benefiting all enrollees by reducing premiums, those who rely on prescription drugs and are responsible for generating those rebates for the plans are not directly benefiting. We hope the collection of rebate information will create greater drug price transparency and help establish a system in which patients who rely on prescription drugs can directly benefit from the rebates that they generate. Enrollees benefit from negotiated discounts for all other medical services. It is time that patients benefit from prescription drug discounts.

   We realize that the amount of rebates, fees, and other remuneration is often cloaked in secrecy by pharmacy benefit managers (PBMs), insurers, and drug manufacturers and affected parties are concerned with disclosure of competitive practices; however, we believe you have devised a way to overcome these obstacles by requiring the reporting at more of an issuer and drug class level. PBMs, which are frequently not regulated at the state level, have successfully and artfully tried to escape any attempt to report on how the billions in rebates and other fees they collect are distributed to plans, patients, or to their profits. To further add to the complexity, the three largest PBMs, which now account for over 75 percent of all drug claims, are either owned by or own an insurance company. We are pleased that you have resisted their attempts to limit transparency and move forward with these statutory required data reporting without further delay.

We thank you for the opportunity to share these comments and look forward to working with you and each of the other agencies implementing the prescription drug data reporting system.

If you have any questions or comments, please contact me at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director