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# Average Manufacturer Price cap removal: Implications for state Medicaid programs

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## Background

Since 2010, a rebate cap has been in place that prevents state Medicaid programs from receiving rebate payments that exceed the Average Manufacturer Price (AMP) of a product. However, provisions in the American Rescue Plan Act of 2021 will remove this cap, effective January 1, 2024.[1]

Without the AMP rebate cap in place, states may benefit from higher rebate payments that are greater than the sale price of the drug, which, absent other changes, could result in substantial savings to Medicaid programs. States should be aware of changes to the prescription drug market such as list price reductions, product discontinuations, the launch of new generics, or changes that impact components of the Medicaid unit rebate amount (URA) calculation. While not necessarily a direct correlation to the AMP cap removal, some products have already experienced list price reductions (e.g., insulin products) or have been discontinued. The AMP cap removal is straightforward at the surface, but the different paths for downstream effects must be accounted for to manage expenditures and maintain patient access to medications.

With different considerations for state Medicaid programs and pharmacy products, a more granular evaluation process is needed to describe consistent macro and product-specific impacts. Below, we outline immediate steps to ensure that pharmacy programs have the necessary monitoring and reporting to identify risk and manage implications for their programs.

More details of the AMP, URA, and Medicaid Drug Rebate Program (MDRP) program dynamics, including example calculations, are provided in Appendix A.

## What can state Medicaid programs do to ensure readiness in a post-AMP cap era?

**1. EVALUATE GROSS AND NET PRICE REPORTING STRUCTURES:**

- Identify how potential pharmacy product strategies resulting from the AMP cap removal would manifest in pharmacy data sources:
  i. List price reductions
  ii. AMP and URA changes
  iii. New authorized generics or Abbreviated New Drug Application (ANDA) products
  iv. Product discontinuations, particularly for brand products, such as those listed on the U.S. Food and Drug Administration (FDA) website[2]
  v. MDRP participation changes

1 CMS (June 3, 2021). Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Related Provisions in the American Rescue Plan Act of 2021. Retrieved November 14, 2023, from https://www.medicaid.gov/sites/default/files/2021-11/cib060321.pdf.

2 FDA. FDA Drug Shortages. Retrieved November 14, 2023, from https://www.accessdata.fda.gov/scripts/drugshortages/.

- Develop monitoring reports to meet need:
  i. Establish automated processes to identify material changes in list price, AMP, URA, new generic launches, product discontinuations, and MDRP participation changes.
  ii. Develop a watch list and identifier in monitoring reports for products at a greater risk of change due to the AMP cap removal such as "penny priced" drugs.
    - Penny-priced drugs have a net cost to the state of $0.01/unit; this occurs when the AMP minus the URA is $0.01. Based on a recent publication from IQVIA, approximately 15% to 20% of brand drugs are capped at the AMP,[3] which highlights the significant number of medications that may be impacted due to the AMP cap removal.

Be aware of products with gross price changes that have historically increased at a rate greater than inflation and monitor for changes impacting penny-priced drugs as Medicaid programs have relied on their near net zero cost to keep program costs contained. The net cost of these drugs could be materially impacted (increased) by strategies resulting from the AMP rebate cap removal.

**2. ESTABLISH YOUR PREFERRED DRUG LIST (PDL) MANAGEMENT APPROACH TO ADDRESS THE AMP CAP REMOVAL:**

- Review PDL management policies and procedures:
  i. Evaluate the need to modify standard operating procedures (SOPs) for the communication cascade between pharmacy cost reporting, the drug utilization review (DUR) board, and the pharmacy and therapeutic (P&T) committee.
  ii. Prepare your DUR board and P&T committee for discussions around potential disruption driven by cost, if appropriate.
  iii. Evaluate frequency and flexibility with earlier timing of routine therapeutic class reviews that could lead to savings or mitigate net cost increases.
- Evaluate gross and net cost financial reports:
  i. Consider the frequency of gross and financial report review to align with a potentially more volatile pricing environment.
  ii. Consider and evaluate brand over generic strategies.
  iii. Evaluate the need for inclusion of additional therapeutic classes for PDL management.
- Evaluate supplemental rebate contracts:
  i. Review preferred product mix within therapeutic classes, giving consideration to clinical aspects regarding safety and efficacy and changes in net costs. If preferred product changes are warranted, consider the impact on supplemental rebate contracts, patient medication access, and prescription changes of off-cycle changes. While drugs that have a total rebate amount that currently exceeds the AMP cap may not have supplemental rebate agreements due to the federal statutory rebate requirement, there may be new opportunities for supplemental rebate agreements for products with a price reduction and/or for other products in the therapeutic class.

Net cost changes for products within the MDRP may be positive or negative, so it is important to stay on top of therapeutic classes that have impacted products due to the AMP cap removal and PDL management strategies. In situations where certain penny-priced brands are preferred over equivalent generics due to a lower net cost, changes such as list price reductions could result in the generic becoming the lowest net cost product, rather than brand.

3 IQVIA (April 24, 2023). The Impact of AMP Cap Removal on Medicaid Drug Prices. Retrieved November 14, 2023, from https://www.iqvia.com/locations/united-states/blogs/2023/04/the-impact-of-amp-cap-removal-on-medicaid-drug-prices.

**3. CONSIDER MANAGED CARE CAPITATION RATES:**

- Evaluate the impact to capitation rates resulting from the AMP cap removal such as:
  i. List price changes that impact the gross drug costs utilized in capitation rate development
  ii. Market availability of products such as drug shortages or brands and generics entering or leaving the market influencing drug mix and impacting gross costs
  iii. Changes to a uniform or universal PDL and managed care formularies impacting drug mix and gross costs

While the capitation rate development process accounts for pricing and drug mix changes, it is important to ensure changes resulting from the AMP cap removal are considered. While some changes are already known (e.g., announced price list reductions and product discontinuations), other changes post-AMP cap removal are unknown at this time and may need to be addressed through future rate amendments.

**4. MAP AND MODEL OTHER DOWNSTREAM IMPACTS OF THE AMP CAP REMOVAL:**

- Gross or net price changes may impact 340B covered entities (CEs):
  i. Consider impacts to 340B CEs' margin and state expenditures due to the AMP cap removal for covered outpatient drugs as changes to the URA can impact the 340B ceiling price (CP) and/or 340B actual acquisition costs (AACs).
  ii. Consider review of 340B reimbursement methodologies.
  iii. See Appendix B for more details on the impact to 340B.
- Changes to drug pricing strategies:
  i. Monitor changes to net trends due to lower price increases over time as compared to historical pricing strategies, reducing inflationary rebates.
  ii. Consider the potential for higher drug launch prices to reduce the need for future price increases.

It is critical to monitor for downstream impacts of the AMP cap removal and potential unintended consequences that may lead to opportunities to revisit (or initiate) program and policy changes.

## In Summary

Effective January 1, 2024, Medicaid statutory rebates will no longer be capped at 100% of AMP. This change, absent any other market changes, has the potential to increase manufacturer rebates paid to state Medicaid programs. However, impacts to gross costs, such as announced list price decreases and changes to net costs, may decrease overall total rebates of some drugs to state Medicaid programs. In summary, due to the potential of varying influences discussed in this paper, states should continue to monitor their pharmacy programs and PDL management at the gross and net cost levels and consider downstream effects of the AMP cap removal legislation, such as 340B reimbursement and managed care capitation payments.



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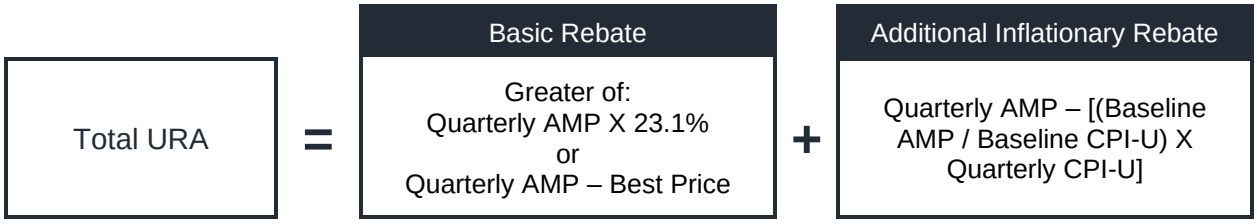
# Appendix A: AMP, URA, and MDRP Program Dynamics Overview

## MDRP AND URA CALCULATION

Inclusion of a drug in the MDRP statutorily requires Medicaid programs to generally provide coverage for all covered outpatient drugs from manufacturers that have entered into a National Drug Rebate Agreement (NRDA) with the Secretary of the U.S. Health and Human Services (HHS).[4] This requires manufacturers to provide statutory federal rebates to Medicaid for covered outpatient drugs,[5] with the intent of offsetting federal and state costs for these drugs. The statutory Medicaid URA calculation under current regulations[6] for most single source or innovator multiple source drugs or biologicals is shown in Figure 1. The calculation has two key components: the basic rebate component and the additional inflationary rebate component. These components rely on the AMP, the best price, and the consumer price index for all urban consumers (CPI-U), defined as follows:

- **AMP:**[7] The average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.
- **Best price:**[8] The lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments).
- **CPI-U:**[9] A measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services.

**FIGURE 1: URA CALCULATION**




**Basic rebate:** For most single source and innovator multiple source drugs, the basic URA is equal to the greater of 23.1%[10] of the AMP or the difference between the AMP and the best price.

**Additional inflationary rebate:**[11] This additional rebate is the difference between the current quarter AMP and the baseline (market date) AMP, adjusted for CPI-U (i.e., adjusted for inflation). If this result is equal to or less than the quarterly AMP, then the additional inflationary rebate is zero. The inflationary rebate limits the rate of cost increases to the rate of inflation.[12] When a drug's price consistently increases faster than inflation, the additional rebate may contribute to most of the URA.

4 Medicaid. Medicaid Drug Rebate Program (MDRP). Retrieved November 14, 2023, from https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.

5 Social Security. Payment for Covered Outpatient Drugs. Social Security Act §1927 Retrieved November 14, 2023, from https://www.ssa.gov/OP_Home/ssact/title19/1927.htm.

6 Medicaid. Unit Rebate Amount Information. Retrieved November 14, 2023, from https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-amount-calculation/index.html.

7 See § CFR 447.504, Determination of average manufacturer price, available at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.504.

8 See § CFR 447.505, Determination of best price, available at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.505.

9 CPI-U is the consumer price index for all urban consumers (U.S. city average) as published by the U.S. Bureau of Labor Statistics (https://www.bls.gov/).

10 17.1% for blood-clotting factors or exclusively pediatric drugs.

11: Medicaid, Unit Rebate Amount Information, op cit., Statutory Formulas: Rebate Amount Calculation per Unit of Drug. Available at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-amount-calculation/index.html.

12 MACPAC (June 2018). Chapter 1: Improving Operations of the Medicaid Drug Rebate Program. Report to Congress on Medicaid and CHIP. Retrieved November 14, 2023, from https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf.

## AMP REBATE CAP REMOVAL

Removal of the AMP rebate cap requires manufacturers to pay the full URA, even if it exceeds the AMP. In a 2019 report that explored the removal of the AMP cap, the Medicaid and CHIP Payment and Access Commission (MACPAC) estimated that eliminating the rebate cap would save between $15 billion and $20 billion in federal spending over 10 years.[13] This estimate is based on an analysis by the Congressional Budget Office (CBO),[14] which indicated that the rebate cap led to $3 billion less federal and state rebates in 2019. These estimates are based on historical experience and do not account for changes to market dynamics, such as pricing reductions or product discontinuation.

Figure 2 illustrates the impact of the AMP cap removal to Medicaid net cost if the pricing components remain status quo. In this hypothetical case, the drug's AMP has increased more quickly than the rate of inflation since the drug's initial launch. The current price for the hypothetical drug ($11.00) is nearly twice as high as the launch price adjusted for inflation ($5.00), leading to an additional inflationary rebate greater than the AMP.

**FIGURE 2: IMPACT TO MEDICAID NET COST OF AMP CAP REMOVAL WHEN TOTAL URA EXCEEDS AMP – STATUS QUO**

| | AMP CAPPED – CURRENT | | AMP UNCAPPED – 1/1/2024 | |
|---|---|---|---|---|
| | **Current Pricing** | | **Current Pricing** | |
| | Current AMP | $11.00 | Current AMP | $11.00 |
| | Best Price | $4.00 | Best Price | $4.00 |
| | **Step 1: Greater of AMP * 23.1% and AMP – Best Price** | | **Step 1: Greater of AMP * 23.1% and AMP – Best Price** | |
| **A** | AMP * 23.1% | $2.54 | AMP * 23.1% | $2.54 |
| **B** | AMP - Best Price | $7.00 | AMP - Best Price | $7.00 |
| | **Basic Rebate Greater of A & B** | **$7.00** | **Basic Rebate Greater of A & B** | **$7.00** |
| | **Step 2: Current AMP – CPI-U Adjusted Base AMP*** | | **Step 2: Current AMP – CPI-U Adjusted Base AMP*** | |
| | Base AMP | $3.00 | Base AMP | $3.00 |
| **C** | Current AMP | $11.00 | Current AMP | $11.00 |
| **D** | CPI-U Adjusted Base AMP | $5.00 | CPI-U Adjusted Base AMP | $5.00 |
| | **Additional Inflationary Rebate Greater of (C – D) and 0** | **$6.00** | **Additional Inflationary Rebate Greater of (C – D) and 0** | **$6.00** |
| | **Total URA (capped at AMP) Lesser of (Step 1 + Step 2) and Current AMP** | **$11.00** | **Total URA Step 1 + Step 2** | **$13.00** |
| | **Medicaid Net Cost / (Revenue)** Lesser of $0.01 and (Current AMP – Total URA)** | **$0.01** | **Medicaid Net Cost / (Revenue)** Current AMP – Total URA** | **($2.00)** |

Note: Values for AMP, best price, and inflation used for the calculations are for illustrative purposes only.

* Step 2's CPI-U Adjusted Base AMP applies an average annual inflation rate of 3.2% over 16 years to the base AMP of $3 for an Adjusted Base AMP of $5.

** Medicaid net cost / (revenue) represents the per unit difference between AMP and total URA. Actual net cost / revenue to Medicaid will vary depending on the ingredient and dispensing fee reimbursement methodology.

13 MACPAC (June 2019). Chapter 1: Next Steps in Improving Medicaid Prescription Drug Policy. Report to Congress on Medicaid and CHIP. Retrieved November 14, 2023, from https://www.macpac.gov/wp-content/uploads/2019/06/Next-Steps-in-Improving-Medicaid-Prescription-Drug-Policy.pdf.

14 CBO (March 10, 2021). Estimated Budgetary Effects of H.R. 1319, American Rescue Plan Act of 2021. Retrieved November 14, 2023, from https://www.cbo.gov/publication/57056.

Figure 3 illustrates two hypothetical scenarios, demonstrating the potential impact of the AMP cap removal on URA and Medicaid net cost when the product's list price is reduced. Table A illustrates an uncapped scenario *without* a price reduction and Table B illustrates an uncapped scenario *with* a price reduction. In this example, a price reduction where AMP is decreased by 64% (from $11 to $4), matching the previous best price and eliminating the additional inflationary rebate, the result is a net *cost* to a state Medicaid program instead of a net *revenue*.

**FIGURE 3: IMPACT TO MEDICAID NET COST OF AMP CAP REMOVAL WITH AND WITHOUT REDUCING LIST PRICE**

**TABLE A**

| | AMP Uncapped – 1/1/2024 with no price reduction | |
|---|---|---|
| | **Current Pricing** | |
| | Current AMP | $11.00 |
| | Best Price | $4.00 |
| | **Step 1: Greater of AMP * 23.1% or AMP – Best Price** | |
| **A** | AMP * 23.1% | $2.54 |
| **B** | AMP – Best Price | $7.00 |
| | **Basic Rebate Greater of A & B** | **$7.00** |
| | **Step 2: Current AMP – CPI-U Adjusted Base AMP** | |
| | Base AMP | $3.00 |
| **C** | Current AMP | $11.00 |
| **D** | CPI-U Adjusted Base AMP* | $5.00 |
| | **Additional Inflationary Rebate Greater of (C – D) and 0** | **$6.00** |
| | **Total URA Step 1 + Step 2** | **$13.00** |
| | **Medicaid Net Cost / (Revenue)** Current AMP – Total URA** | **($2.00)** |

**TABLE B**

| AMP Uncapped – 1/1/2024 with price reduction | |
|---|---|
| **Reduced Pricing** | |
| Updated AMP | $4.00 |
| Best Price | $4.00 |
| **Step 1: Greater of AMP * 23.1% or AMP – Best Price** | |
| AMP * 23.1% | $0.92 |
| AMP – Best Price | $0.00 |
| **Basic Rebate Greater of A & B** | **$0.92** |
| **Step 2: Current AMP – CPI-U Adjusted Base AMP** | |
| Base AMP | $3.00 |
| Updated AMP | $4.00 |
| CPI-U Adjusted Base AMP* | $5.00 |
| **Additional Inflationary Rebate Greater of (C – D) and 0** | **$0.00** |
| **Total URA Step 1 + Step 2** | **$0.92** |
| **Medicaid Net Cost / (Revenue)** Current AMP – Total URA** | **$3.08** |

Note: Values for AMP, best price, and inflation used for the calculations are for illustrative purposes only.

* Step 2's CPI-U Adjusted Base AMP applies an average annual inflation rate of 3.2% over 16 years to the base AMP of $3 for an Adjusted Base AMP of $5.

** Medicaid net cost / (revenue) represents the per unit difference between AMP and total URA. Actual net cost / revenue to Medicaid will vary depending on the ingredient and dispensing fee reimbursement methodology.

# Appendix B: 340B Program Dynamics Overview

While a state is prohibited from collecting statutory rebates for 340B claims, this discount from the manufacturer is extended to the CE's purchase price, otherwise known as the 340B ceiling price, which is the maximum amount a 340B CE can be charged to purchase the drug. The 340B ceiling price is calculated by reducing the AMP by the URA. When AMP minus URA is less than $0.01, then the 340B CP is set to $0.01. If the AMP or URA is impacted by pricing reductions, then the 340B purchase price may increase. In addition, reimbursement to 340B CEs may decrease depending on their payment methodology for 340B claims. The following two general reimbursement methodologies for 340B claims are considered for purposes of illustrating the potential impact to 340B CEs and state expenditures:

1. **340B rate (CP or AAC):** Ingredient cost reimbursement is based on the 340B CE's CP or AAC, in which the impact to *the 340B CE's ingredient margin will be unchanged or less impacted, but Medicaid expenditures could increase*. This reimbursement is most common in fee-for-service (FFS) Medicaid due to requirements related to 340B reimbursement in the Centers for Medicare and Medicaid Services (CMS) Covered Outpatient Drugs Final Rule.[15] Figure 4 illustrates the impact to CEs that are reimbursed at a CP or AAC reimbursement methodology rate.
2. **Standard rate:** Ingredient cost reimbursement is based on an amount above the 340B CP or AAC, e.g., non-340B rates such as wholesale acquisition cost (WAC), in which *a significant reduction in the CE's ingredient margin may occur, but Medicaid expenditures could decrease*. This reimbursement is most common in managed care Medicaid as the CMS Covered Outpatient Drugs Final Rule is not applicable to managed care; however, some states require managed care to follow FFS reimbursement methodologies. Figure 5 illustrates the impact to CEs that are reimbursed at a standard 340B methodology.

**FIGURE 4: IMPACT TO 340B COVERED ENTITY MARGIN – 340B RATE INGREDIENT REIMBURSEMENT**

| AMP Capped – Prior to 1/1/2024 | | AMP Uncapped – 1/1/2024 | |
|---|---|---|---|
| **Current Pricing** | | **Updated Pricing** | |
| Provider Ingredient Reimbursement | $0.01 | Provider Ingredient Reimbursement | $1.50 |
| Covered Entity Purchase Price | $0.01 | Covered Entity Purchase Price | $1.50 |
| **Covered Entity Margin per Unit** | **$0.00** | **Covered Entity Margin per Unit** | **$0.00** |

In this example, the CE's margin per unit is not impacted and the ingredient cost reimbursement by Medicaid increases from $0.01 to $1.50, resulting in an ingredient expenditure cost to the state of $1.49.

**FIGURE 5: IMPACT TO 340B COVERED ENTITY MARGIN – STANDARD RATE INGREDIENT REIMBURSEMENT**

| AMP capped – Prior to 1/1/2024 | | AMP Uncapped – 1/1/2024 | |
|---|---|---|---|
| **Current Pricing: WAC = $10.00** | | **Updated Pricing: WAC = $3.00** | |
| Provider Ingredient Reimbursement | $10.00 | Provider Ingredient Reimbursement | $3.00 |
| Covered Entity Purchase Price | $0.01 | Covered Entity Purchase Price | $1.50 |
| **Covered Entity Margin per Unit** | **$9.99** | **Covered Entity Margin per Unit** | **$1.50** |

In this example, the CE's margin per unit is reduced by $8.49 and the ingredient cost reimbursement by Medicaid is reduced from $10.00 to $3.00, resulting in an ingredient expenditure savings to the state of $7.00.

15 The full text of the Final Rule is available at https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf.

States that utilize a standard reimbursement rate pay a higher net cost for 340B claims than non-340B claims because they cannot collect federal statutory rebates for 340B claims. If no changes are made for penny-priced drugs and the URA is allowed to exceed AMP, then the amount of rebates the state will forgo will increase the difference between the cost of 340B claims and non-340B claims. Figure 6 provides an illustration of the difference in 340B and non-340B cost due to the forgone rebate amount.

**FIGURE 6: FORGONE MEDICAID REBATES – STANDARD RATE INGREDIENT REIMBURSEMENT**

| AMP Capped – Prior to 1/1/2024 | |
|---|---|
| **Current Pricing: WAC = $10.00** | |
| Provider Reimbursement | $10.00 |
| URA | $9.99 |
| Medicaid Net Ingredient Cost – 340B | $10.00 |
| Medicaid Net Ingredient Cost – Non-340B | $0.01 |
| **340B vs. Non-340B Difference** | **$9.99** |

| AMP Uncapped – 1/1/2024 | |
|---|---|
| **Current Pricing: WAC = $10.00** | |
| Provider Reimbursement | $10.00 |
| URA | $12.00 |
| Medicaid Net Ingredient Cost – 340B | $10.00 |
| Medicaid Net Ingredient Cost – Non-340B | -$2.00 |
| **340B vs. Non-340B Difference** | **$12.00** |

In this example, the net ingredient cost reimbursement by Medicaid for 340B claims is $9.99 higher than for non-340B claims and increases by an additional $2.00 due to the impact of the forgone rebate amount.