

Inflation Rebate Provisions

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Module teacher



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PRINCIPAL ECONOMIST | OHE

Health economist with special interest in the economics of innovation, particularly in areas of global unmet need such as antibiotics and vaccines.

Module Overview

01. Introduction

- Current inflation rebates in Medicaid
 - Fundamentals of the IRA Prescription Drug Rebate provisions
-

02. Medicare Part B

- Medicare Part B inflation rebates in depth
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03. Medicare Part D

- Medicare Part D inflation rebates in depth

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MODULE 2

Session 1: Introduction

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Prescription medicines are covered by Part D, and to a lesser degree, Part B of Medicare



Part A

Inpatient/hospital coverage,
including inpatient medicines

Part B

Outpatient/medical coverage;
prescription medicines
administered by a provider
(20% patient co-insurance)

Part C

(Medicare Advantage)

Part D

Retail prescription medicines
(patient cost sharing varies)

Manufacturers must already rebate Medicaid if their prices rise faster than inflation.



Price changes are measured cumulatively against a fixed benchmark



Minimum Medicaid statutory rebates *plus inflationary component*

Manufacturers must pay the following statutory rebates, **plus an inflationary component if the average manufacturer price (AMP) has increased faster than CPI-U:**

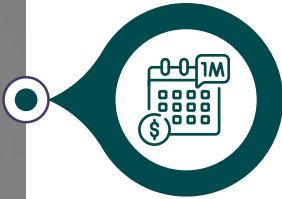
Branded medicines	<i>Greater of:</i> <ul style="list-style-type: none"> ▪ 23.1% of AMP ▪ AMP minus best price 	+ Inflationary component
Branded medicines approved exclusively for pediatric indications and certain clotting factors	<i>Greater of:</i> <ul style="list-style-type: none"> ▪ 17.1% of AMP ▪ AMP minus best price 	+ Inflationary component
Generic medicines	13.0% of AMP	+ Inflationary component

IRA brings inflationary rebates to Medicare but with a different reference date.

$$\text{Rebate} = \text{Quantity sold} \times \text{Price Growth in Excess of Inflation}$$

- The benchmark price is **Q3 2021 for Part B** medicines, and **January through September 2021 for Part D** medicines.
- The benchmark CPI-U for both rebates is **January 2021**.
- Price is measured based on average sales price (ASP) in Part B and average manufacturer price (AMP) in Part D
- Most branded drugs are included in the provision but there are some exceptions:
 - For **Medicare Part B**, medicines with an annual cost of <\$100 in 2023 and preventative vaccines are *excluded*. Single-source drugs and biologics, plus certain biosimilars, are *included* in the mandatory rebate scheme.
 - For **Medicare Part D**, drugs with annual cost of <\$100 in 2023.

Rebates are calculated by the Secretary of the Department of Health and Human Services and key determinations *are not subject to judicial or administrative review.*



Invoices will be sent to manufacturers no later than 6 months after the end of the quarter for Part B drugs, and 9 months after the end of the 12-month rebate period for Part D drugs.*



Rebate payments are required within 30 days of receipt of invoice, and are to be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund.

*For Part B, the Secretary may delay invoices for all quarters in 2023 and 2024 until Sept 30, 2025; for Part D, the Secretary may delay invoices for the rebate periods beginning Oct 1, 2022 and Oct 1, 2023 until Dec 31, 2025.

For medicines that owe an inflation rebate under Part B, IRA will reduce patient cost sharing to 20% of the inflation-adjusted price.



- Currently, under Medicare Part B, patient cost sharing for most medicines is 20% of the Medicare-approved amount
- As of April 1st 2023, patient cost sharing will be reduced to 20% of the inflation-adjusted payment amount for medicines that owe an inflation rebate
- There will be no effect on patient cost sharing for Medicare Part D

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Session 2: Medicare Part B inflation rebates in depth

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What we have learnt so far & what we are learning in this session

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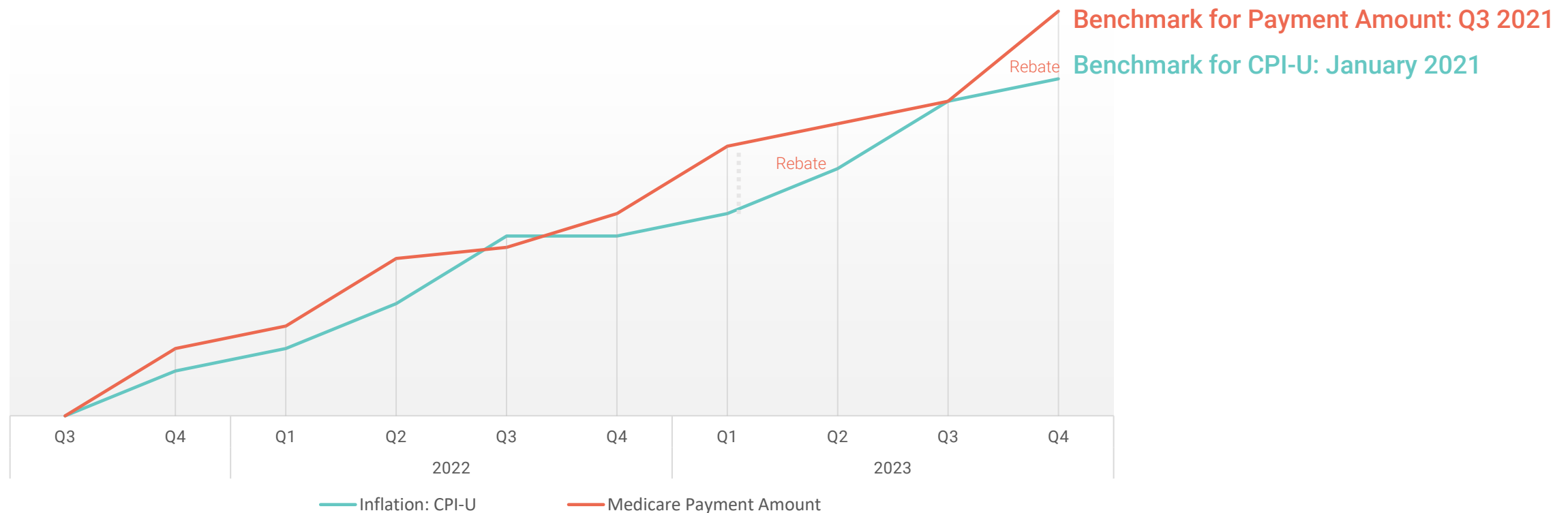
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As of January 1st 2023, manufacturers pay a rebate in any quarter where the Medicare payment amount rises more quickly than inflation.



Inflation rebates will apply to most single-source Part B products with an average total cost per patient greater than \$100 in 2023.

Part B Rebate Inclusions & Exclusions

- ✓ Single-source Part B medicines and biologics, including certain biosimilars, with an average annual cost per patient greater than \$100* in 2023.
- ✓ Part B medicines subject to price setting
- ✗ Preventive vaccines

** Minimum cost threshold will increase with inflation (CPI-U).*

The Secretary of Health and Human Services is required to waive or reduce the amount of the rebate owed for medicines in shortage or experiencing severe supply chain disruptions.

As of April 1, 2023, patient cost sharing will be reduced to 20% of the inflation-adjusted payment amount.

How are payment amounts and inflation measured? **OHE**

Single-source drugs and biologics*

(Lesser of ASP or WAC) + 6%

MFP + 6%
(for selected drugs)

Eligible biosimilars

ASP + 6% of
reference biologic
ASP

Inflation

Consumer Price
Index for all Urban
Consumers (CPI-U)

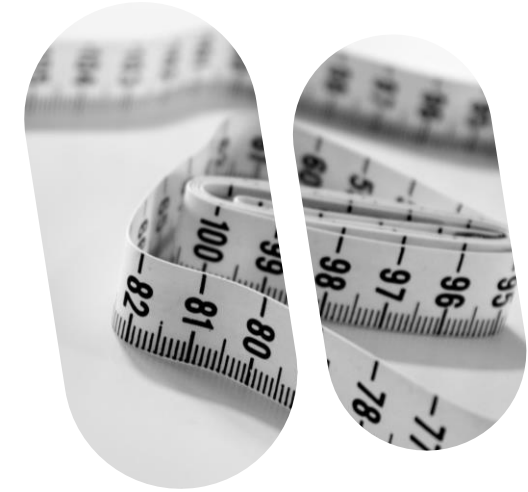
Medicines post price-setting

MFP + 6% for Q1
of last price
applicability year

CPI-U for July of
year before the last
price applicability

ASP = Average Sales Price, WAC = Wholesale Acquisition Cost

* For medicines subject to negotiation, price will be the maximum fair price (MFP) + 6%



Each quarter, each product's payment amount will be compared against its benchmark price adjusted by change in CPI-U.



If payment amount exceeds “inflation-adjusted payment amount”, a rebate will be owed:

$$\text{Quantity} \times ([\text{Payment Amount (e.g., ASP + 6\%)}] - [\text{Payment Amount Benchmark (e.g., ASP + 6\%)}] \times [\text{Growth in CPI-U}])$$

Quantity = units dispensed under billing and payment code in the Part B fee-for-service program during the applicable quarter. Units where a Medicaid rebate or 340B discount is paid are excluded.

Units that are packaged (not separately paid) are also excluded

For medicines approved or licensed prior to December 1, 2020, the benchmark payment amount is the applicable payment amount in Q3 2021.

For medicines approved or licensed after December 1, 2020, the benchmark payment amount is the applicable payment amount for the third full calendar quarter after a medicine is first marketed.

How is the rebate amount calculated?



Benchmark metrics	
[A] Benchmark payment amount (e.g., ASP + 6% per unit in Q3 2021)	\$50.00
[B] Benchmark CPI-U (CPI-U in January 2021)	261.582
Q1 2023	
[C] Applicable payment amount (e.g., ASP + 6% per unit in Q1 2023)	\$57.50
[D] Rebate period inflation metric (CPI-U in July 2022)	296.276
[E] Inflation-adjusted payment amount ($[D] / [B] \times [A]$)	\$56.63
[F] Rebate per unit ($[C] - [E]$, if positive)	\$0.87
[G] Total part B separately-paid units dispensed in Q3 2021 for billing and payment code	10,000,000
[H] Units where a Medicaid rebate was paid	3,000,000
[I] Units where a 340B rebate was paid	2,000,000
[J] Total applicable units ($[G] - [H] - [I]$)	5,000,000
[K] Total rebate amount ($[F] \times [J]$)	\$4,342,137.46

→ Payment Amount increased by 15.0%

→ CPI-U increased by 13.3%

Secretary must invoice any penalties within 6 months; payment is due within 30 days. *Failure to comply can lead to civil money penalties equal to 125% of the rebate due.*



- A transition rule allows the Secretary to delay sending invoices for 2023 and 2024
- Rebate payments are deposited into the Medicare Supplementary Medical Insurance (SMI) Trust Fund
- Number of applicable units; determination of rebate eligibility; calculation of rebate amount; calculated reduction in beneficiary coinsurance; and calculation of Part B amount paid to account for reduced beneficiary coinsurance *are not subject to judicial or administrative review.*

Inflation rebate payments are *excluded* from calculations of Medicaid best price, average sales price, and average manufacturer price



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Session 3: Medicare Part D

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The Part D inflation rebate program began in October 2022. Rebates are payable directly to Medicare.

Part D Rebate Inclusions & Exclusions

- ✓ All medicines, biologics and biosimilars, including those subject to price negotiations, except:
 - ✗ Medicines with average annual cost per patient less than \$100* in 2023
 - ✗ Most generics

** Minimum cost threshold will increase with inflation (CPI-U).*

Quantity will be based on all dosage forms and strengths dispensed for a medicine under the Part D program during the applicable 12-month period. From 2026, units where a 340B discount is paid will not be included.

The Secretary of Health and Human Services is required to waive or reduce the amount of the rebate owed for medicines in shortage or experiencing severe supply chain disruptions.

For most products, average manufacturer price (AMP) will be averaged over four quarters, weighted by units used in AMP calculation, to create an annual manufacturer price (AnMP).

If payment amount exceeds “inflation-adjusted payment amount”, a rebate will be owed:

$$\text{Quantity} \times (\text{AnMP} - [\text{Benchmark AMP} \times \text{Growth in Inflation}])$$

For each applicable 12-month period, the applicable CPI-U will be the CPI-U in October.

*For medicines approved or licensed on or **before October 1, 2021**, the benchmark price is the average quarterly AMP from January 2021 through September 2021 (Q1 through Q3), weighted by quantity.*

*For medicines approved or licensed **after October 1, 2021**, the benchmark price is the AMP averaged over the first calendar year beginning after the day a medicine is first marketed.*

For products selected for price setting, a different benchmark price and CPI-U will apply once the price of the medicine is no longer set.



- **Benchmark price** will be AMP averaged over the last year the drug is subject to price setting.
- **Benchmark inflation** will be the CPI-U in January of the last year the drug is subject to price setting.
- Unlike the Part B inflation rebate, patient cost sharing is not adjusted for rebate payments made on medicines covered under Part D.

Quantity will be based on all dosage forms and strengths dispensed for a medicine under the Part D program during the applicable 12-month period. Beginning in 2026, units where a 340B discount is paid will not be included.

How is the rebate amount calculated?



Benchmark metrics	
[A] Benchmark price (weighted average quarterly AMP from Q1 2021 - Q3 2021)	\$30
[B] Benchmark CPI-U (CPI-U in January 2021)	261.582
Rebate period October 2023 - September 2024	
[C] Annual manufacturer price (weighted avg quarterly AMP during period)	\$36
[D] Rebate period inflation metric (CPI-U in October 2023)	303.552
[E] Inflation-adjusted payment amount ($[D] / [B] \times [A]$)	\$34.81
[F] Rebate per unit ($[C] - [E]$, if positive)	\$1.19
[G] Total Part D units dispensed during rebate period	5,000,000
[H] Units where a 340B rebate was paid	N/A*
[I] Total applicable units ($[G] - [H]$)	5,000,000
[K] Total rebate amount ($[F] \times [J]$)	\$5,932,977

→ Price increased by 20.0%

→ CPI-U increased by 16.0%

Secretary must invoice any penalties within 9 months; payment is due within 30 days. *Failure to comply can lead to civil money penalties equal to 125% of the rebate due.*



- A transition rule allows the Secretary to delay sending invoices for 2023 and 2024
- Rebate payments are deposited into the Medicare Supplementary Medical Insurance (SMI) Trust Fund
- Whether a medicine is a “Part D rebatable drug”, the determination of units, and calculation of the rebate amount **are not subject to judicial or administrative review.**

Inflation rebate payments are *excluded* from calculations of Medicaid best price, average sales price, and average manufacturer price



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SUMMARY

Inflation Rebates for Medicare Part B and D

- The Inflation Reduction Act introduces new inflation rebates for many of the drugs covered by Medicare Part B and D
- If prices of these drugs have risen faster than inflation during this period, companies are required to pay the difference in the form of a rebate to Medicare
- For Medicare Part B drugs, the provisions will reduce patient cost sharing to 20% of the inflation-adjusted payment amount for medicines that owe an inflation rebate



MODULE 3

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Medicare Part D Benefit Redesign and Other Provisions

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PLEASE TAKE THE TIME TO COMPLETE THE FEEDBACK FORM

