



PRESS RELEASE

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## **Trump Administration Medicaid Proposal Endangers Patient Assistance Programs in Private Insurance Market**

***Will Further Put Cost of Drugs  
Out of Reach for Patients***

*Washington DC...*In a setback to patients' ability to afford prescription drugs, the Trump administration has again attacked the use of drug manufacturer copay assistance for prescription drugs in the private insurance market, this time in a roundabout fashion through a proposed Medicaid rule.

In a little noticed section of a proposed rule focusing on value-based purchasing, HHS is requiring drug companies to do something that they cannot do and penalize patients in the process. Currently, drug companies—in determining their best price of a drug, which sets the price state Medicaid programs pay for drugs—can exclude the amount of copay assistance they offer to patients. As copay accumulator programs have become more common, HHS has correctly stated that the discounts offered through coupons are not always directly benefiting patients but instead benefiting the plans. Therefore, HHS is now proposing that companies can no longer exclude the value of the coupons in determining best price because they cannot ensure they are going to patients. HHS incorrectly states that drug companies can determine what patients are subject to copay accumulator programs and which ones are not in order to comply with its proposal.

“This proposed rule, if finalized, would be another setback to copay assistance programs that patients need to afford their medications, particularly in the era of high deductibles and high copays in the form of co-insurance,” said **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**. “Drug manufacturers will 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. This is on top of another recent Trump administration rule that gave insurers the green light to implement copay accumulator programs. I thought this administration was working to make sure medications are affordable to patients; instead, they are doing the opposite—again.”

Another proposal in the rule that has not yet attracted attention but will have significant ramifications in the development of HIV, hepatitis, and other medications is a change in the definition of “line-extension.” 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 decades old, and not start the calculation of mandatory rebates with the new innovative combination drug.

“These complicated drug pricing laws and regulations are hard for anyone to understand, but what is clear,” commented Schmid, “is that if this regulation is finalized, there will be fewer financial incentives to develop new and improved drugs, including highly anticipated long-acting HIV medications for both prevention and treatment.”

The proposed changes were announced on June 17th with only a 30-day public comment that includes the July 4th holiday. During this limited time, **HIV+Hepatitis Policy Institute** hopes that the public will be made aware of the major ramifications of these proposals so that HHS does not move forward with them. Added to urgency is that most patients are currently focused on the COVID-19 pandemic and not on convoluted government drug pricing calculation formulas. **HIV+Hep** is joining with other groups to request an extension of the public comment period to August 20th.

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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.