

HIV+HEP
POLICY INSTITUTE

PRESS RELEASE

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**Trump Administration Temporarily Backs Off from
Proposal that Would Endanger Patient Copay
Assistance**

***Also Removes Provision that Would Impede
Development of Combination Drugs***

Washington DC... In a victory for patients' ability to afford prescription drugs, the Trump administration has delayed for two years implementation of a provision included in a proposed [Medicaid rule](#) that would have endangered manufacturer copay assistance for prescription drugs in the private insurance market. Additionally, in the [final rule](#) the Centers for Medicare & Medicaid Services (CMS) backed away from a proposal that would have impacted the development of combination drugs, which are important to the treatment and prevention of HIV, along with hepatitis and other illnesses.

CMS had proposed that drug manufacturers consider the value of coupon assistance in their determination of best price for Medicaid unless they could ensure that it went to the benefit of the patient. With the growth of copay accumulator programs (issuer and PBM policies that do not count copay assistance towards a beneficiary's deductible and out-of-pocket maximum), the value of the coupons is not directly benefiting patients but is instead going to the plans, and, according to CMS, should be considered in determining best price.

The **HIV+Hepatitis Policy Institute** contended that CMS would be requiring drug companies to do something that they cannot do and penalize patients in the process. CMS still believes drug companies can determine which patients are subject to copay accumulator programs and are now giving them two years to comply with it.

“While we are thankful that HHS is not immediately implementing this policy that would endanger copay assistance programs that patients rely on to afford their medications, particularly during the COVID pandemic, we still question the policy and will work with the next administration to revisit it,” said **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**. “If this policy were to be implemented, drug manufacturers would be less willing to offer copay assistance to

patients in the private market, all due to a Medicaid rule and damaging actions that are being taken by insurers and their PBMs.”

CMS had proposed to include “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 would have required drug manufacturers to use existing rebates from the original drug that could be decades old, and not start over the calculation of mandatory rebates with the new innovative combination drug. In the final rule, “combination drugs” were not included in the definition of a “line extension”; however, “new routes of administration” remained.

“We are pleased that HHS heard the concerns of the HIV community and the value of innovative drugs, including combination therapies,” added Schmid. “Without these changes, development of new and improved HIV and hepatitis medications could have been jeopardized.”

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The **HIV+Hepatitis Policy Institute** is 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.