



Costly Consequences: Medicaid Generics Penalty Threatens Patient Access to Affordable Medicine

Starting in 2017, a new penalty is imposed on generic manufacturers participating in the Medicaid program for generic medicines with price increases exceeding the rate of inflation. The Medicaid Generics Penalty is modeled on a fundamentally different market, ignores the differences and highly competitive nature of the generics drug market, unfairly penalizes manufacturers for price fluctuations outside of their control, increases the risk of drug shortages and ultimately threatens the availability of low-cost generics to patients.

Access to safe, affordable generic medication is a critical lifeline to millions of patients, in particular individuals and families with Medicaid coverage, and reduced prescription drug costs for Medicaid recipients by \$512 on average last year.¹ Congress should immediately repeal the new penalty on generic drugs.

Inappropriate New Penalties Threaten the Competitive Generic Drug Market

- Generic drug manufacturers operate in highly competitive markets. As more manufacturers gain FDA approval and enter the market, competition reduces the cost of medication for patients.²
- The Medicaid Generics Penalty increases the cost of providing patients with access to more affordable generic alternatives. As new costs such as these penalties pile up, manufacturers will be left with no choice other than to leave the most competitive markets — reducing the availability of products on the market.
- The penalty is based on overall changes to prices in the economy (CPI-U) and does not reflect the underlying costs associated with manufacturing generic drugs.
 - » In each of the last five years, CPI-U was less than +2 percent.³ At the same time, many generic drugs are sold for pennies per unit, which means that any one-cent change in price would create penalty liability for every sale to a Medicaid beneficiary.
- Changes in the price of active pharmaceutical ingredients used to make generic drugs, for example, often fluctuate due to normal market conditions and are outside the control of manufacturers.
- Moreover, the Medicaid Generics Penalty inappropriately uses the average manufacturer price (AMP) — a volatile barometer that does not adequately reflect manufacturer behavior, and can instead often reflect changes among purchasers.

- This results in the penalty applying unnecessarily to a broad range of Medicaid generic drugs.
 - » More than 40 percent of generic drugs reviewed by the Department of Health and Human Services (HHS) showed at least one quarter where the AMP exceeded the baseline.⁴
 - » The penalty is being applied at the same time that HHS's Office of the Assistant Secretary for Planning and Evaluation has recognized that more than two thirds of generic products saw a yearly decrease in overall price, and "that generic drug prices are not an important part of the drug cost problem facing the nation."⁵

Patient Access to Generics Threatened by Increased Risk of Drug Shortages

- With the increased costs associated with the Medicaid Generics Penalty, analysis from Bates White concludes the policy "will not only have little effect on generic prices, but it will also have the unanticipated and unintended consequence of increasing the likelihood of shortages for generic medicines."⁶
- The penalty exacerbates the problem with drug shortages by reducing the incentive to manufacture certain generic drugs, especially in already challenging low-volume markets dominated by consolidated purchasers.
- Independent research estimates the overall costs of drug shortages at more than \$400 million annually,⁷ largely due to patients and doctors turning to alternative forms of treatment, which can lead to medical errors and other unintended outcomes.⁸

Congress Should Repeal the Medicaid Generics Penalty on Medicaid Generic Drugs

- Generic drugs drive savings to Medicaid and increase access to safe, affordable medicines for millions of individuals and families.
 - » Nearly \$38 billion in Medicaid savings was generated in 2016 due to the availability of generics.⁹
- The unintended consequences of this policy, enacted as part of the Bipartisan Budget Act of 2015, could harm patient access to generics. It should be immediately repealed.

References

1. AAM, "Generic Drug Access & Savings in the U.S.," June 2017 ([link](#)).
2. FDA, "Generic Competition and Drug Prices," May 2015 ([link](#)).
3. Bureau of Labor & Statistics, "Consumer Price Index," July 2017 ([link](#)).
4. HHS OIG Report, December 2015 ([link](#)).
5. HHS ASPE Report, "Understanding Recent Trends in Generic Drug Prices." January 2016 ([link](#)).
6. Bates White, "Penalizing Generic Drugs with the CPI Rebate Will Reduce Competition and Increase the Likelihood of Drug Shortages," September 2017. ([link](#)).
7. Wall Street Journal, "America has a big drug shortage problem." July 2017 ([link](#)).
8. Mayo Clinic, "Drug Shortages: A Complex Healthcare Crisis." March 2014.
9. Ibid., AAM.