

Proposed Elimination of Medicaid Rebate Cap Could Negatively Impact Innovator Pharmaceutical Industry

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Both houses of Congress are currently working on a "budget reconciliation" process that could ultimately lead to enactment of a bill that, among other things, would authorize \$1.9 trillion in additional government spending. As part of this process, on February 9, 2021, the House Energy and Commerce Committee ("House E&C Committee") announced it is considering the elimination of a cap on certain rebates pharmaceutical companies pay to the Medicaid program. This change, if implemented, could result in billions of dollars in additional costs for the pharmaceutical industry. The Democratic-controlled House is expected to support the measure, but the outcome in the Senate is less clear. As the Senate is evenly split (with Vice President Harris breaking any ties), one key question will be whether centrist Democratic senators Joe Manchin (D-WV) or Kyrsten Sinema (D-AZ) will support these provisions.

Medicaid Drug Rebate Program Overview

Pharmaceutical companies participating in state Medicaid programs are required to enter into agreements with the Department of Health and Human Services that typically include the following rebates:¹

- The greater of (i) 23.1% of the "average manufacturer price" ("AMP")² of a drug or (ii) the difference between a drug's AMP and "best price."³
- The difference between the drug's AMP for the current quarter and the baseline AMP (defined as the AMP in the first full quarter after launch), adjusted by the Consumer Price Index for All Urban Consumers.

Separate rules govern rebates for certain drugs approved exclusively for pediatric conditions, clotting factors, and generic drugs.

AMP is defined as "the average price paid to the manufacturer for the drug in the United States by
(i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer."

³ "Best price" is defined as "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," with certain exclusions.



These rebates listed above are collectively capped at 100% of AMP. Additionally, nearly all states require pharmaceutical manufacturers to provide certain forms of supplemental rebates.

The Proposed Elimination of the Rebate Cap

The House E&C Committee is considering elimination of the cap on rebates at 100% of AMP. This change, if implemented, would negatively impact pharmaceutical companies that have significantly increased the price of their products in recent years. According to one report, in the fourth quarter of 2015, 18.5% of innovator manufacturers reached the rebate cap; the elimination of the cap would trigger larger rebates for such manufacturers. These additional rebates would largely result in increased savings for the federal and state governments, not Medicaid beneficiaries, because Medicaid beneficiaries typically pay only a small fixed fee for each covered drug.

Elimination of the rebate cap would likely lead certain innovator pharmaceutical manufacturers to evaluate pricing strategies for new drugs because the rebate amounts are linked to price increases. Under such circumstances, innovators may determine that it is prudent to start with a relatively higher baseline price, with the aim of limiting the size of future price increases that could trigger larger rebate amounts.

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We will keep you apprised of future developments. Please do not hesitate to contact us with any questions.



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