



Understanding the Prescription Drug Provisions of the Inflation Reduction Act

September 21, 2022

John Murphy, Chief Policy Officer, BIO

Crystal Kuntz, VP Health Policy and Research, BIO

Ken Choe, Partner, Hogan Lovells

Alice Valder Curran, Partner, Hogan Lovells

Melissa Bianchi, Partner, Hogan Lovells

Inflation Reduction Act and Prescription Drugs

- The **Inflation Reduction Act of 2022** (IRA) was signed into law on August 16, 2022
- The law includes three primary components related to prescription drugs:
 - **Drug Price Negotiation Program**
 - **Medicare Part B and Part D Inflation Rebates**
 - **Medicare Part D Redesign**

Questions Today That Aren't Answered?

Please reach out to Crystal Kuntz
ckuntz@bio.org

Out-of-Pocket Relief in Inflation Reduction Act

OOP Relief for beneficiaries has been a long-standing BIO priority

- **Part D \$2,000 Out-of-Pocket (OOP) Cap and Option to Spread Cost Sharing throughout Year**
 - 1.4 million beneficiaries had spending above \$2,000 in 2020
 - Millions more will benefit from the ability to spread their cost sharing over the course of the year
- **Additional Cost Sharing Relief for Beneficiaries**
 - Beginning in 2023, limits copayments for insulin to \$35/m – 3.3 m beneficiaries used insulin in 2020, and 1.7 m of those individuals did not qualify for low-income subsidies
 - Starting in 2023, adult vaccines recommended by Advisory Committee on Immunization Practices (ACIP) will be covered under Part D with no deductible and no coinsurance or other cost sharing – 4.1 million beneficiaries received a vaccine in 2020
 - Starting the first quarter that begins at least 1 year post enactment, adult vaccines recommended by ACIP will be covered under Medicaid/CHIP with no deductible and no coinsurance or other cost sharing (currently half of states don't cover all recommended vaccines)

Agenda

- Introduction and Context (*4 minutes*):
 - John Murphy, Chief Policy Officer, BIO
- Inflation Reduction Act Background (*3 minutes*):
 - Crystal Kuntz, VP Health Policy and Research, BIO
- Drug Price Negotiation Program (*37 minutes*):
 - Ken Choe, Partner, Hogan Lovells
- Medicare Part B and Part D Inflation Rebates (*35 minutes*):
 - Alice Valder Curran, Partner, Hogan Lovells
- Medicare Part D Redesign (*34 minutes*):
 - Melissa Bianchi, Partner, Hogan Lovells
- Conclusion and Next Steps (*4 minutes*):
 - John Murphy, Chief Policy Officer, BIO

Drug Price Negotiation Program

Negotiation Program: Overview

- **High Medicare Spend Drugs:** The Drug Price Negotiation Program will reduce the prices of certain high Medicare spend drugs
- **Negotiation Process:** The Secretary of Health and Human Services will select a specified number of drugs for negotiation each year, generally two years before the negotiated price applies
- **Maximum Fair Price:** A manufacturer of a drug selected for negotiation will be required to offer a “maximum fair price” with respect to such drug with respect to Medicare beneficiaries
- **Timeline:** The first set of drugs will be selected for negotiation in 2023, with the first set of negotiated prices taking effect in “initial price applicability year” 2026

What drugs are subject to negotiation?

Drugs Subject to Negotiation

Qualifying Single Source Drugs

- **Certain drugs/biologics approved/licensed by FDA:**
 - **Drugs at least 7 years post-approval** by the selection date
 - **Biologics at least 11 years post-licensure** by the selection date
- With **no generic/biosimilar on the market** (an “authorized generic drug” does not count)

Negotiation-Eligible Drugs

- The **50 qualifying single source drugs with highest total expenditures under Part D** and the **50 qualifying single source drugs with highest total expenditures under Part B** during a specified 12-month lookback period.

Selected Drugs

- A specified number of the **highest ranked negotiation-eligible drugs**, published by February 1 of the selection year, which is two years before the initial price applicability year:
- The selection of drugs for negotiation is **cumulative**: The Secretary must select **10 drugs for 2026**, another **15 for 2027**, another **15 for 2028**, and another **20 for 2029 and each year thereafter**
- **Only Part D drugs may be selected for 2026 and 2027**

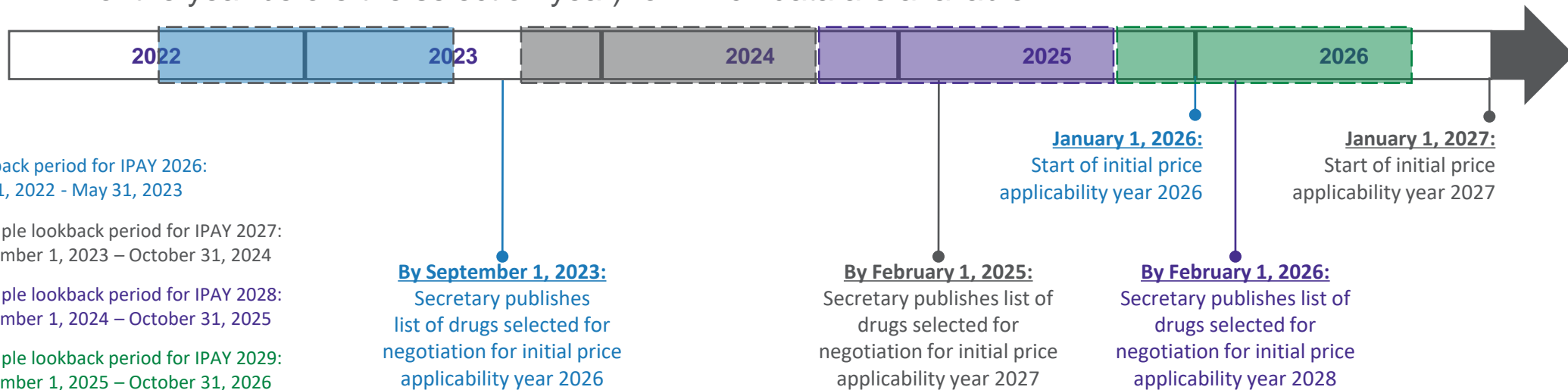
Drugs subject to negotiation

Exclusions and the Small Biotech Drug Phase-In

- **The following drugs are always ineligible for negotiation:**
 - ***Certain orphan drugs:*** Drugs/biologics designated as an orphan drug for only one rare disease or condition and for which the only approved indication/s is/are for such disease or condition
 - ***Low Medicare spend drugs:*** Drugs/biologics for which total Parts B and D expenditures during a specified lookback period are less than \$200 million, increased over time by an inflation factor
 - ***Plasma-derived products:*** Biologics derived from human whole blood or plasma
- **Small biotech drugs are temporarily ineligible for negotiation, for initial price applicability years 2026, 2027, and 2028**
 - A small biotech drug is a drug whose total **2021** Part B/Part D expenditures constitute:
 - ≤1%** of total 2021 Part B/Part D expenditures for all Part B/Part D drugs of ***all manufacturers***
 - ≥80%** of total 2021 Part B/Part D expenditures for all Part B/Part D drugs of ***the small biotech manufacturer***
 - The following are ineligible for the small biotech drug phase-in:
 - ❖ A ***new formulation***
 - ❖ A drug of a manufacturer ***acquired post-2021 by a non-”specified manufacturer”***

Ranking Negotiation-Eligible Drugs

- **How are total expenditures under Part B/Part D determined?**
 - **Part B drugs:** Excludes bundled or packaged units
 - **Part D drugs:** Includes total “gross covered prescription drug costs”
 - Aggregated across **dosage forms and strengths**, including **new formulations**, and not broken out by specific formulation, package size, or package type
- **What is the 12-month lookback period?**
 - For initial price applicability year 2026: June 1, 2022, through May 31, 2023
 - For initial price applicability years thereafter: The most recent 12-month period (ending no later than October 31 of the year before the selection year) for which data are available



Lookback period for IPAY 2026:
June 1, 2022 - May 31, 2023

Example lookback period for IPAY 2027:
November 1, 2023 – October 31, 2024

Example lookback period for IPAY 2028:
November 1, 2024 – October 31, 2025

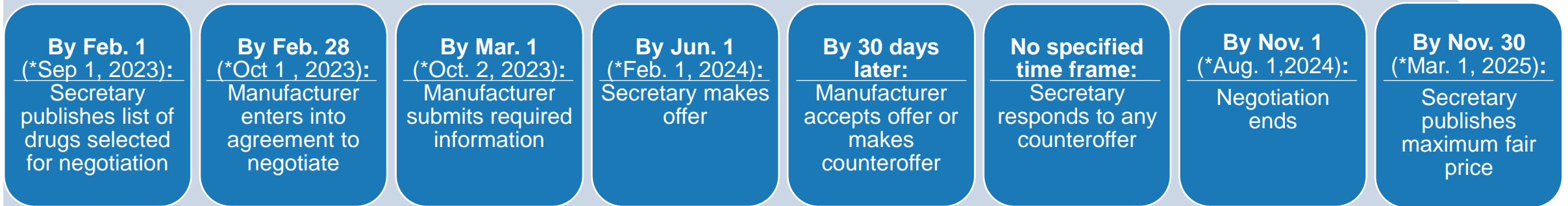
Example lookback period for IPAY 2029:
November 1, 2025 – October 31, 2026

How is the negotiated price determined?

Negotiation Process

- For each drug selected, the Secretary engages in a **negotiation process** with the manufacturer, beginning **two years before** the initial price applicability year
- There is a **different timeline for initial price applicability year 2026**

Two years before the initial price applicability year:



*The timeline for initial price applicability year 2026

Maximum Fair Price: Limits

- The Secretary must develop and use a ***consistent negotiation methodology and process*** that aims to achieve the ***lowest maximum fair price***
- The following limits apply:
 - **All selected drugs:** There is a maximum fair price ***ceiling***
 - **Small biotech drugs:** There is also a ***temporary*** maximum fair price ***floor*** for initial price applicability years 2029 and 2030 as part of the small biotech drug phase-in
 - ❖ Temporary floor: The maximum fair price must be at least ***66 percent of average non-FAMP for 2021, increased by an inflation factor***

Maximum Fair Price: Ceiling

| | Part B | Part D |
|------------|---|--|
| Lowest of: | 1 An “applicable percentage” of average non-FAMP for 2021, increased by an inflation factor | |
| | 2 An “applicable percentage” of average non-FAMP for the year before the selection year* (*inapplicable to initial price applicability year 2026) | |
| | 3 The lower of ASP or WAC for the year before the selection year | The sum of the enrollment-weighted net Part D negotiated prices under each Part D/MA-PD plan for the most recent year for which data are available |

Maximum Fair Price: Applicable Percentage

- **Long-monopoly drugs: *At least 16 years*** will have elapsed since approval/licensure at the start of the initial price applicability year (excluding vaccines) ▶ **40%**
- **Extended-monopoly drugs: *At least 12 years but less than 16 years*** will have elapsed since approval/licensure at the start of the initial price applicability year (excluding vaccines, and drugs selected for negotiation for an initial price applicability year before initial price applicability year 2030) ▶ **65%**
- **Short-monopoly drugs: *All other*** drugs ▶ **75%**



Maximum Fair Price: Negotiation Factors

- **Manufacturer-specific data:**
 - **Research and development costs** and the extent to which the manufacturer has recouped such costs
 - Current **unit costs of production and distribution**
 - Prior **federal financial support** for discovery and development
 - Data on **pending and approved patents and exclusivity**
 - **Market data and revenue and sales volume data**
- **Evidence about alternative treatments:**
 - The extent to which the drug represents a **therapeutic advance** as compared to existing therapeutic alternatives and the costs of such alternatives
 - FDA-approved **prescribing information** for the drug and the alternatives
 - **Comparative effectiveness** of the drug and the alternatives, including effects on specific patient populations
 - The extent to which the drug and the alternatives address **unmet medical needs**

Maximum Fair Price: Annual Increase and Renegotiation

- **Annual Increase:** For each year after the initial price applicability year, the maximum fair price will be *increased by an inflation factor*
 - The new maximum fair price will be published by **November 30** of the year that is two years before the year in which it will take effect
- **Renegotiation:** Drugs will first be subject to selection for renegotiation in **2028**, with any resulting renegotiated prices first taking effect in initial price applicability year **2030**
 - Four circumstances in which the Secretary may renegotiate the maximum fair price:
 - 1 **Transition to extended-monopoly drug status** from short-monopoly drug status
 - 2 **Transition to long-monopoly drug status** from extended-monopoly drug status
 - 3 **New indication**
 - 4 **Material change** in the factors considered during the negotiation process

The Secretary is **required** to renegotiate

The Secretary is **permitted** to renegotiate



What happens after the negotiated price is set?

Offering the Maximum Fair Price

- During the price applicability period, the manufacturer must offer the maximum fair price to:
 - **Hospitals, physicians, and other providers and suppliers, with respect to Part B beneficiaries**
 - ❖ The Part B reimbursement rate is set at ***106 percent of the maximum fair price***
 - **Pharmacies, mail order services, or other dispensers, with respect to Part D beneficiaries (and Part D beneficiaries at the point of sale)**
 - ❖ A Part D/MA-PD plan is generally ***required to include the drug on its formulary***, but may remove the drug from its formulary if it adds a newly available therapeutically equivalent generic to its formulary and provides the requisite notice
 - ❖ The Part D negotiated price is capped at ***the maximum fair price plus any dispensing fee***

Broader Implications

- **Best price:** The maximum fair price is *included in best price*
- **AMP:** The maximum fair price is *excluded from AMP*
 - As to both best price and AMP, the maximum fair price can *increase* Medicaid Drug Rebate Program and 340B Program liability
- **ASP:** The maximum fair price is *included in ASP*
- **340B Program:** The manufacturer must offer covered entities the *lower* of the 340B price or the maximum fair price (but *not both*)
- **Part B and Part D inflation rebates:*** The Part B and Part D inflation rebate *benchmark periods reset* where a drug ceases to be subject to the maximum fair price
- **Part D Manufacturer Discount Program:*** A drug is *not subject to the Part D Manufacturer Discount Program* while it is subject to the maximum fair price
- **Commercial market:** The negotiation program *does not directly affect* the price for commercial patients
 - **Potential for diversion:** Unclear how maximum fair price units for Medicare beneficiaries and commercial units for commercial patients will be differentiated
 - **Potential anchor for commercial prices:** Potential for commercial customers to seek a price approximating the maximum fair price

What happens if a
generic/biosimilar launches?

Actual Generic/Biosimilar Market Entry

Timing is important: The impact of the launch of a generic/biosimilar depends on the when the generic/biosimilar enters the market

- **Ineligibility for Selection for Negotiation:** If a generic/biosimilar launches *before selection of the drug/biologic* for negotiation, the drug/biologic is ineligible for selection for negotiation
- **Termination of Negotiation:** If a generic/biosimilar launches *before the end of the negotiation period* of the drug/biologic, negotiation of a maximum fair price for the drug/biologic terminates
- **Termination of Maximum Fair Price:** If a generic/biosimilar launches *after the end of the negotiation period* of the drug/biologic, the drug/biologic generally ceases to be subject to the maximum fair price at the start of the first year that begins at least 9 months after the generic/biosimilar entered the market
 - If a generic/biosimilar launches *on or before April 1*, the drug/biologic ceases to be subject to the maximum fair price *at the start of the first year after launch*
 - If a generic/biosimilar launches *after April 1*, the drug/biologic ceases to be subject to the maximum fair price *at the start of the second year after launch*

Anticipated Biosimilar Market Entry

- **The Secretary may delay selection of a biologic for negotiation by one or two years if:**
 - **Extended-monopoly drug:** The biologic that otherwise would have been selected is an extended-monopoly drug;
 - **Request by biosimilar manufacture:** The delay is requested by a biosimilar manufacturer; and
 - **High likelihood that the biosimilar will launch:** The Secretary determines that there is a high likelihood that the biosimilar will launch within 2 years of what otherwise would have been the reference product's selection date
- **A delay is not permitted where:**
 - **Biosimilar is licensed but not marketed:** The biosimilar is more than one year post-licensure and has not yet been marketed;
 - **Same manufacturer:** The biosimilar manufacturer also manufactures the reference product;
 - **Agreement between manufacturers:** The biosimilar manufacturer entered an agreement with the reference product manufacturer:
 - ❖ Requiring or incentivizing the biosimilar manufacturer to request the delay; or
 - ❖ Restricting the quantity of the biosimilar that may be sold in the United States; or
 - **Long-monopoly transition:** A biologic is ineligible for a second year of delay if it transitioned to long-monopoly status
- **The reference product manufacturer will owe a rebate for each year a delay was granted if:**
 - After the first year of delay, there is **no longer a high likelihood** that the biosimilar will launch within the specified time
 - After a second year of delay, the **biosimilar has not launched**
 - The rebate amount is based on the difference in the price offered during the delay and the maximum fair price



How will compliance with the program be enforced?

Excise Tax

- **A noncompliant manufacturer is subject to an excise tax on each sale of the drug during the period of noncompliance, with the amount of the tax escalating over time**
 - ***The excise tax applies where the manufacturer has failed to timely:***
 - ❖ Enter into a negotiation agreement;
 - ❖ Agree to a maximum fair price; or
 - ❖ Submit required data to the Secretary
 - ***The excise tax ceases to apply where:***
 - ❖ The manufacturer comes into compliance
 - ❖ A generic/biosimilar launches
 - ❖ The manufacturer terminates its Part D Coverage Gap Discount Program, Part D Manufacturer Discount Program, and Medicaid Drug Rebate Program agreements, and none of its drugs are subject to any such agreement
- **The amount of the tax is calculated escalates over time** (e.g., the tax is 1.85x the sale price on sales during days 1-90 of noncompliance, but 19x the sale price after 270 days of noncompliance)

Civil Monetary Penalties

- A manufacturer is subject to significant CMPs for:
 - **Failing to offer the maximum fair price** with respect to Part B/Part D beneficiaries
 - ❖ The CMP amount is equal to (1) **ten times** (2) the product of (a) the number of units administered/dispensed to Part B/Part D beneficiaries during the year and (b) the difference in between (i) the price and (ii) the maximum fair price
 - **Violating terms of the negotiation agreement**, including the requirement to submit required data to the Secretary
 - ❖ The CMP amount is **\$1 million per day of noncompliance**
 - **Knowingly providing false information** with respect to eligibility as a small biotech drug, or eligibility for the delay for biosimilar market entry
 - ❖ The CMP amount is **\$100 million for each item of false information**

Preclusions of Administrative and Judicial Review

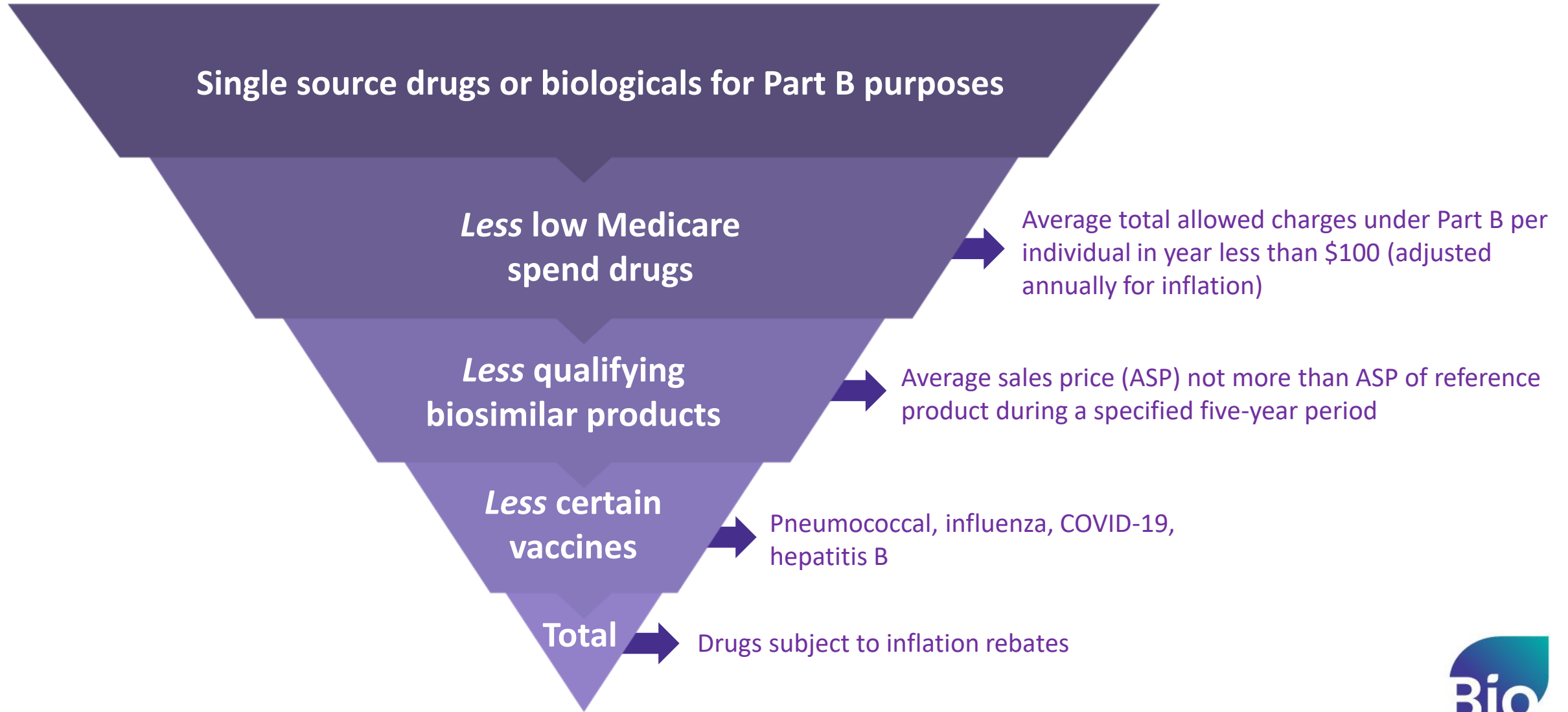
- ***No administrative or judicial review of:***
 - Determination of a unit
 - Determination of a qualifying single source drug
 - Determination of a negotiation-eligible drug
 - Selection of a drug for negotiation
 - Determination a maximum fair price
 - Determination of a renegotiation-eligible drug
 - Selection of a drug for renegotiation

Medicare Part B and D Inflation Rebates

Part B Inflation Rebates



What Drugs Are Subject to Part B Inflation Rebates?



What Utilization is Subject to Part B inflation Rebates?

- **Units reimbursed by Part B, less:**
 - Packaged units
 - 340B units
 - Medicaid units
- **Secretary required to waive or reduce rebate amount:**
 - Products on 506E shortage list
 - Biosimilars experiencing severe supply chain disruptions

What Is the Rebate Formula?

Part B inflation rebate calculated by multiplying:

- Total amount of **eligible Part B utilization** of drug in rebate quarter
- By **the amount** (if any) by which rebate quarter Part B payment amount **exceeds** inflation-adjusted Part B payment amount

Inflation-adjusted Part B payment rate calculated by multiplying:

- The payment amount for the benchmark quarter
- By **the percentage** (if any) by which rebate period urban consumer price index (CPI-U) **exceeds** benchmark period CPI-U

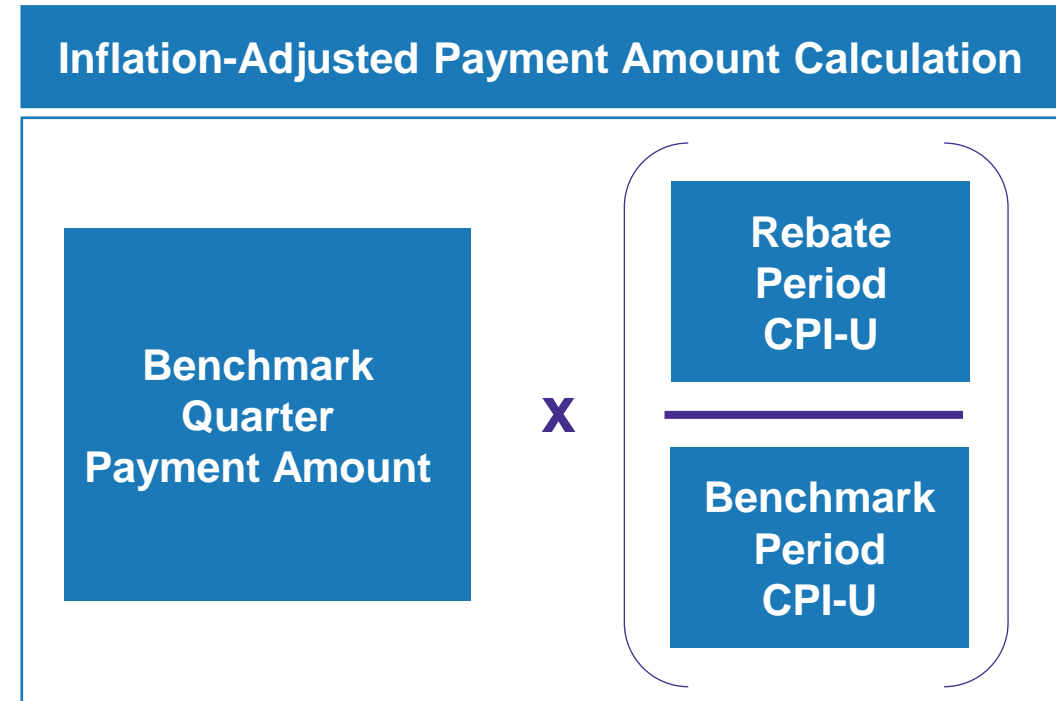
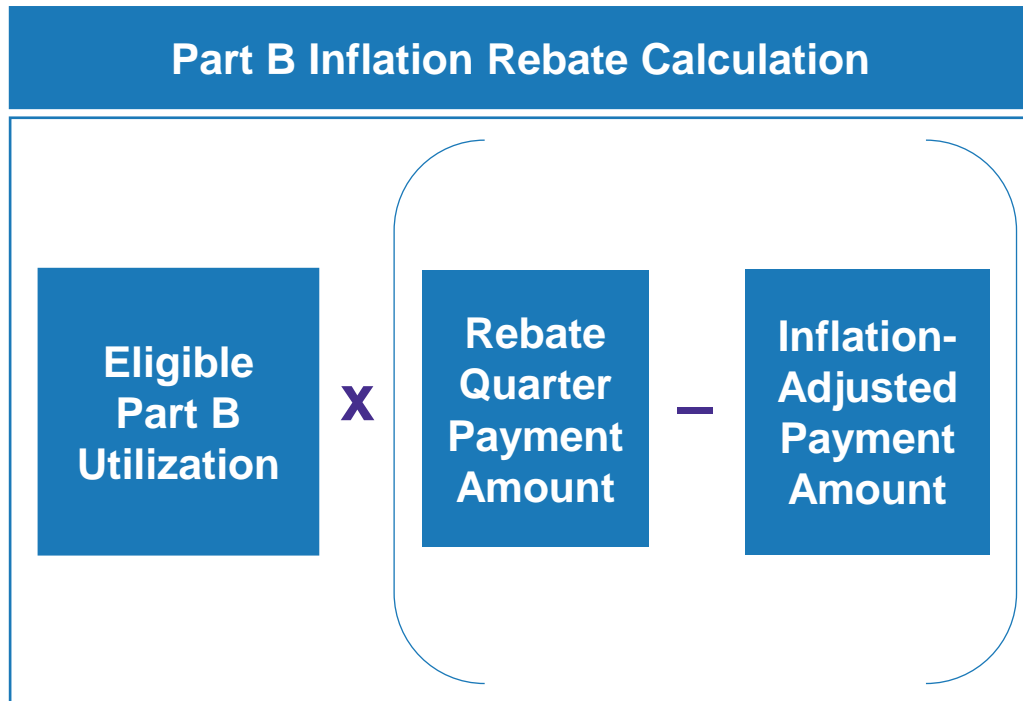
What If the Drug Is Selected For Negotiation?

- No exceptions: Drugs selected for negotiation under the price negotiation program still are **subject to the standard Part B inflation rebate calculation**
- But the benchmarks change: should drug **no longer qualify as a selected drug** (i.e., price applicability period ends), benchmarks would reset

What Are the Benchmarks?

| Part B Inflation Rebates | Drugs approved <u>before/on</u> 12/1/2020 | Drugs approved <u>after</u> 12/1/2020 (i.e., “subsequently approved” drugs) | “Selected Drugs” previously but no longer subject to MFP |
|----------------------------------|---|---|---|
| Benchmark Payment Quarter | Q3 2021 | Third full quarter after drug first marketed | Q1 of last year of the price applicability period (i.e., last year that drug was subject to a maximum fair price (MFP) under the negotiation program) |
| Benchmark Period CPI-U | CPI-U for January 2021 | CPI-U for first month of first full calendar quarter after drug was first marketed | July of year preceding the last year of the price applicability period |
| Rebate Period CPI-U | Greater of <ul style="list-style-type: none"> • Benchmark Period CPI-U, and • CPI-U for the first month of quarter that is two quarters prior to rebate quarter | | |
| Rebate Liability Starts | Q1 2023 | Later of <ul style="list-style-type: none"> • Q1 2023, and • Sixth full calendar quarter after drug is first marketed | Rebate liability does not cease during period as selected drug |

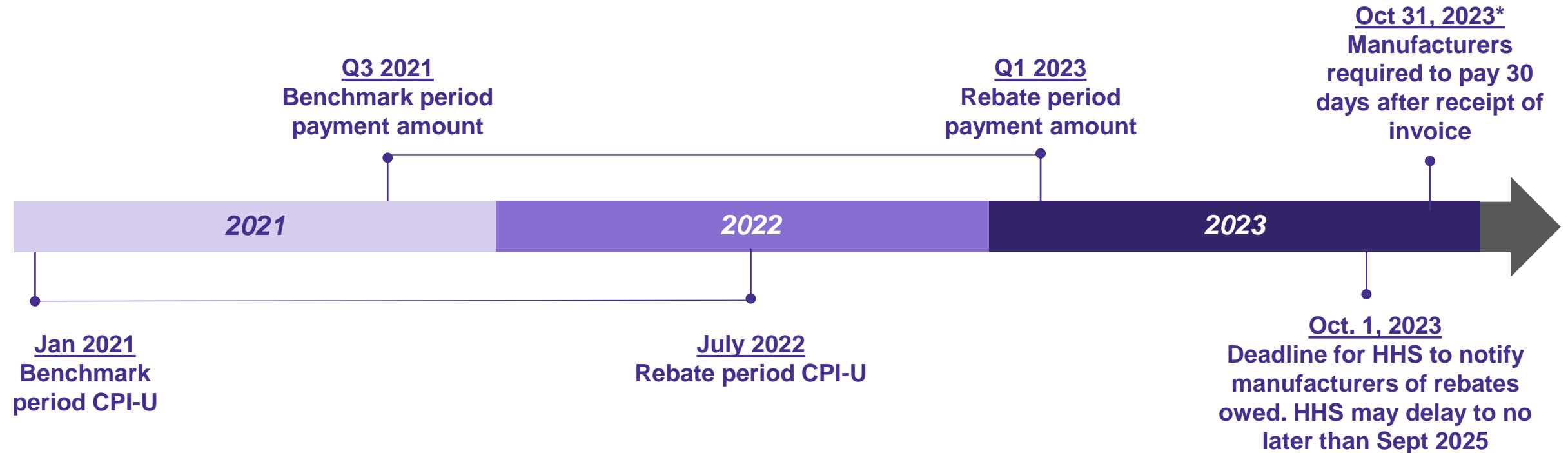
Rebate Formula Visualized



What Is the Rebate Invoicing Process?

- CMS to issue rebate invoices within **6 months of the end of each rebate calendar quarter**
 - Secretary **may choose** to delay invoice dates for calendar quarters in 2023 and 2024 to not later than September 25, 2025
- The invoice will include:
 - Part B utilization subject to rebate
 - Amount by which the rebate quarter Part B payment amount exceeded the inflation-adjusted Part B payment amount
 - Total rebate amount owed
- Manufacturers required to pay the rebate **within 30 days after receipt of invoice**

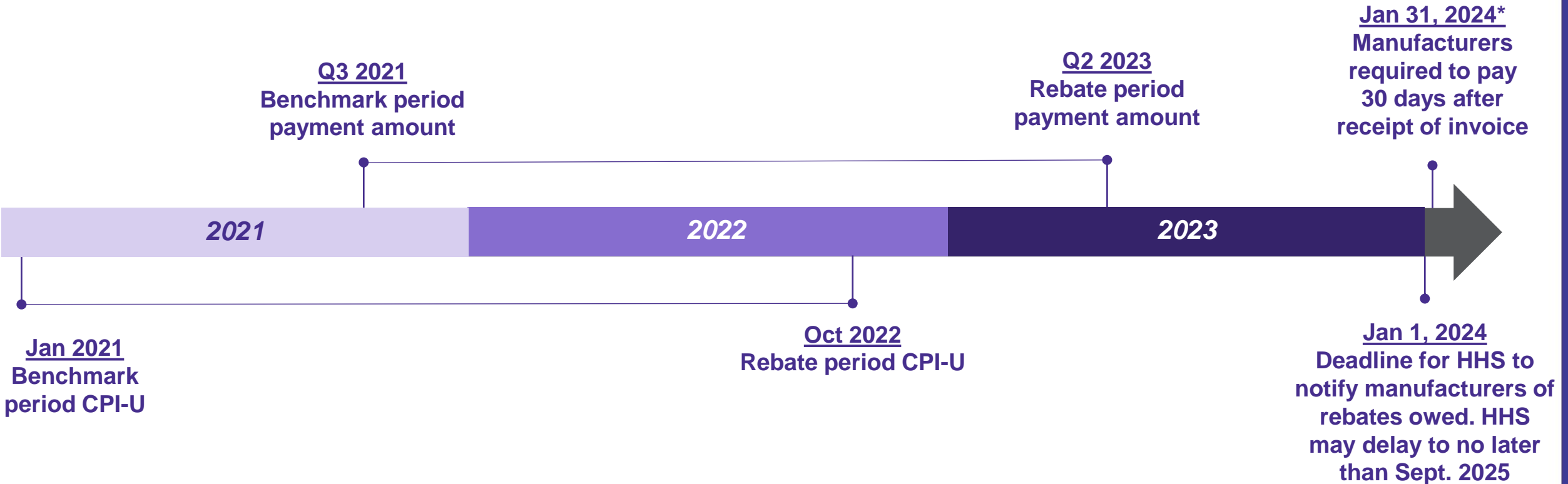
Part B Inflation Rebate Timeline for 1st Quarter (Q1 2023)



* Assuming invoice sent out in Oct. 1, 2023



Part B Inflation Rebate Timeline for 2nd Quarter (Q2 2023)



* Assuming invoice sent out on Jan. 1, 2024



Will Beneficiaries Share In the Savings?

Yes, but it's complicated:

- Part B beneficiary coinsurance for drug will be **set at 20 percent of the Part B inflation-adjusted payment amount**
- Effective Q2 2023

Providers made whole: CMS reimburses providers

- 80% of Part B payment amount; plus
- Difference between
 - 20% of the Part B payment amount, and
 - 20% of inflation adjusted payment amount

Is There A Process For Rebate Adjustments?

- No: Unlike with Part D, IRA does not specify process for rebate adjustments for Part B inflation rebates
- At least not yet: Unclear whether CMS will account for adjustments to inflation rebate liability in response to manufacturer ASP restatements

Enforcement and Judicial Review

Civil Monetary Penalties (CMPs): A manufacturer that does not timely pay a rebate subject to a CMP **at least equal to 125 percent of the rebate amount**

Judicial Review: No administrative or judicial review for:

- Determination of rebate units
- Determination of whether a drug qualifies as a rebatable drug
- Calculation of the rebate amount
- Calculation of the beneficiary coinsurance amount
- Computation of payment amount for Part B rebatable drugs

Implementation

- No obligation to issue guidance:
 - Unlike with Part D inflation rebates, CMS ***NOT expressly directed to implement the Part B inflation rebates through guidance*** for initial years
- Regulation for CMPs:
 - CMS directed to implement process for assessing CMPs ***via regulation***, which process should be in place ***before CMS can begin assessing CMPs***
 - While not required, CMS could implement other inflation rebate provisions through regulation
- Government price reporting:
 - Inflation rebates excluded from ***ASP, Best Price, and average manufacturer price (AMP)*** calculations

Part D Inflation Rebates

What Drugs Are Subject to Part D Inflation Rebates?



Generics excluded, except where:
(1) reference drug is not marketed,
(2) no therapeutically equivalent generics are marketed,
(3) manufacturer is not a “first applicant” during the “180-day exclusivity period,” and
(4) manufacturer is not a “first approved applicant” for a competitive genetic therapy

Average total allowed charges under Part D per individual in year less than \$100 (adjusted annually for inflation)

What Utilization Is Subject to Part B inflation Rebates?

- **Units reimbursed by Part D, less:**
 - 340B units (starting in 2026)
- **Secretary required to waive or reduce rebate amount:**
 - Products on 506E shortage list
 - Biosimilars experiencing severe supply chain disruptions

What Is the Rebate Formula?

Part D inflation rebate calculated by multiplying:

- Total amount of **eligible Part D utilization** of the drug in applicable year (i.e., rebate year)
- **By the amount** (if any) by which the volume-weighted average annualized AMP (**VAAMP**) for the rebate year **exceeds** the inflation-adjusted volume-weighted average annualized AMP (**IVAAMP**) in the payment amount benchmark period

VAAMP calculated by:

- **Multiplying** quarterly AMP for a unit of a drug
- **By the ratio** of the number of AMP-reported units for the quarter to the number of AMP-reported units for the year **and**
- **Adding** the result to the same calculation for each of the remaining three quarters in the year

IVAAMP calculated by:

- **Increasing** VAAMP for the payment amount benchmark period **by**
- **The percentage** (if any) by which the applicable period CPI-U **exceeds** the benchmark period CPI-U

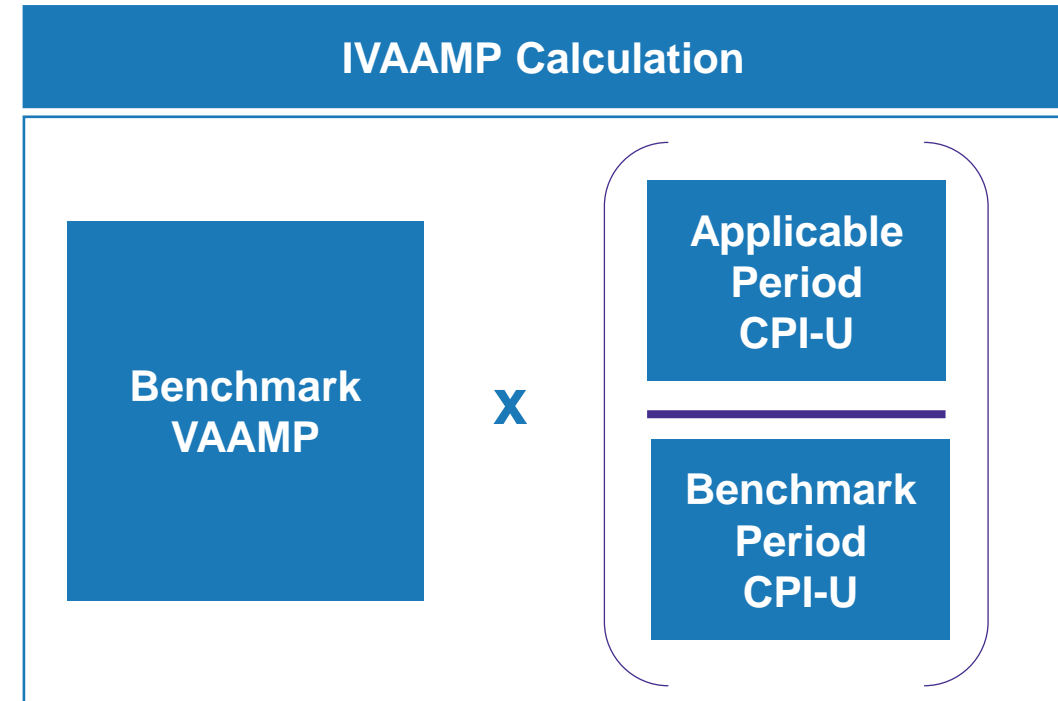
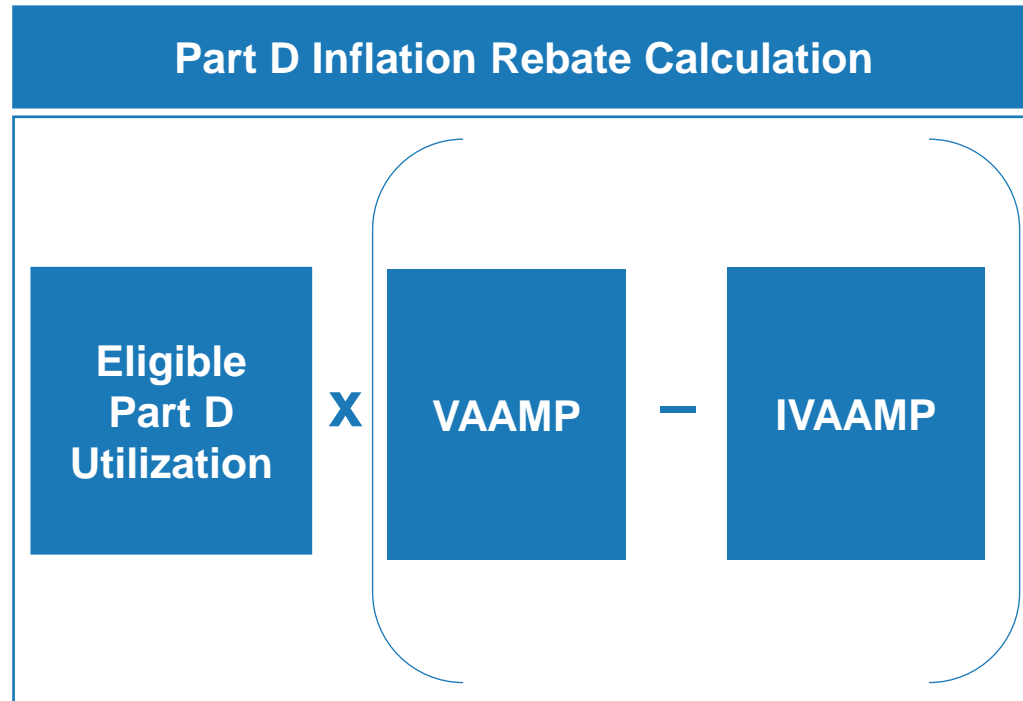
What If the Drug Is Selected for Negotiation?

- No exceptions: Drugs selected for negotiation under the price negotiation program still are **subject to the standard Part D inflation rebate calculation**
- But the benchmarks change: should drug **no longer qualify as a selected drug** (i.e., price applicability period ends), benchmarks would reset

What Are the Benchmarks?

| Part D Inflation Rebates | Drugs approved <i>before/on</i> 10/1/2021 | Drugs approved <i>after</i> 10/1/2021 (i.e., subsequently approved drugs) | “Selected Drugs” previously but no longer subject to MFP |
|--------------------------------|---|--|--|
| Benchmark Period | Q1-Q3 2021 | First calendar year after drug first marketed | Last year beginning during the price applicability period |
| Benchmark Period CPI-U | CPI-U for January 2021 | CPI-U for January of the first calendar year beginning after the date on which the drug was first marketed | January of the last year beginning during price applicability period |
| Applicable Period CPI-U | CPI-U for first month of rebate year | | |
| Rebate Liability Starts | Q4 2022 | | Rebate liability does not cease during period as selected drug |

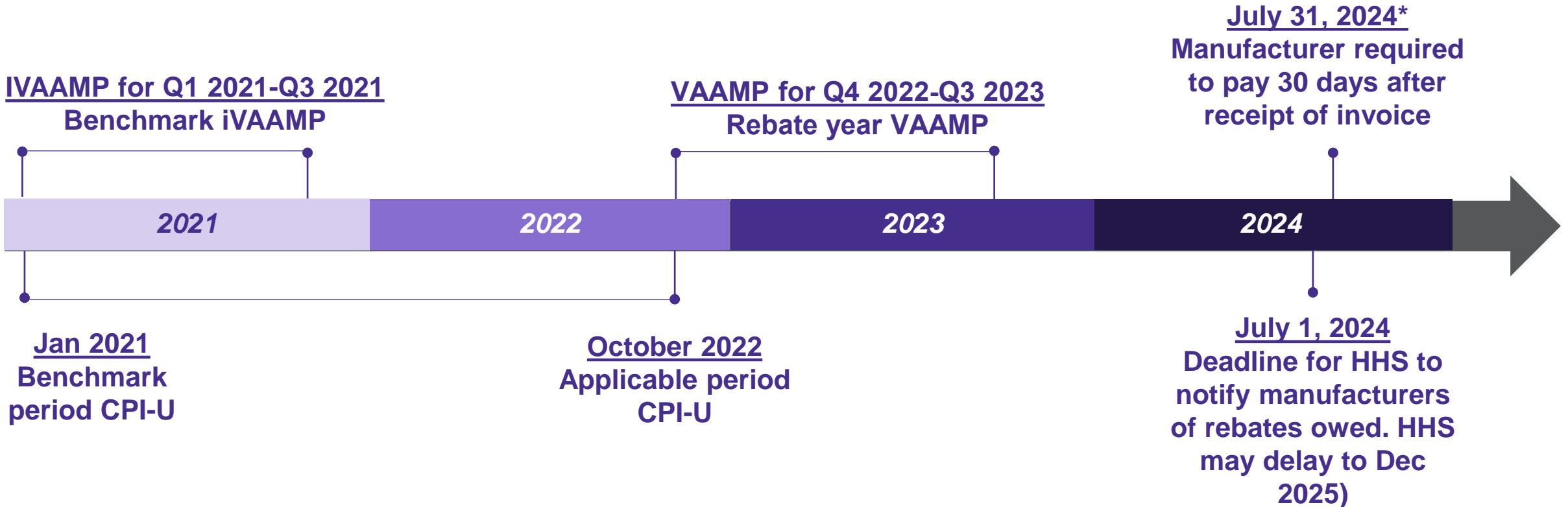
Rebate Formula Visualized



What Is the Rebate Invoicing Process?

- CMS to issue rebate invoices within **9 months of the end of each rebate year**
 - Secretary **may choose** to delay invoice dates for calendar years beginning Oct. 1, 2022, and Oct. 1, 2023, to not later than Dec. 31, 2025
- The invoice will include:
 - The amount of the excess VAAMP relative to the IVAAMP
 - Total rebate amount owed
- Unlike with Part B inflation, Secretary **not required** to include information on Part D utilization subject to rebates
- Manufacturers required to pay the rebate **within 30 days after receipt of invoice**

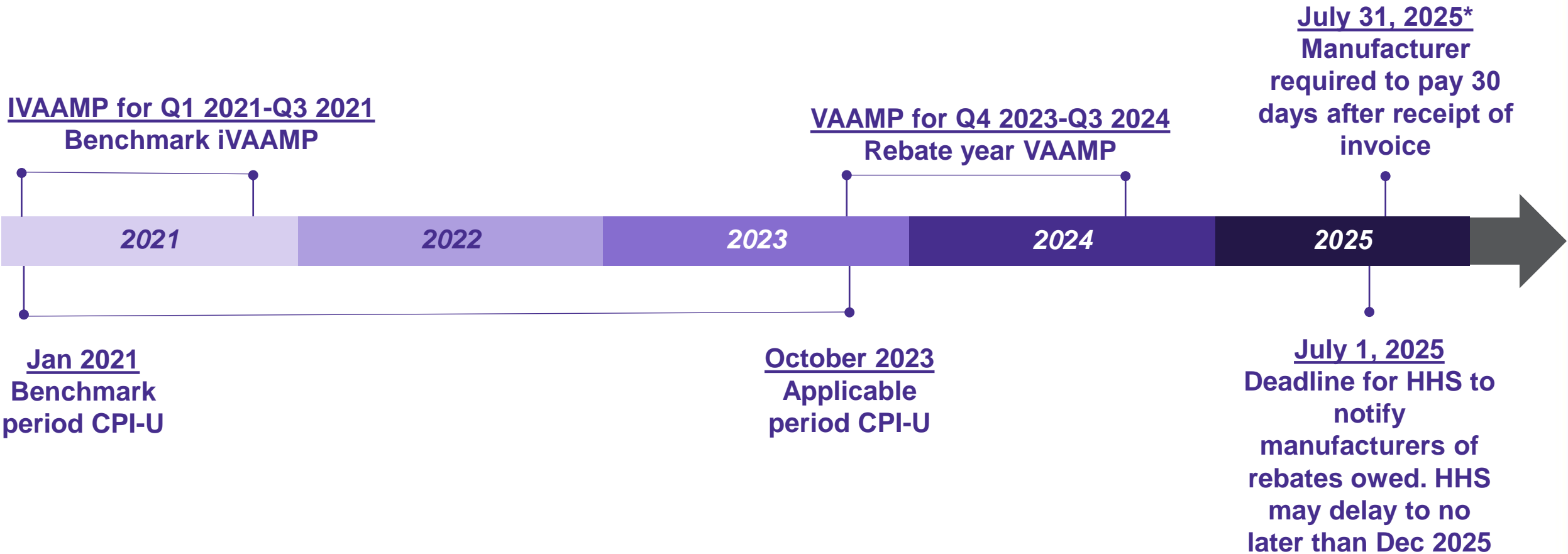
Part D Inflation Rebate Timeline for 1st Rebate Year (Q4 2022 – Q3 2023)



* Assuming invoice sent out on July 1, 2024



Part D Inflation Rebate Timeline for 1st Rebate Year (Q4 2023 – Q3 2024)



* Assuming invoice sent out on July 31, 2025



What About Line Extensions?

- To align with Medicaid:
 - Secretary must establish rebate calculation for line extensions of oral solid dosage form Part D rebatable drugs ***consistent with treatment under the Medicaid Drug Rebate Program*** (MDRP)
 - Line extension definition = MDRP
 - Expressly ***includes*** new formulations, such as extended release, but ***excludes*** abuse-deterrent formulations
 - Under MDRP, “new formulation” defined very broadly
 - “a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients”

Rebate Adjustments

Process to be created:

- Secretary must establish process for adjusting rebate calculations where prescription drug plan or Medicare Advantage prescription drug (MA-PD) plan **restates Part D utilization for rebatable drug**
- Statute provides for reconciliation process for overpayments and underpayments
- Manufacturer must rectify resulting underpayment within 30 days

Not addressed:

- Changes in rebate liability *not* due to utilization data, *i.e.* due to change in AMP

Enforcement and Judicial Review

Civil Monetary Penalties:

- A manufacturer that does not timely pay a rebate would be subject to a CMP in an amount **equal to 125 percent of the rebate amount**
- Differs from Part B CMP provision, which provides that CMP shall be equal to ***at least*** 125 percent

Judicial Review: No administrative or judicial review for:

- Determination of rebate utilization
- Determination of whether a drug qualifies as a rebatable drug
- Calculation of the rebate amount

Implementation

- Guidance:
 - CMS is directed to implement the Part D inflation rebates through *guidance for years 2022, 2023, and 2024*
- Rulemaking:
 - While *not required* to, CMS could decide to undertake one or more rulemakings to implement inflation rebate provisions
- Secretary *required to rely on information submitted by*:
 - **Manufacturers**, including AMP data and other information reported under the MDRP
 - **States**, including the number of units paid for by each state Medicaid program
 - **Prescription drug plans and MA-PD plans under Part D**
- Government price reporting:
 - Inflation rebates excluded from *ASP, Best Price, and average manufacturer price (AMP)* calculations

Medicare Part D Benefit Redesign

Overview of Existing Medicare Part D Benefit Structure

| | |
|-------------------------------|---|
| Premium | 25.5%, with no cap on premium growth |
| Deductible | 100% beneficiary |
| Initial Coverage Phase | 25% beneficiary 75% plan |
| Coverage Gap | 25% beneficiary 5% plan 70% drug company |
| Catastrophic Phase | 5% beneficiary 80% govt 15% plan |

**Generic drugs and drugs subject to Medicare negotiation are exempt from 10%/20% obligation*



Changes to Beneficiary Cost-Sharing

- **Beneficiary OOP threshold lowered to \$2,000 starting in 2025**, increased annually by an inflation factor.
 - OOP cap is a longstanding BIO priority
- **Coverage gap eliminated starting in 2025**
 - Beneficiaries who have met their applicable deductibles will have prescription drug coverage under an initial coverage phase and then a catastrophic coverage phase, without a coverage gap
 - Replaced with a new Manufacturer Discount Program
- **Beneficiary cost sharing in catastrophic phase eliminated starting in 2024**, after beneficiaries reach the OOP threshold
 - Beneficiaries currently pay 5% in the catastrophic phase

Changes to Beneficiary Cost-Sharing (cont.)

- **Permits smoothing of beneficiary OOP costs**

- Starting in 2025, a beneficiary would be able to opt to pay OOP costs ***on a monthly basis subject to a cap***, defined as the beneficiary's outstanding OOP costs for a plan year divided by the remaining months in the plan year
- Beneficiaries can take advantage of option at beginning or during plan year
- If an enrollee fails to make a monthly payment, ***monthly election is terminated***
- Smoothing of beneficiary OOP costs is a longstanding BIO priority

Reduction in Medicare Reinsurance Amount

- From **80 percent to 20 percent** where a drug is subject to the new Manufacturer Discount Program, and from **80 percent to 40 percent** where a drug is not subject to the program
- Takes effect in 2025

Premiums and LIS Eligibility

Premium Stabilization Changes

- Premium growth (base beneficiary premium) ***capped at 6%*** year from 2024-2029
- For 2030 and subsequent, Secretary authorized to ***make permanent adjustment to beneficiary premium percentage*** to ensure premium growth (base beneficiary premium) for 2030 is capped at 6%

Expands Low-Income Subsidy (LIS) Eligibility

- Modifies Part D LIS eligibility such that beneficiaries with incomes ***up to 150% of the federal poverty level*** will be eligible for more significant low-income subsidy benefits
- Previously beneficiaries between 135% and up to 150% (“partial LIS”) received less help
- Takes effect in 2024

Insulin and Vaccines

- **Insulin**

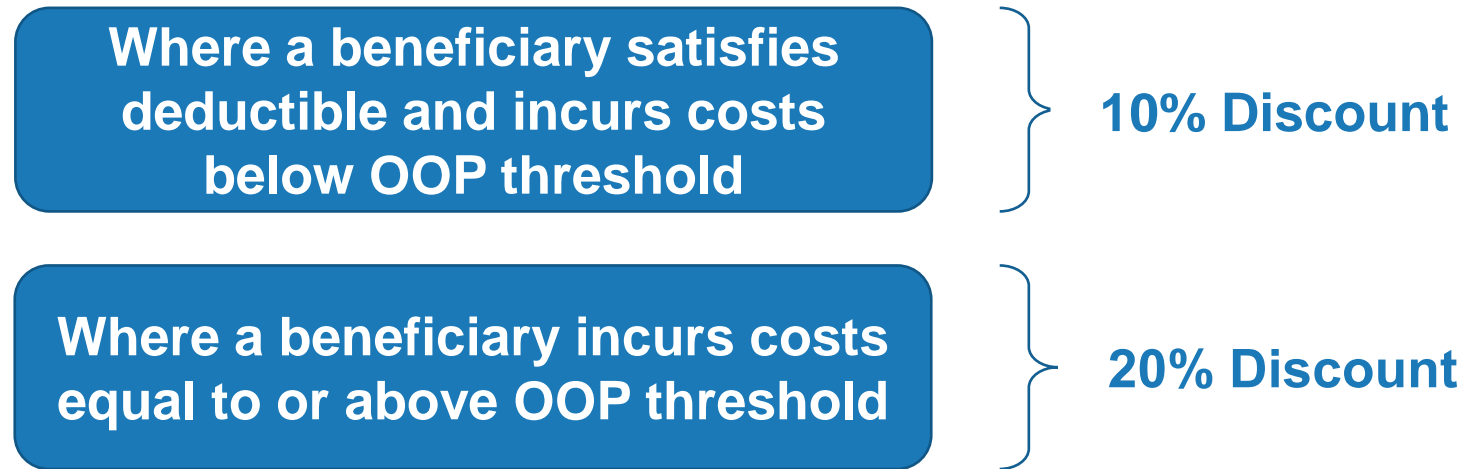
- Cost sharing for insulin **would be set at no more than \$35** in 2023-2025 in all phases of coverage, including deductible
- For 2026 and in subsequent years, cost sharing is the lessor of \$35, 25% of the Maximum Fair Price, or 25% of the negotiated price of the insulin product under Part D
- For plan year 2023 only, **requires the Secretary to subsidize** prescription drug and MA-PD plans for the cost of this change

- **Vaccines**

- Starting in 2023, vaccines recommended by the Advisory Committee on Immunization Practices would be **covered under Part D with no deductible and no coinsurance or other cost sharing**
- For plan year 2023 only, **requires the Secretary to subsidize** prescription drug and MA-PD plans for cost of this change
- No cost sharing for vaccines is longstanding BIO priority

Manufacturer Discount Program

- Establishes a new Manufacturer Discount Program to replace the coverage gap discount program
- Starting in 2025, manufacturers participating in Part D required to enter a Manufacturer Discount Program agreement to provide discounts ***off the negotiated price under Part D for applicable drugs dispensed to applicable beneficiaries***



Applicability

- **Applicable drug**

- A covered Part D drug approved under a ***new drug application or licensed as a biologic or biosimilar biological product*** (i.e., not including drugs approved under an abbreviated new drug application)
- for which benefits are available through a Part D plan (on a formulary or otherwise) but
- ***excluding*** drugs subject to the Medicare negotiation program (i.e., selected drugs)

- **Applicable beneficiary**

- A beneficiary enrolled in a prescription drug plan (or a Medicare Advantage prescription drug (MA-PD) plan) but not in a qualified retiree prescription drug plan (employment-based retiree health coverage)
- ***that has satisfied his or her deductible***

Manufacturer Agreement and Collection of Data

- **Manufacturer Agreement**

- Secretary required to establish a **manufacturer agreement** governing the terms of the Manufacturer Discount Program
- Manufacturers required to enter the agreement for fiscal year 2025 by **March 1, 2024**, and for subsequent years by the deadline set by CMS
- Agreement would be effective for **at least 12 months** and would automatically renew for at least another year unless terminated

- **Collection of Data**

- Manufacturers required to collect and have available **“appropriate data, as determined by the Secretary”** to demonstrate compliance with the program
- Secretary **permitted to collect appropriate data** from prescription drug plans and MA-PD plans in a timeframe that allows discounted prices to be provided

Drugs selected for Medicare negotiation

- A drug selected for Medicare negotiation (i.e., selected drug) is ***not subject to the Manufacturer Discount Program*** while it is subject to the maximum fair price (MFP)
- However, IRA ensures that ***Medicare, and not the plan, covers the discount*** that the manufacturer would have paid had the drug qualified as an applicable drug

Where a beneficiary who has ***NOT satisfied*** annual OOP threshold is dispensed a drug that does ***NOT*** qualify as an applicable drug because it is a ***selected drug***

Secretary must provide plan with a ***10 percent subsidy off the negotiated price***

Where a beneficiary who has ***exceeded*** annual OOP threshold is dispensed a drug that does ***NOT*** qualify as an ***applicable drug***, including because it is a selected drug

Medicare reinsurance would be set at 40%, which is 20% more than the standard amount

Phase-In for Drugs Dispensed to LIS Beneficiaries

- Discounts phased-in for drugs marketed as of the date of enactment and dispensed to LIS beneficiaries by **specified manufacturers**, defined to mean a manufacturer that, in 2021:
 - 1) Had a coverage gap discount program agreement,
 - 2) For which the total expenditures for all drugs of that manufacturer **under Part D** are less than 1% of total expenditures under Medicare Part D, and
 - 3) For which the total expenditures for all single source drugs and biologicals of that manufacturer for which **payment may be made under Part B** are less than 1% percent of total expenditures for all drugs or biologics for which payment may be made under Medicare Part B

Phase-In for Specified Small Manufacturers

- Discounts are phased-in for drugs marketed as of the date of enactment by **specified small manufacturers**, defined to a manufacturer that, for 2021:
 - 1) Qualifies as a **“specified manufacturer,”** as previously defined, and
 - 2) For which the total expenditures for **a single drug** of that manufacturer under Part D **are equal to or exceed** 80 percent of the total expenditures for the drugs of that manufacturer under Part D for 2021 that were covered under a coverage gap agreement in that year

Discounts Phased-In As Follows

Where the beneficiary hasn't reached the OOP threshold

2025, 1%

2026, 2%

2027, 5%

2028, 8%

2029 & →,
10%

Where the beneficiary has reached the OOP threshold

2025,
1%

2026,
2%

2027,
5%

2028,
8%

2029,
10%

2030,
15%

2031 &
→, 20%

Additional Eligibility Criteria for Both Phase-In Discounts

- **Aggregation rule**

- Entities treated as a single employer under Section 52(a) or (b) of the IRS Code of 1986 are treated as a single manufacturer

- **Acquisition by a non-eligible manufacturer**

- An otherwise eligible manufacturer does not qualify for the phase-in if it is acquired by a non-eligible manufacturer after 2021

- **Total Expenditures** means

- With respect to Part D, includes ***total gross covered prescription drug costs***
- With respect to Part B, excludes expenditures for drugs or biologicals that are ***bundled or packaged into the payment for service***

Enforcement & Dispute Resolution

- **Civil Monetary Penalties (CMPs)**

- Manufacturers ***that fail to provide discounted prices*** for an applicable drug are subject CMPs equal to ***1.25 percent times the discount*** that the manufacturer should have paid under the agreement

- **Termination**

- The Secretary may ***terminate*** an agreement with a manufacturer for ***a knowing and willful violation of the terms of the agreement*** as established by the Secretary

- **Dispute Resolution**

- Secretary required to establish a ***dispute resolution mechanism*** to resolve disagreements between manufacturers, prescription drug plans and MA-PD plans, and the Secretary

Price Reporting Exclusions

- Discounted prices offered under the Manufacturer Discount Program are ***excluded from Best Price and AMP reporting*** under the Medicaid Drug Rebate Program

Implementation

Guidance

- CMS is permitted to implement most of the Part D changes for **2024 through 2026 by program instruction or other guidance**, meaning it is **not** necessary for CMS to adopt rules for those years.

Funding

- The IRA appropriates over \$300 million to CMS to implement the Part D related changes

Overview Medicare Part D Benefit Restructure

| Current Structure (2022) | New Structure (2025) |
|--|--|
| <p>Premium 25.5%, with no cap on premium growth</p> | <p>Premium 25.5%, but premium growth capped at 6% from 2024-2029, with adjustment to percentage in 2030</p> |
| <p>Deductible 100% beneficiary</p> | <p>Deductible 100% beneficiary</p> |
| <p>Initial Coverage Phase 25% beneficiary 75% plan</p> | <p>Initial Coverage Phase 25% beneficiary 65% plan 10% drug company*</p> |
| <p>Coverage Gap 25% beneficiary 5% plan 70% drug company</p> | <p>Coverage Gap ELIMINATED</p> |
| <p>Catastrophic Phase 5% beneficiary 80% govt 15% plan</p> | <p>Catastrophic Phase 0% beneficiary 20% government (or 40% where drug not subject to discount program) 60% plan 20% drug company*</p> |

**Generic drugs and drugs subject to Medicare negotiation are exempt from 10%/20% obligation*



Important Dates

| January 1, 2023 | January 1, 2024 | March 1, 2024 | January 1, 2025 |
|---|--|--|--|
| Insulin and vaccine coverage changes go into effect | Premium stabilization changes, elimination of cost-sharing in catastrophic phase, and expansion of LIS program benefits go into effect | Deadline for manufacturer to enter into manufacturer discount program agreement for 2025 | Manufacturer discount program, lowering the beneficiary OOP threshold to \$2,000, elimination of the coverage gap program, optional smoothing of beneficiary OOP costs, and lowering of the Medicare reinsurance payment amount go into effect |



Conclusion and Next Steps

John Murphy

Chief Policy Officer, BIO

Speakers



Alice Valder Curran
Partner, Hogan Lovells
Alice.Valder.Curran@hoganlovells.com
+1 202 637 5997



Melissa K. Bianchi
Partner, Hogan Lovells
Melissa.Bianchi@hoganlovells.com
+1 202 637 3653



Ken Choe
Partner, Hogan Lovells
Ken.Cho@hoganlovells.com
+1 202 637 5675

Questions Today That Aren't Answered?

Please reach out to Crystal Kuntz
ckuntz@bio.org



Understanding the Prescription Drug Provisions of the Inflation Reduction Act

September 21, 2022

John Murphy, Chief Policy Officer, BIO

Crystal Kuntz, VP Health Policy and Research, BIO

Ken Choe, Partner, Hogan Lovells

Alice Valder Curran, Partner, Hogan Lovells

Melissa Bianchi, Partner, Hogan Lovells