

IMPLICATIONS OF THE 2024 Medicaid AMP Rebate Cap Removal

Executive Summary:

The cap on Medicaid rebates will sunset in 2024 and some manufacturers may pay rebates higher than the price of their drugs. The provision has the potential to increase rebates and significantly impact gross to net and reduce profitability.

Why the AMP Matters



TODAY

Manufacturers pay rebates to Medicaid capped at the quarterly Average Manufacturer's Price (AMP) for any given drug. This means that, at most, a manufacturer's Medicaid rebate is equivalent to the average price. This caps Medicaid losses at roughly break even.



IN 2024

A provision of the American Rescue Plan Act of 2021 will terminate the section of the Social Security Act, which previously capped Medicaid drug rebates.



THE IMPACT

For drugs at the cap today, the provision has the potential to increase rebates and significantly impact gross to net and reduce profitability.



How the Medicaid Drug Rebate Calculation Works

Formula for calculating the Medicaid rebate for branded drugs:

Greater between 23.1% of AMP or AMP minus best price plus inflation penalties

EXAMPLE CALCULATION

for a drug with inflation penalties and moderate best price

Quarterly AMP	\$	100
- Best Price	\$	40
Base URA	\$	60
+ Inflation Penalties	\$	50
Total URA	S	110

- A product with an AMP of \$100 and best price of \$40 has a base URA of \$60
 - \$60 = \$100 AMP minus best price of \$60
- Inflation penalties are added to base URA to calculate the total rebate
- Historically the rebate would be capped at AMP or \$100
- Starting in 2024, the liability will be greater than AMP at \$110

Thus, the manufacturer will begin losing money on every Medicaid script for this product.



Manufacturers Have Three Options in Response to the AMP Cap Removal

What options do manufacturers have if they are at the AMP cap and will start losing money in Medicaid in 2024? And what are the pros and cons of each?



PRICE REDUCTION

 Manufacturers can lower their list price, which would reset the AMP and reduce or remove the inflation penalties.

– PRO:

Would reduce overall rebate liability to Medicaid

- CON:

Reducing price will impact all segments and cause renegotiations with payers for rebates and coverage



TAKE THE LOSS

- Manufacturers can take the loss in Medicaid if they are able to offset those losses in other profitable segments of the business.
 - PRO:

Can maintain formulary positions and rebate rates in other segments

- CON: Profitability will decline



LEAVE MDRP

 Participation in the Medicaid Drug Rebate Program (MDRP) is optional, and some manufacturers may consider leaving the program.

 PRO: Manufacturer would no longer need to lose money on Medicaid volume

- CON:

Manufacturer would no longer be able to serve the Medicare or Medicaid patient populations



Estimate the Potential Impact

To decide which option is best, manufacturers should forecast how the AMP cap removal would impact your 340B strategies and how you process Medicaid rebate claims.

To help you estimate the impact of the AMP cap removal to your therapeutic area, consider working with Valuate Health.

Valuate's Principals and Analysts can help you:



MODEL VARIOUS SCENARIOS

to see what is best for your business considering MDRP rebates for you and your top competitors



PRESERVE GROSS TO NET

by leveraging our extensive experience



TEST VARIOUS STRATEGIES

via Valuate's direct relationships with more than 1,200 market access customers

Patient Protection and Affordable Care Act § 2501 (e), Pub. L. No. 111-148, 124 Stat. 119, 309 (2010). ²SSA § 1927(c)(2)(D) (Maximum Rebate Amount). ³S Amend 821 117th Cana & 8216 (2021) (amending American Rescue Plan Act of 2021, HR 1319, 117th Can

²⁵ Amend. 891, 117th Cong. § 9816 (2021) (amending American Rescue Plan Act of 2021, HR 1319, 117th Cong. § 3106 (2021)). The Senate version of the bill — which later passed in the House and was signed by the President — amended the effective date of the rebate cap elimination in the original House passed bill from 2023 to 2024. ⁴⁸³ Fed. Reg. 22,692, 22,698 (May 16, 2018).





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