



LATHAM & WATKINS HEALTHCARE & LIFE SCIENCES PRACTICE

# Inflation Reduction Act: Roadmap of Drug Pricing Provisions

Second Edition | September 2023

**LATHAM & WATKINS** LLP



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LATHAM & WATKINS<sup>LLP</sup>

## Full Text of the Inflation Reduction Act of 2022



## Online Version of this Client Alert



## Full Text of June 30, 2026 Final Negotiation Guidance



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# Introduction

## **Inflation Reduction Act Implementation Continues Historic Changes to the U.S. Healthcare System**

The Inflation Reduction Act of 2022 (IRA), signed into law by President Biden on August 16, 2022, marks Congress's most significant involvement with the pharmaceutical industry since passage of the Affordable Care Act in 2010. In a departure from long-standing law and policy, the IRA imposes a requirement on manufacturers to negotiate drug prices with Medicare, with prices subject to a cap. The IRA also grants the Centers for Medicare & Medicaid Services (CMS) significant new powers to implement the IRA's provisions.

Most recently, on June 30, 2023, CMS issued final guidance implementing the IRA's negotiation provisions for 2026, the initial price applicability year, and then published the initial list of 10 qualifying single source drugs subject to negotiation on August 29, 2023. Meanwhile, multiple lawsuits have been brought to challenge the broad reach of the IRA.

CMS has also issued proposed guidance to implement the IRA's new Medicare Part B and D inflation rebates and Medicare Part D redesign, which includes a new Medicare Part D discount requirement for manufacturers.

The IRA is the product of a lengthy legislative process, which may explain why the drug pricing provisions are highly complex. The Latham roadmap to the statute presents the topics in a thoughtful order, while providing citations to the IRA for easy reference to the legislative text. The appendix provides a cross reference to Title 42 of the United States Code.

***Please refer to the contact information on the back cover if you have any questions, or tune into the Latham Drug Pricing Podcast, where we discuss significant developments, and conclude by asking: Which Olympic sport is it like?***

# Medicare Price Negotiation

The Secretary of the Department of Health and Human Services is charged with establishing a price negotiation program for Medicare, and \$3 billion is appropriated to CMS for fiscal year 2022, to remain available until expended, to implement the program. [IRA 11004]<sup>1</sup>

For 2026, 2027, and 2028, the Secretary must implement the negotiation program by program instruction or other forms of program guidance. [1198(c), IRA 11002(c)]

Certain determinations, such as unit determinations, drug selection, and maximum fair price determinations, will not be subject to administrative or judicial review. [1198(a)]

## Subject Drugs

Drugs that qualify for being “selected” for negotiation:

- Single-source Medicare Part D and Part B drugs and biologics:
  - Approved under a New Drug Application (NDA) at least seven years ago with no generic on the market [1192(e)(1)(A)]
  - Approved under a Biologics License Application (BLA) at least 11 years ago with no biosimilar on the market [1192(e)(1)(B)]
  - Drugs marketed under the same approval (e.g., an authorized generic marketed under the NDA) are treated as the same drug as the approved drug [1192(e)(2)]
- Exclusions — the following do not qualify:
  - Orphan drugs designated for only one rare disease or condition and approved only for such disease or condition [1192(e)(3)(A)]

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<sup>1</sup> Citations are to the Social Security Act, as amended by the Act, unless preceded by “IRA.” Please refer to the Appendix for a cross-reference table to the U.S. Code.

- Low spend Medicare drugs, with total expenditures under Parts B and D, from June 1, 2022, until May 31, 2023, of less than \$200 million. This threshold is applicable for 2026, and in subsequent years is increased for inflation by reference to the Consumer Price Index for All Urban Consumers (CPI-U) [1192(e)(3)(B)]
- Plasma-derived products, meaning a biological product that is derived from human whole blood or plasma [1192(3)(c)(C)]
- Certain small biotech drugs for 2026, 2027, and 2028 (explained below in connection with the drug selection process) [1192(d)(2)]
- Biologicals as to which market entry of a biosimilar is highly likely, allowing for up to a two year delay (explained below in connection with the drug selection process)<sup>2</sup>

## Number of Selected Drugs

Number of drugs selected for negotiation: [1192(a)]

- 2026 — 10 Part D high-spend drugs
- 2027 — 15 Part D high-spend drugs
- 2028 — 15 Part D and Part B high-spend drugs, in total
- 2029 and each subsequent year — 20 Part D or Part B high-spend drugs, in total
- The selected drug numbers are cumulative, and drugs that are already “selected” will not count toward these thresholds in subsequent years

When is a drug no longer “selected”:

- A selected drug that was “included on the list published ... with respect to an initial price applicability year” remains a selected drug “with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product” for the selected drug, as applicable, is approved and “marketed” [1192(c)(1)]

<sup>2</sup> See IRA Section 11002, which confusingly amends Section 1192 of the Social Security Act, as already amended by the IRA.



## Maximum Fair Price Definition

The price offered by the Secretary in the negotiation [1194(b)(2)(F)] and the ultimately negotiated price [1194(c)(1)(A)] (maximum fair price) may not be above a ceiling or (for small biotech drugs) below a floor:

- Maximum fair price ceiling: Lower of (1) and (2)
  - (1) Historic spend
    - For Part B drugs: Payment amount for the drug or biologic for the year prior to the publication date [1194(c)(1)(B)(ii)]
    - For Part D drugs: The sum of the plan specific enrollment weighted amounts for each Part D plan or Medicare Advantage Prescription Drug Plan (MA-PD) [1194(c)(1)(B)(i)], which is net of all price concessions received by the plan [1194(c)(2)]
  - (2) Applicable percentage of 2021 Non-Federal Average Manufacturer Price (Non-FAMP) [1194(c)(1)(C)], which is the average of the four 2021 quarterly Non-FAMP figures [1194(c)(6)]
    - 2026 — average Non-FAMP for 2021, increased for inflation by reference to CPI-U [1194(c)(1)(C)(i)]
    - 2027 and subsequent [1194(c)(1)(C)(ii)] — lower of
      - Average Non-FAMP for 2021, increased for inflation by reference to CPI-U, and
      - Average Non-FAMP for year prior to publication date
- Applicable percentage of Non-FAMP:
  - Short-monopoly drug: 75% [1194(c)(3)(A)] — approved for less than 12 years
  - Extended-monopoly drug: 65% [1194(c)(3)(B)] — approved between 12 and 16 years [1194(c)(4)(A)], excluding vaccines and a selected drug with a negotiation agreement entered into before 2030 [1194(c)(v)(B)]

- Long-monopoly drug: 40% [1194(c)(3)(C)] — approved for more than 16 years [1194(c)(5)(A)], excluding vaccines [1194(c)(5)(B)]
- Temporary maximum fair price floor for small biotech drugs:
  - Applies only to small biotech drugs (as defined below in connection with drug selection), and only in 2029 and 2030 [1194(d)]
  - The floor is 66% of average Non-FAMP for 2021, increased for inflation by reference to CPI-U

Maximum fair price for selected drugs in subsequent years:

- The maximum fair price is increased for inflation by reference to CPI-U [1195(b)(1)(A)], unless the drug is subject to renegotiation (as discussed below)

### **Where the Maximum Fair Price Applies**

The maximum fair price applies to maximum fair price eligible individuals, which include Part D and Part B beneficiaries: [1191(c)(2)]

- Part D:
  - The maximum fair price must be provided to pharmacies, mail order services, and other dispensers, when eligible individuals are dispensed the drug [1193(a)(1)(A)]
  - The maximum fair price must be provided to individuals at the pharmacy, mail order service, or other dispenser at the point-of-sale of the drug [1193(a)(3)(A)]
- Part B:
  - The maximum fair price must be provided to hospitals, physicians, and other providers of services and suppliers, when eligible individuals are administered the drug [1193(a)(1)(B), (a)(3)(B)]
- The maximum fair price must be applied before coverage or financial assistance under health benefit plans or programs or other discounts [1196(a)(1)]

## How the Secretary Selects Drugs for Negotiation

Drugs are selected for negotiation based on the highest Part D and Part B total expenditure.

- Total expenditure definition:
  - For Part D, total gross covered prescription drug cost [1191(c)(5)]
  - For Part B, the expenditures for drugs or biologicals under that title, excluding expenditures for a drug or biological that is bundled or packaged into the payment for a service [1191(c)(5)]

The Secretary ranks “negotiation-eligible” drugs according to the total expenditures, from high to low, for such drugs under Parts B and D during the most recent 12-month period where data are available, ending no later than October 31 of the year prior to the drug publication date (described below). [1192(b)(1)(A)] (For the 2026 price applicability period, the relevant time period is June 1, 2022, until May 31, 2023.) [1191(d)(3)(A)]

- For the 2026 and 2027 price applicability periods, only Part D expenditures [1192(b)(2)] and drugs [1192(d)(1)] are considered
- The list of negotiation-eligible drugs comprises the 50 drugs with the highest Part D expenditures (2026 and 2027) and also the 50 drugs with the highest Part B expenditures (2028 and subsequent) [1192(d)(1)]
- Drugs that are already selected drugs are not included [1192(d)(3)(A)(i)]
- From the list of negotiation-eligible drugs, the Secretary will select for negotiation the drugs with the highest rankings [1192(b)(1)(B)]

## Small Biotech Exception

An exception from being included on the list of negotiation-eligible drugs is available for small biotech drugs:

- For the 2026, 2027, and 2028 price applicability periods, a drug will be excluded from the negotiation-eligible drugs if, in 2021: [1192(d)(2)(A)(i) and (ii)]

- Total Part D or Part B expenditures for the drug were less than 1% of total Part D or Part B expenditures, respectively, and,
- Total Part D or Part B expenditures for the drug, as applicable, represented at least 80% of total Part D or Part B expenditures, as applicable, of the manufacturer
- Persons treated as a single employer under Section 52(a) or (b) of the Internal Revenue Code of 1986 are treated as one manufacturer [1192(d)(2)(B)(i)]
- The exclusion no longer applies if the manufacturer of the small biotech drug is acquired after 2021 by another manufacturer that does not qualify as a “specified manufacturer” [1192(d)(2)(B)(ii)]
  - Specified manufacturer means a manufacturer that in 2021 had a coverage gap discount agreement, total expenditures for all specified drugs of the manufacturer under that agreement represented less than 1% of total Part D drug expenditures, and the total expenditures for the manufacturer’s specified drugs that are single-source drugs or biologicals under Part B represented less than 1% of total Part B drug expenditures [IRA 11201(c)(1), adding 1860D-14C(g)(4)(B)(ii)]
- The small biotech exception does not apply to new formulations [1192(d)(2)(C)]

### **Selection Delay for Biologics if Biosimilar Entry is Highly Likely**

This provision applies to a biological that is an extended-monopoly drug (as defined above, a drug that has been approved for between 12 and 16 years, with no biosimilar on the market) and that would be a selected drug. Such a drug is excluded from the list of negotiation-eligible drugs, and thus not selected, for up to two years, if the Secretary determines there is a “high likelihood” that a biosimilar product will be licensed prior to the price application period (i.e., within two years of when the drug would otherwise be selected for publication). [1192(f)(1)(A)]

- To come under the exception, the manufacturer of the biosimilar that will reference the otherwise selected biological must make a request [1192(f)(1)(B)(i)], which includes the submission of information supporting the Secretary's determination of high likelihood [1192(f)(1)(B)(ii)]
  - A request will not be permitted if:
    - The biosimilar manufacturer is the same as the biological manufacturer, or
    - The biosimilar manufacturer has an agreement with the biological manufacturer that either (i) incentivizes the biosimilar manufacturer to submit the application for delay, or (ii) restricts the quantity of biosimilar product that may be sold in the US [1192(f)(2)(D)(iv)]
  - Persons treated as a single employer under Section 52(a) or (b) of the Internal Revenue Code of 1986 are treated as one manufacturer, as are those in a partnership, which includes a joint venture [1192(f)(1)(C)]
- “High likelihood” exists if an application for licensure of the biosimilar has been accepted for review or approved by FDA, and the request for delay includes clear and convincing evidence that the biosimilar product will be marketed prior to the price application period (i.e., within two years of when the drug would otherwise be selected for publication) [1192(f)(3)]
- If the Secretary determines there is a high likelihood that a biosimilar will be licensed within two years of the publication date, inclusion of the biological as a selected drug will be delayed for one year [1192(f)(2)(A)]
  - If the biosimilar is not licensed and marketed during the one-year delay period, at the request of the manufacturer, the Secretary will reevaluate whether there is a high likelihood the biosimilar will be licensed and marketed in the next year, and whether the biosimilar manufacturer made significant progress toward licensing and marketing [1192(f)(2)(B)(i)]

- If the Secretary determines there is not a high likelihood, or there has not been significant progress, the biological will be included as a selected drug for the next year, and the manufacturer of the biological product will owe a rebate with respect to the delay year [1192(f)(2)(B)(ii)]
- If the Secretary determines there is a high likelihood and there has been significant progress, the Secretary will delay inclusion of the biological as a selected drug for a further year [1192(f)(2)(B)(iii)]
- A second one-year delay is not available for biologics that transitioned to a long-monopoly drug (as defined below, a drug that has been approved for more than 16 years, with no biosimilar on the market) during the delay [1192(f)(2)(D)(ii)]
  - If the biosimilar is not licensed and marketed during the second one-year delay period, the biological will be included as a selected drug for the next year, and the manufacturer of the biological product will owe a rebate with respect to both delay years [1192(f)(2)(C)]
- Rebate: Applies to Part D and Part B units during the delay period, and is based on [1192(f)(4)]
  - For Part D drugs, a percentage of how much Average Manufacturer Price (AMP) exceeded the maximum fair price for the drug, and
  - For Part B drugs, a percentage of how much the Part B payment amount exceeded the maximum fair price
  - A different formula applies to delayed biological products that become long-monopoly drugs

## **Negotiation Timeline**

The negotiation timeline for periods after the 2026 price applicability period is as follows:

- Selected drug publication: February 1, two years before the price applicability period, the Secretary will publish the list of selected drugs for the price applicability period [1191(b)(3)]

- Entry into agreement to negotiate: No later than February 28 of that year, the manufacturer of a selected drug must enter into an agreement with the Secretary governing the negotiation. [1193(a)]; the agreement remains in force until the drug is no longer a selected drug [1193(b)]
- Negotiation period: Upon entry into agreement to negotiate, but no later than February 28 of that year, the negotiation period will begin; the negotiation period will end on November 1 of that year [1191(b)(4)]
- Publication of maximum fair prices: No later than November 30 of that year, the Secretary will publish the maximum fair prices for the selected drugs [1195(a)(1)]
- Publication of explanation: No later than March 1 of the next year (i.e., one year prior to the price applicability period), the Secretary will publish an explanation for the maximum fair prices with respect to the negotiation factors (described below), subject to confidentiality requirements [1195(a)(2)]

For 2026, the first price applicability period, the negotiation timeline is modified:

- Selected drug publication: September 1, 2023 [1191(d)(1)]<sup>3</sup>
- Entry into agreement to negotiate: No later than October 1, 2023 [1191(d)(4)]; the agreement will remain in force until the drug is no longer a selected drug [1193(b)]
- Negotiation period: Upon entry into agreement to negotiate, but no later than October 1, 2023, the negotiation period will begin; the negotiation period will end on August 1, 2024 [1191(d)(2)]
- Publication of maximum fair prices: No later than September 1, 2024, the Secretary will publish the maximum fair prices for the selected drugs [1191(d)(6)]
- Publication of explanation: As with periods after 2026, no later than March 1 of the next year (i.e., one year prior to the price applicability period), the Secretary will publish an explanation for the maximum fair prices with respect to the negotiation factors (described below), subject to confidentiality requirements [1195(a)(2)]

<sup>3</sup> CMS published the list of selected drugs on August 29, 2023.

## Negotiation Process

The negotiation process, to be established by the Secretary, is as follows:

- The Secretary will develop a consistent methodology and process that aims to achieve the lowest maximum fair price [1194(b)(1)]
- No later than March 1 (after the February 1 selected drug publication), the manufacturer will submit information to the Secretary [1194(b)(2)(A)]
- No later than June 1 of that year, the Secretary will provide a written initial offer with a concise justification based on the negotiation factors (see below) [1194(b)(2)(B)]
- No later than 30 days after receipt of the initial offer, the manufacturer will accept the offer or make a counteroffer, which must be justified based on the negotiation factors [1194(b)(2)(C)]
- The Secretary will respond to the counteroffer [1194(b)(2)(D)]
- All negotiations will end prior to November 1 of that year [1194(b)(2)(E)]

The “negotiation factors” that the Secretary will base the offer on are as follows: [1194(e)]

- Manufacturer-specific data: [1194(e)(1)]
  - Research and development costs and their recoupment
  - Current unit costs of production and distribution
  - Prior federal financial support of discovery and development
  - FDA applications and approvals and patent applications
  - US market data, revenue, and sales volume
- Evidence about alternative treatments: [1194(e)(2)]
  - Therapeutic advance represented by the drug and costs of existing therapeutic alternatives
  - Prescribing information for the drug and therapeutic alternatives



- Comparative effectiveness of the drug and therapeutic alternatives
- Unmet medical needs that the drug and therapeutic alternatives address

Drugs that are selected drugs may be subject to a renegotiation process:

- For years beginning 2028, the Secretary will provide a process for renegotiation [1194(f)(1)]
- The process, to the extent practicable, must be consistent with the initial negotiation process [1194(f)(4)(B)]
- The following drugs are eligible for renegotiation: [1194(f)(2)]
  - A short-monopoly drug becoming an extended-monopoly drug, or an extended-monopoly drug becoming a long-monopoly drug — the Secretary must select these renegotiation eligible drugs for renegotiation [1194(f)(3)(A) and (B)]
  - Drugs that have a new indication added, or experience a material change to any of the negotiation factors — the Secretary will select drugs for which the Secretary expects renegotiation to likely result in a significant change in the maximum fair price [1194(f)(3)(C)]

## **Manufacturer Reporting Obligations**

As part of the negotiation process, the manufacturer must report data and information to the Secretary:

- Non-FAMP: Reported to the Secretary for the applicable year or period [1193(a)(4)(A)]
- Information that the Secretary requires to carry out the negotiation [1193(a)(4)(B)]

Manufacturer-submitted information that is proprietary information (as determined by the Secretary) is used only by the Secretary or disclosed to and used by the Comptroller General for purposes of carrying out the negotiation program [1193(c)]

## Interactions With Other Federal Programs

The maximum fair price for a selected drug has implications for the other federal programs:

- 340B drug pricing program:
  - The maximum fair price is not required to be given to 340B covered entities with respect to maximum fair price entitled individuals if the 340B ceiling price is lower [1193(d)(1)]
  - The maximum fair price is required to be given to 340B covered entities with respect to maximum fair price entitled individuals if the 340B ceiling price is higher [1193(d)(2)]
- Medicare Part B reimbursement:
  - Part B reimbursement for a selected drug is not ASP plus 6%, but the maximum fair price plus 6% [1198(b)(1)(A)]
- Medicare Part D:
  - Part D negotiated prices used for payment will be no greater than the maximum fair price [1198(b)(1)(D)]
  - For 2026 and thereafter, Part D prescription drug plans must include each Part D drug that is a selected drug and for which a maximum fair price is in effect [1198(b)(1)(E)]
- Medicaid Drug Rebate Program:
  - The maximum fair price is included in Best Price [1198(b)(2)]
  - The maximum fair price is excluded from AMP [1198(b)(3)]

## Penalties and Enforcement

The Secretary is required to monitor manufacturer compliance and establish a mechanism for reporting violations [1196(b)]

Penalties include:

- If a manufacturer charges more than the maximum fair price, a civil monetary penalty equal to 10 times the amount of the overcharge will apply [1197(a)]

- Failure to comply with the agreement to negotiate, and to provide information, will give rise to a civil monetary penalty of \$1 million for each day of violation [1197(b)]
- Knowing submission of false information in connection with the small biotech exception from negotiation eligible drugs will result in a \$100 million civil monetary penalty for each item of false information [1197(c)]

## **Excise Tax**

In addition to the civil monetary penalties associated with entry into the agreement to negotiate, manufacturers may also become subject to an excise tax:

- Failure to enter into the agreement to negotiate, to provide the required information to the Secretary, or to accept CMS's final maximum fair price offer will trigger an excise tax that will increase in increments if the non-compliance is prolonged [IRA 11003]
- The excise tax does not apply if the manufacturer has terminated "all applicable agreements" and none of the manufacturer's drugs are covered by a coverage gap discount program agreement or the IRA's replacement discount program agreement [IRA 11003]
- "Applicable agreements" include the coverage gap discount agreement, the IRA's replacement discount program agreement, and the Medicaid National Drug Rebate Agreement [IRA 11003]

# Medicare Part B Inflation Rebates

A rebate will be due on single-source drugs and biologicals with Part B payment rate increases that outpace inflation, beginning with Q1 2023. The rebate is only due on Part B units, not on commercial units.

## Drugs Subject to Rebate

The rebate is due with respect to a single source drug or biological (as defined at 1847A(c)(6)(D)), including a biosimilar. [1847A(i)(2)(A)]

Exceptions:

- Qualifying biosimilars, within a five-year period [1847A(i)(2)(A)]
  - a biosimilar with an ASP for the quarter that is not greater than the ASP for the reference drug [1847A(b)(8)(B)(iii)]
    - The five-year period for a biosimilar for which payment was made as of September 30, 2022, begins on October 1, 2022, and for drugs for which payment was first made between October 1, 2022, and December 31, 2027, begins on the first day of the calendar quarter when payment was first made [1847A(b)(8)(B)(ii)]
- Low-cost products — if the Secretary determines that the average total allowed charges for a year per individual using the product are less than \$100 [1847A(i)(2)(A)(i)]
  - In subsequent years, the \$100 amount will be adjusted for inflation by reference to CPI-U [1847A(i)(2)(B)]
- Vaccines [1847A(i)(2)(A)(ii)]

## Rebate Process and Timing of Initial Rebate

The rebate process will begin when the Secretary provides the following information to the manufacturer for each rebatable drug: [1847A(i)(1)(A)]

- Total units for the billing and payment code for the quarter
- Amount by which the current payment rate exceeds the inflation-adjusted baseline payment rate
- Rebate amount

Timeline:

- The Secretary will provide the information no later than six months after the end of each calendar quarter
- The manufacturer will pay the rebate no later than 30 days after receiving the information from the Secretary [1847A(i)(1)(B)]

When the rebate is first due:

- For drugs FDA approved before December 1, 2020:
  - The first quarter for which information must be provided by the Secretary, and for which a rebate is due: Q1 2023 [1847A(i)(1)(A), (i)(1)(B)]
- For drugs FDA approved on or after December 1, 2020:
  - The first quarter for which information must be provided by the Secretary, and for which a rebate is due: The later of Q1 2023 or the sixth full calendar quarter after the drug is first marketed [1847A(i)(4)(B)]
- The Secretary may delay providing the required information for calendar quarters in 2023 and 2024 until no later than September 30, 2025 [1847A(i)(1)(C)]

## Rebate Formula

Formula:

- The total number of units for the billing and payment code (i.e., Part B units), subject to exclusions noted below, multiplied by
- The amount, if any, by which the Part B payment rate for the quarter exceeds the inflation-adjusted benchmark quarter payment rate [1847A(i)(3)(A)]

- The inflation-adjusted benchmark quarter payment rate is derived by increasing the Part B payment rate for the benchmark quarter by the percentage by which rebate quarter CPI-U exceeds the benchmark quarter CPI-U [1847A(i)(3)(C)]
- Excluded units: [1847A(i)(3)(B)]
  - Units discounted under the 340B drug pricing program
  - Units subject to a Medicaid rebate
  - Units that are packaged and not separately payable

### **Benchmark Definitions**

- For drugs first approved before December 1, 2020
  - Benchmark quarter: Q3 2021 [1847A(i)(3)(D)]
  - Benchmark quarter CPI-U: For January 2021 [1847A(i)(3)(E)]
  - Rebate quarter CPI-U: Greater of benchmark quarter CPI-U and the CPI-U for the first month in the calendar quarter that is two calendar quarters prior to the rebate quarter [1847A(i)(3)(F)]
- For drugs first approved on or after December 1, 2020
  - Benchmark quarter: Third full calendar quarter after the drug is first marketed [1847A(i)(4)(A)]
  - Benchmark quarter CPI-U: For first month of the first full calendar quarter after the drug is first marketed [1847A(i)(4)(A)]
  - Rebate quarter CPI-U: Greater of benchmark quarter CPI-U and the CPI-U for the first month in the calendar quarter that is two calendar quarters prior to the rebate quarter [1847A(i)(3)(F)]

- For selected drugs (i.e., drugs subject to a maximum fair price) that have exited selected-drug status
  - Benchmark quarter: Q1 of the last price applicability period (i.e., the last year that the drug was subject to a maximum fair price) [1847A(i)(4)(C)]
  - Benchmark quarter CPI-U: For July of the year preceding the last price applicability period [1847A(i)(4)(C)]
  - Rebate quarter CPI-U: Greater of benchmark quarter CPI-U and the CPI-U for the first month in the calendar quarter that is two calendar quarters prior to the rebate quarter [1847A(i)(3)(F)]

Reduction or waiver: The Secretary will reduce or waive the rebate due with respect to:

- A product that is in shortage and on the shortage list published by FDA [1847A(i)(3)(G)(i)]
- A biosimilar, if the Secretary determines there is a severe supply chain disruption [1847A(i)(3)(G)(ii)]

## **Coinsurance and Payment Amounts**

Application to beneficiary coinsurance: For a Part B rebatable drug furnished on or after April 1, 2023:

- In all quarters when the rebate is triggered, any Part B coinsurance will be equal to 20% of the inflation-adjusted benchmark quarter payment rate [1847A(i)(5)]

Part B payment amount: For a Part B rebatable drug furnished on or after April 1, 2023

- In all quarters when the rebate is triggered, the Part B payment amount will be calculated by deducting the amount of coinsurance (calculated as 20% of the inflation-adjusted benchmark quarter payment amount) from the otherwise applicable payment amount (e.g., 106% of ASP) [1833(a)(1)(EE)]

## Penalties and Enforcement

Civil monetary penalties:

- Failure to pay the rebate will result in a civil monetary penalty equal to at least 125% of the rebate amount [1847A(i)(7)]

Limitation of administrative or judicial review: No administrative or judicial review is available as to: [1847A(i)(8)]

- Determination of units
- Determination of whether a drug is a rebatable drug
- Calculation of the rebate amount
- Computation of coinsurance
- Computation of Part B payment amounts

## Price Reporting

The rebate amount is excluded from ASP and Medicaid Drug Rebate Program price reporting:

- ASP — Part B inflation rebates are excluded from ASP [1847A(c)(3)]
- Medicaid Drug Rebate Program:
  - Best Price — Part B inflation rebates are excluded from Best Price [1927(c)(1)(C)(ii)(I)]
  - AMP — Part B inflation rebates are excluded from AMP [1927(k)(1)(B)(i)(VII)]



# Medicare Part D Inflation Rebates

A rebate will be due on drugs and biologicals with AMP increases that outpace inflation, beginning with the 12 months beginning on October 1, 2022. The rebate is only due on Part D units, not on commercial units.

For 2022, 2023, and 2024, the Secretary will implement the rebate program by program instruction or other forms of program guidance. [1860D-14B(h)]

## Drugs Subject to Rebate

The rebate is due with respect to a drug or biological covered under Part D [1860D-14B(g)(1)(A)] that is one of the following: [1860D-14B(g)(1)(C)]

- NDA approved
- BLA approved
- ANDA approved, and all of the following apply:
  - The reference listed drug, including any authorized generic, is not being marketed
  - No other drug is marketed that is therapeutically equivalent
  - The manufacturer is not a “first applicant” during the “180-day exclusivity period,” as defined in Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act
  - The manufacturer is not a “first approved applicant” for a competitive generic therapy, as defined in Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act

Exceptions:

- Low-cost products — if the Secretary determines that the average annual total cost under Part D for the rebate period per individual using the product is less than \$100 [1860D-14B(g)(1)(B)(i)]
  - In subsequent years, the \$100 amount will be adjusted for inflation by reference to CPI-U [1860D-14B(g)(1)(B)(i)]

**Rebate Process and Timing of Initial Rebate**

The rebate process will begin when the Secretary provides the following information to the manufacturer for each rebatable drug: [1860D-14B(a)(1)]

- Amount by which the current annual manufacturer price exceeds the inflation-adjusted benchmark period manufacturer price
- Rebate amount

Timeline:

- The Secretary will provide the information no later than nine months after each applicable period
- The applicable period will be 12 months beginning on October 1 of each year, with the initial applicable period beginning on October 1, 2022 [1860D-14B(g)(7)]
- The manufacturer will pay the rebate no later than 30 days after receiving the information from the Secretary [1860D-14B(a)(2)]

When the rebate is first due:

- The initial applicable period for which a rebate is due will run from October 1, 2022, through September 30, 2023, and the Secretary will provide the required information no later than nine months after the end of the applicable period, before the end of June 2024; [1860D-14B(a)(1)] the rebate will be due 30 days later, before the end of July 2024 [1860D-14B(a)(2)]
- The Secretary may delay providing the required information for applicable periods that begin October 1, 2022, and October 1, 2023, until no later than December 31, 2025 [1860D-14B(a)(3)]

## Rebate Formula

Formula:

- The total units of the drug dispensed under Part D during the applicable period, multiplied by
- The amount, if any, by which the annual manufacturer price for the applicable period exceeds the inflation-adjusted benchmark period manufacturer price [1860D-14B(b)(1)(A)]
  - The inflation-adjusted benchmark period manufacturer price is derived by increasing the benchmark period manufacturer price by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U [1860D-14B(b)(3)]
- Excluded units:
  - Beginning with the 2026 plan year, units discounted under the 340B drug pricing program [1860D-14B(b)(1)(B)]

The annual manufacturer price [1860D-14B(b)(2)] or benchmark period manufacturer price [1860D-14B(b)(4)] is calculated as:

- AMP for each calendar quarter in the period, multiplied by
- AMP units for the quarter, divided by AMP units for the period
  - AMP is defined by reference to the Medicaid Drug Rebate Program definition at 1927(k)(1) [1860D-14B(g)(6)]

## Benchmark Definitions

- For drugs first approved on or before October 1, 2021:
  - Benchmark period: January 1, 2021, through September 30, 2021 [1860D-14B(g)(3)]
  - Benchmark period CPI-U: For January 2021 [1860D-14B(g)(4)]
  - Applicable period CPI-U: For the first month of the applicable period [1860D-14B(g)(5)]

- For drugs first approved after October 1, 2021:
  - Benchmark period: First calendar year after the drug is first marketed [1860D- 14B(b)(5)(A)]
  - Benchmark period CPI-U: For January of the first calendar year after the drug is first marketed [1860D-14B(b)(5)(A)]
  - Applicable period CPI-U: For the first month of the applicable period [1860D-14B(g)(5)]
- For selected drugs (i.e., drugs subject to a maximum fair price) that have exited selected-drug status
  - Benchmark period: Last year the drug was a selected drug [1860D-14B(b)(5)(C)]
  - Benchmark period CPI-U: For January of the last year the drug was a selected drug [1860D-14B(b)(5)(C)]
  - Applicable period CPI-U: For the first month of the applicable period [1860D-14B(g)(5)]

Reduction or waiver: The Secretary will reduce or waive the rebate due with respect to:

- A drug that is in shortage and on the shortage list published by FDA [1860D-14B(b)(1)(C)(i)]
- A generic, if the Secretary determines that without reduction or waiver, the drug is likely to be in shortage [1860D-14B(b)(1)(C)(iii)]
- A generic or biosimilar, if the Secretary determines there is a severe supply chain disruption [1860D-14B(b)(1)(C)(ii)]

Different rebate formula for line extensions:

- The Secretary will establish a rebate formula, consistent with the line extension alternative formula for the Medicaid rebate under 1927(c)(2)(C) with respect to the Medicaid Drug Rebate Program [1860D-14B(b)(5)(B)(i)]

- Line extension is defined as a new formulation, such as an extended release formulation, not including abuse-deterrent formulations, which is the same definition as under the Medicaid Drug Rebate Program [1860D-14B(b)(5)(B)(ii)]

## Information and Reconciliation

To carry out the rebate program, the Secretary will use information submitted by the following: [1860D- 14B(d)]

- Manufacturers pursuant to 1927(b)(3), which includes AMP and Best Price
- States under 1927(b)(2)(A), which includes the number of units the state Medicaid program paid for
- Part D plan sponsors of prescription drug plans and MA organizations offering MA-PD plans

Unit number reconciliation:

- The Secretary will provide for a method and process under which, if a Part D plan sponsor or MA organization offering an MA-PD plan submits revisions to the number of units dispensed, the Secretary will determine adjustments, if any, to the rebate calculation and manufacturer rebate amount, and will reconcile over- or underpayments [1860D-14B(b)(6)]

Notably, there is no mechanism for the Secretary to address AMP restatements by manufacturers.

## Penalties and Enforcement

Civil monetary penalties:

- Failure to pay the rebate will result in a civil monetary penalty equal to 125% of the rebate amount [1860D-14B(e)]

Limitation of administrative or judicial review: No administrative or judicial review is available as to: [1860D-14B(f)]

- Determination of units
- Determination of whether a drug is a rebatable drug
- Calculation of the rebate amount

## Price Reporting

The rebate amount is excluded from ASP and Medicaid Drug Rebate Program price reporting:

- ASP — Part D inflation rebates are excluded from ASP [1847A(c)(3)]
- Medicaid Drug Rebate Program:
  - Best Price — Part D inflation rebates are excluded from Best Price [1927(c)(1)(C)(ii)(I)]
  - AMP — Part D inflation rebates are excluded from AMP [1927(k)(1)(B)(i)(VIII)]

# Medicare Part D Benefit Redesign

The Act will change the Part D benefit in the following ways.

- Patient out-of-pocket spending will be capped at \$2,000, starting in 2025
- A \$35 limit will apply to the copayment for insulin covered under Part D or furnished through durable medical equipment under Part B, with no deductible
- Starting in 2025, Medicare reinsurance will be reduced, with greater costs borne by Part D plans and manufacturers
- The coverage gap will be eliminated, resulting in three phases: The deductible phase, the initial coverage phase, and the catastrophic coverage phase
- Under a new manufacturer discount program (described below), effectuated through an agreement with the Secretary, the manufacturer will provide a 10% discount in the initial coverage phase and a 20% discount in the catastrophic phase on innovator drugs

Below are key provisions of the manufacturer discount program.

## Implementation Timeline

The discount program will be effectuated through an agreement between the manufacturer and the Secretary. The agreement will require the manufacturer to provide discounted prices for applicable drugs dispensed to applicable beneficiaries after January 1, 2025.

[1860D-14C](b)(1)(A)]

Timeline:

- For 2025, the manufacturer will enter into the agreement no later than March 1, 2024, in order for the agreement to be in effect from January 1, 2025, until December 31, 2025
- [1860D- 14C(b)(1)(C)(i)]

- For 2026 and subsequent years — The manufacturer will enter into the agreement no later than a calendar quarter or semi-annual deadline to be established by the Secretary [1860D- 14C(b)(1)(C)(ii)]

For 2024, 2025, and 2026, the Secretary will implement the discount program by program instruction or other forms of program guidance. [1860D-14D(f)]

## **Drugs Subject to the Discount**

The discount program will apply to:

- Drugs that are NDA or BLA approved [1860D-14C(g)(2)(A)(i)], and
- Drugs that are covered by Part D prescription drug plan or MA-PD plan [1860D-14C(g)(2)(A)(ii)]

ANDA-approved drugs will not be subject to the discount. Drugs that are selected drugs (i.e., subject to a maximum fair price) under Section 1192(c) during a price applicability period will also not be subject to the discount. [1860D-14C(g)(2)(B)]

## **Beneficiaries Entitled to Discounted Drugs**

Applicable beneficiaries will be entitled to discounted drugs. Such a beneficiary is an individual who, on the date of dispensing: [1860D-14C(g)(1)]

- Is enrolled in a prescription drug plan or an MA-PD plan
- Is not enrolled in a qualified retiree prescription drug plan
  - The term qualified retiree prescription drug plan generally refers to employment-based retiree health coverage and is defined in 1860D-22(a)(2) [1860D-14C(g)(7)]
- Has incurred costs for covered Part D drugs in the year that exceed the annual deductible specified in 1860D-2(b)(1)

## **Definition of Discounted Price**

The discounted price will result in a 10% discount in the initial coverage phase and a 20% discount in the catastrophic phase:



- For beneficiaries who have not reached the out-of-pocket threshold, the price will be equal to 90% of the negotiated price [1860D-14C(g)(4)(A)(i)]
- For beneficiaries who have reached the out-of-pocket threshold, the price will be equal to 80% of the negotiated price [1860D-14C(g)(4)(A)(ii)]
  - The negotiated price is as defined in 1860D-2(d)(1)(B) and includes any dispensing fee or vaccine administration fee [1860D-14C(g)(6)]

### **Discounted Price Phase-In for Drugs Dispensed to LIS Beneficiaries**

For drugs dispensed to Low-Income Subsidy (LIS) beneficiaries, the discount is phased in over time before reaching the 80% and 90% levels.

The phase-in is available:

- For drugs that are marketed as of the date of enactment of the Act (i.e., August 16, 2022) [1860D-14C(g)(4)(B)(i)]
- For drugs dispensed to a beneficiary who is eligible for LIS subsidy under 1860D-14(a)(3) [1860D-14C(g)(4)(B)(i)]
- If the manufacturer: [1860D-14C(g)(4)(B)(ii)]
  - Had a coverage gap discount agreement in place in 2021;
  - Total expenditure in 2021 for drugs under that agreement represented less than 1% of total Part D expenditures; and
  - Total expenditure in 2021 for the manufacturer's drugs that are single-source drugs or biologicals under Part B represented less than 1% of total Part B drug expenditures
    - Total Part D expenditures include the total gross covered prescription drug costs defined in 1860D-15(b)(3) [1860D-14C(g)(4)(D)]
    - Total Part B expenditures exclude expenditures for a product that is bundled or packaged into the payment rate for another service [1860D-14C(g)(4)(D)]

Limitations on manufacturer eligibility:

- Persons treated as a single employer under Section 52(a) or (b) of the Internal Revenue Code of 1986 are treated as one manufacturer [1860D-14C(g)(4)(B)(ii)(II)(bb)]
- The manufacturer's drugs are no longer eligible for the phase-in if the manufacturer is acquired after 2021 by another manufacturer that does not qualify under the foregoing criteria, effective at the beginning of the plan year immediately following the acquisition, or if acquired before 2025, effective January 1, 2025 [1860D-14C(g)(4)(B)(ii)(III)]

If the conditions are met, then the discounted price will be equal to the following percentage of the negotiated price for the drug: [1860D-14C(g)(4)(B)(i)]

- For beneficiaries who have not reached the out-of-pocket threshold: [1860D-14C(g)(4)(B)(iii)(I)]
  - 2025, 99%;
  - 2026, 98%;
  - 2027, 95%;
  - 2028, 92%; and
  - 2029 and each subsequent year, 90%
- For beneficiaries who have reached the out-of-pocket threshold: [1860D-14C(g)(4)(B)(iii)(II)]
  - 2025, 99%;
  - 2026, 98%;
  - 2027, 95%;
  - 2028, 92%;
  - 2029, 90%;
  - 2030, 85%; and
  - 2031 and each subsequent year, 80%

## Discounted Price Phase-In for Drugs of Small Manufacturers

For drugs of manufacturers that qualify as “small manufacturers,” the discount is phased in over time before reaching the 80% and 90% levels.

Importantly, while the small manufacturer phase-in is similar to the small biotech exception from negotiation, the two provisions operate differently and have different eligibility criteria.

The phase-in is available:

- For drugs that are marketed as of the date of enactment of the Act (i.e., August 16, 2022) [1860D-14C(g)(4)(C)(i)]
- If the manufacturer: [1860D-14C(g)(4)(C)(ii)(I)(aa)]
  - Had a coverage gap discount agreement in place in 2021;
  - Total expenditure in 2021 for drugs under that agreement represented less than 1% of total Part D expenditures;
  - Total expenditure in 2021 for the manufacturer’s drugs that are single-source drugs or biologicals under Part B represented less than 1% of total Part B drug expenditures; and
  - Total Part D expenditure in 2021 for any of the manufacturer’s drugs under that agreement represents at least 80% of total Part D expenditures of that manufacturer [1860D-14C(g)(4)(C)(ii)(I)(bb)]
    - Total Part D expenditures include the total gross covered prescription drug costs defined in 1860D-15(b)(3) [1860D-14C(g)(4)(D)]
    - Total Part B expenditures exclude expenditures for a product that is bundled or packaged into the payment rate for another service [1860D-14C(g)(4)(D)]

Limitations on manufacturer eligibility:

- Persons treated as a single employer under Section 52(a) or (b) of the Internal Revenue Code of 1986 are treated as one manufacturer [1860D-14C(g)(4)(C)(ii)(II)(bb)]

- The manufacturer is no longer eligible for the phase-in if it is acquired after 2021 by another manufacturer that does not qualify under the foregoing criteria, effective at the beginning of the plan year immediately following the acquisition, or if acquired before 2025, effective January 1, 2025 [1860D-14C(g)(4)(C)(ii)(III)]

If the conditions are met, then the discounted price will be equal to the following percentage of the negotiated price for the drug: [1860D-14C(g)(4)(C)(i)]

- For beneficiaries who have not reached the out-of-pocket threshold: [1860D-14C(g)(4)(C)(iii)(I)]
  - 2025, 99%;
  - 2026, 98%;
  - 2027, 95%;
  - 2028, 92%; and
  - 2029 and each subsequent year, 90%
- For beneficiaries who have reached the out-of-pocket threshold: [1860D-14C(g)(4)(C)(iii)(II)]
  - 2025, 99%;
  - 2026, 98%;
  - 2027, 95%;
  - 2028, 92%;
  - 2029, 90%;
  - 2030, 85%; and
  - 2031 and each subsequent year, 80%

### **Duties of the Secretary in Administering the Program**

As part of administering the program, the Secretary is obligated to: [1860D-14C(c)(1)]

- Determine the amount of the discounted price of the drug [1860D-14C(c)(1)(A)]

- Establish procedures so that the pharmacy or mail order service is reimbursed for the difference between the negotiated price of the drug and the discounted price of the drug no later than: [1860D-14C(c)(1)(B)]
  - For claims for reimbursement submitted electronically, 14 days after dispensing [1860D- 14C(g)(3)(A)]
  - For claims for reimbursement submitted otherwise, 30 days after dispensing [1860D- 14C(g)(3)(B)]
- Establish procedures so that the discounted price is applied before any coverage or financial assistance under other health plans [1860D-14C(c)(1)(C)]
- Provide a dispute resolution mechanism to address disagreements between manufacturers, prescription drug plans and MA-PD plans, and the Secretary [1860D-14C(c)(1)(D)]

The Secretary may collect appropriate data from prescription drug plans and MA-PD plans in a timeframe that allows for discounted prices to be provided for drugs. [1860D-14C(c)(3)]

## **Mechanics of the Agreement**

Term and termination:

- The initial term of the agreement is 12 months; it will automatically renew for periods of not less than one year [1860D-14C(b)(4)(A)]
- An agreement will take effect at the start of a calendar quarter or another date specified by the Secretary [1860D-14C(b)(5)]

Termination:

- The Secretary may terminate the agreement for a knowing and willful violation by the manufacturer or for other good cause, and the manufacturer may request a hearing prior to effectiveness of the termination [1860D-14C(b)(4)(B)(i)]
- The manufacturer may terminate the agreement for any reason [1860D-14C(b)(4)(B)(ii)]
  - If terminated before January 31, termination will be effective as of the day after the plan year

- If terminated after January 31, termination will be effective as of the day after the succeeding plan year

## **Compliance and Enforcement**

The manufacturer must collect and have available appropriate data, as determined by the Secretary, to demonstrate compliance with discount program requirements. [1860D-14C(b)(2)]

The Secretary will monitor compliance by manufacturers with the term of the agreement. [1860D- 14C(c)(2)]

Penalties: [1860D-14C(e)(1)]

- Failure by the manufacturer to provide discounted prices will result in a civil monetary penalty for each failure equal to 25% of the amount the manufacturer would have paid in discounts
- The manufacturer must also pay the discounts it failed to provide

## **Price Reporting**

Discounted prices under this program are excluded from price reporting under the Medicaid Drug Rebate Program:

- Best Price [1927(c)(1)(C)(i)(VI)]
- AMP [1927(k)(1)(B)(i)(V)]

# Appendix: U.S. Code Cross-Reference Table

The following table shows key sections of the Social Security Act that were amended or added by the Inflation Reduction Act of 2022, as well as the corresponding section numbers in Title 42 of the United States Code.

<b>Key Social Security Act Sections Amended by the Inflation Reduction Act of 2022</b>	<b>Title 42 U.S. Code Section</b>
1191	1320f
1192	1320f-1
1193	1320f-2
1194	1320f-3
1195	1320f-4
1196	1320f-5
1197	1320f-6
1198	1320f-7
1860D-14B	1395w-114b
1860D-14C	1395w-114c
1847A	1395w-3a
1927	1396r-8

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