

ISSUE BRIEF

AMP Cap Repeal

As part of the American Rescue Plan Act of 2021, the Medicaid drug rebate cap will be repealed in January 2024.

SIGNIFICANCE OF THE AMP CAP AND ITS REPEAL

The history of the rebate cap begins in 2010 when Congress increased the Medicaid minimum rebate percentages off the average manufacturer price (AMP) as part of the Affordable Care Act.

At the same time, the federal rebate was capped at 100% of AMP so as not to force manufacturers to rebate more than the selling price of their drug. Former US Health and Human Services (HHS) Secretary Alex Azar reported that in 2019, **more than 2,300 drugs** were at the 100% cap on rebates. The Congressional Budget Office estimates that removing the cap on rebates would save the federal government approximately US \$15.9 billion over the 10-year period 2021–2030.

The minimum rebate by itself does not impact the cap; it's the best price (BP) and Consumer Price Index for All Urban Consumers (CPI-U) penalty that can drive the Medicaid rebate up to and beyond 100% of AMP.

Repealing the cap serves two purposes:

- Potentially increase rebates for states and the federal government
- Potentially forces manufacturers to lower their AMP (which reduces the impact of the CPI-U penalty) and/or reduce the discounts offered to commercial payers (which reduce the impact of BP)

MEDICAID STATUTORY REBATE AMOUNTS Brand Drugs

Greater of 23.1% of AMP or AMP minus Best Price plus Inflationary Component

Brand Drugs Approved Exclusively for Pediatric Indications and Certain Clotting Factors

Greater of 17.1% of AMP or AMP minus Best Price plus Inflationary Component

Generic Drugs

13% of AMP plus Inflationary Component

Understanding the calculus of the federal rebate, specifically the impact of the minimum rebate, BP, rebate offset amount, and the CPI-U penalty on total rebate due, is critical for driving a proactive pricing strategy prior to the AMP Cap Repeal.

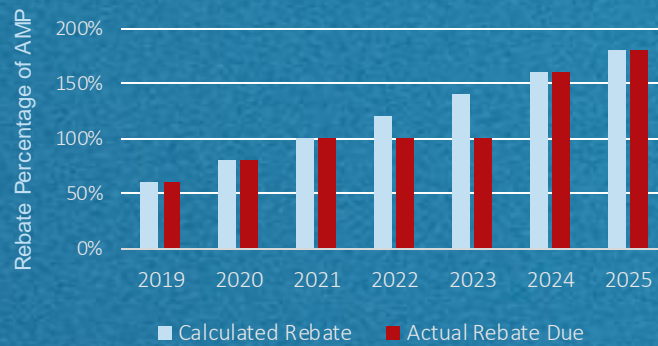
Impact on pharmaceutical manufacturers

At the cap, a manufacturer can increase a drug's price without further consequence to Medicaid pricing, but higher costs are paid by Medicare and commercial payers. These higher prices generate additional rebates for PBMs but also increase acquisition and reimbursement costs throughout the supply chain.

For manufacturers with drugs rebated at 100% of AMP, the repeal of the AMP Cap means a significant increase in federal rebate obligations. Manufacturers can choose to lower their AMP price, reduce the level of discount offered to commercial payers, pay the new "uncapped rebate," or a combination of all three. All options have consequences to profitability, pricing, and margin that require careful consideration.

IMPACT OF AMP CAP REPEAL IN 2024 ON REBATE PAYMENTS OVER TIME:

AN ILLUSTRATIVE EXAMPLE



This change can be **transformative** for both manufacturers and PBMs alike, not only for those **2,300 drugs** but for thousands of other drugs that will hit the cap over the next few years.

There are key actions a manufacturer should consider now in anticipation of the AMP Cap Repeal:

- Identify brands affected by the change and evaluate the payer mix to gauge potential impact
- Consider any potential portfolio and pipeline implications, where a halo effect may expand outside the affected brand
- Re-assess market access strategies, including pricing, contracting, and distribution decisions and arrangements
- Revisit customer messaging and product value propositions, to ensure alignment to potential strategies to mitigate impact of repeal
- Understand the impact that changes in contracting or AMP can have across channels, payers, and – ultimately – patient access
- Evaluate competitive analytics to inform future strategic decisions

While the payer mix, market share, and current federal rebate as a percentage of AMP determine the urgency of re-evaluations, it's critical that manufacturers know their Medicaid rebate obligation today, tomorrow, and in 2024, especially since commercial contracts for FY 2023 and 2024 may currently be in negotiations. If your Medicaid rebate is capped at AMP today, the time to start planning for 2024 is now.

COEUS' Market Access team has extensive real-world experience managing policy changes affecting access, with a particular focus on Medicaid and its impact on other payers and channels. If your brand is or may be affected by the AMP Cap Repeal or if you have other market access questions or challenges, the COEUS team welcomes the opportunity to help you maximize your brand's potential.



Doug Brown
SVP, Access & Value
+1 804.922.2392
dbrown@1COEUS.com



About COEUS

Established in 2009, COEUS is a leading healthcare consulting, communications, technology, and talent firm. The company offers clients a variety of services, as well as SaaS technology platforms, for various stakeholders throughout the healthcare ecosystem including all payers and emerging or more established drug manufacturers. Leveraging the deep knowledge and experience of the company's many subject matter experts, COEUS works on all drug types with a particular focus on gene and cell therapies, rare disease, and oncology. The company also has unique expertise in the creation and management of value-based agreements by leveraging COEBRA™, the company's evidence and outcomes adjudication platform. In its 13-year history, the company has supported the launch of more than 120 pharmaceutical brands and has worked with more than 300 pharma clients including many top global pharmaceutical manufacturers. To learn more about COEUS and the company's offerings, visit 1coeus.com

To learn more about COEUS and the company's offerings, visit 1coeus.com