

Health-Related Provisions of Inflation Reduction Act of 2022 Summary

On August 7, 2022, the Senate passed an amended version of H.R. 5376, Inflation Reduction Act of 2022 (IRA). The House passed this version on August 12, 2022, which was signed by President Biden on August 16, 2022 (P.L. 117-169). This document summarizes the health-related provisions of the new law.

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Subtitle B—Prescription Drug Pricing Reform

PART 1—LOWERING PRICES THROUGH DRUG NEGOTIATION

Sec. 11001. Providing for Lower Prices for Certain High-Priced Single Source Drugs.

Section 11001(a) of the IRA adds a new Part E to Title XI of the Social Security Act (containing new sections 1191 through 1198) that establishes the Drug Price Negotiation Program.

“Sec. 1191. Establishment of Program

The Secretary of Health and Human Services (HHS) must establish a Drug Price Negotiation Program (or “Program”) to reduce Federal and out-of-pocket spending for prescription drugs under Medicare. The Secretary must publish a list of selected drugs, enter into agreements with manufacturers of those selected drugs, and negotiate and renegotiate maximum fair prices (MFP) for each selected drug. (The Secretary must also carry out administrative responsibilities with respect to the Program.) Several key terms are defined in this section as follows:

Initial Price Applicability Year means a year, beginning with 2026.

Price Applicability Period means, for a qualifying single source drug, the period that begins with the initial price applicability year for which a drug is a selected drug and ends with the last year the drug is a selected drug.

Selected Drug Publication Date means, for each initial price applicability year, February 1 of the year that begins 2 years before the initial price applicability year. For example, February 1, 2025 would be the selected drug publication date for the 2027 initial price applicability year. However, as shown in Table 1, the timelines are different for the first initial price applicability year of 2026, in accordance with section 1191(d).

Negotiation Period means, for a selected drug, the period that:

(1) begins on the earlier of (i) the date the manufacturer of the drug and the Secretary enter into an agreement under section 1193 for the drug; or (ii) February 28 following the selected drug publication date for the selected drug; and

(2) ends on November 1 of the year that begins two years before the initial price applicability year (i.e., 9 months after the selected drug publication date for the selected drug).

Manufacturer has the same meaning given that term in the Medicare average sales price payment methodology under section 1847A(c)(6)(A).

Maximum Fair Price means the price negotiated and updated under these provisions for a selected drug during the price applicability period.

Reference Product is defined under the current Public Health Service Act (§351(i)).

Table 1. Timing and Deadlines in Drug Price Negotiation Program

Provision	Initial Price Applicability Year (IPAY)		
	2026	2027	General rule for 2027+
Data for determining negotiation-eligible drugs (50 qualifying single-source drugs with highest Medicare expenditures). §1192(d)(1)	6/1/22-5/31/23	Most recent 12 months ending no later than 10/31/24	Most recent 12 months ending no later than 10/31 of year prior to selected drug publication date
Data for ranking negotiation-eligible drugs based on total Medicare expenditures. §1192(b)(1)	6/1/22-5/31/23	Most recent 12 months ending no later than 10/31/24	Most recent 12 months ending no later than 10/31 of year prior to selected drug publication date
Selected drug publication date. §1191(b)(3)	9/1/23	2/1/2025	February 1 of the year 2 years prior to IPAY
Deadline for Secretary to enter into manufacturer agreement. §1193(a)	10/1/23	2/28/25	February 28 following selected drug publication date
Negotiation period start. §1191(b)(4)(A)	10/1/23	2/28/25	February 28 following selected drug publication date
<ul style="list-style-type: none"> Deadline for manufacturer to submit required information. §1194(b)(2)(A) 	10/2/23	3/1/25	March 1 of the year of the selected drug publication date
<ul style="list-style-type: none"> Deadline for initial offer by the Secretary containing proposed maximum fair price and a concise justification. §1194(b)(2)(B) 	2/1/24	6/1/25	June 1 following the selected drug publication date
<ul style="list-style-type: none"> Deadline for manufacturer response to initial offer. §1194(b)(2)(C) 	Not later than 30 days after Secretary’s initial offer		
Negotiation period end. §§1191(b)(4)(B), 1194(b)(2)(E)	8/1/24	11/1/25*	November 1 of the year 2 years prior to IPAY*
Publication by Secretary of maximum fair prices. §1195(a)(1)	9/1/24	11/30/25	November 30 of the year 2 years prior to IPAY
Publication by Secretary of explanation of maximum fair prices. §1195(a)(2)	3/1/25	3/1/26	March 1 of the year prior to IPAY
Beginning effective date of maximum fair prices	1/1/26	1/1/27	First day of IPAY
<p>Source: HPA analysis of §11001(a) of the IRA, creating new §§1192-1198 of the Social Security Act. Notes: For initial price applicability years 2026 and 2027, the provisions apply to only Part D drugs. Beginning in 2028, the provisions also apply to Part B drugs. For 2027 and later, the negotiation begins the sooner of the date listed or the date on which the Secretary and manufacturer enter into an agreement under §1193. Statutory references refer to general timing; however, timing for IPAY 2026 is specified in §1191(d). * Section 1191(b)(4)(B) states that the negotiation period ends <u>on</u> November 1 of the year that is 2 years prior to the IPAY. However, 1194(b)(2)(E) states that the negotiation period must end <u>prior to</u> November 1 following the selected drug publication date.</p>			

Maximum Fair Price (MFP) Eligible Individual means:

(1) for selected drugs furnished at a pharmacy, through mail order, or by another dispenser, an individual enrolled in a Medicare Part D prescription drug plan (PDP) or enrolled in a Medicare Advantage Prescription Drug plan (MA-PD plan); and

(2) for selected drugs administered by a hospital, physician or other provider of services or supplier, Medicare Part B beneficiaries (including enrollees of Medicare Advantage plans) to the extent the selected drug is covered under such parts.

Thus, these negotiation provisions will affect Medicare beneficiaries' Part B drugs (including those obtained through Medicare Advantage plans) and Part D drugs (including those obtained through Medicare Advantage plans).

Total Expenditures:

- For Part D, includes total gross covered prescription drug costs (defined in current §1860D-15(b)(3), which does not include administrative costs but includes costs directly related to dispensing); and
- For Part B, excludes expenditures for drugs and biologicals that are bundled or packaged into the payment for another service.

Unit means the lowest identifiable amount of a drug or biological that is dispensed or furnished.

“Sec. 1192. Selection of Negotiation-Eligible Drugs as Selected Drugs

Each year, the Secretary must identify a certain number of brand-name drugs that are found to lack price competition and that are high spend Medicare drugs that will be subject to the Program's negotiation process. In general, the Secretary's annual identification of these drugs occurs in the following order, with more detailed definitions below:

- Identify **qualifying single source drugs** (§1192(e));
- From qualifying single source drugs, identify the **negotiation-eligible drugs**, which are (§1192(d)):
 - For initial price applicability year 2026 onward, the 50 qualifying single source drugs with the highest Medicare expenditures under Part D; and
 - For initial price applicability year 2028 onward, the 50 qualifying single source drugs with the highest Medicare expenditures under Part B.
- From negotiation-eligible drugs, **selected drugs** published on the Secretary's list in an initial price applicability year that will be subject to the Program's negotiation process (§1192(c)). Selected drugs are the negotiation-eligible drugs with the highest rankings in terms of total Medicare Part D and/or Part B expenditures (§1192(b)(1)(B)). The number of selected drugs for each initial price applicability year is specified as follows (§1192(a)):
 - For 2026, up to 10 Part D drugs;
 - For 2027, up to an additional 15 Part D drugs;
 - For 2028, up to an additional 15 Part D or Part B drugs; and
 - For 2029 and subsequent years, up to an additional 20 Part D or Part B drugs.

Qualifying Single Source Drug means:

- An FDA-approved drug product¹ that is not the listed drug for any generic drug and for which at least 7 years have elapsed since the date of its approval; or
- A licensed biological product² that is not the reference product for any biosimilar and for which at least 11 years have elapsed since the date of that license.

The practical effect of this definition means that single source drugs will have at least 9 years before being subject to price negotiation and that biologicals will have at least 13 years before being subject to negotiation.

There is a special rule for authorized generic drugs³ under which the authorized generic drug and the listed drug (or reference product) are treated as the same qualifying single source drug for purposes of the Program. Authorized generic drugs are generic drugs that are produced (or authorized to be produced) by the same manufacturer as the brand-name drug, often beginning during the brand-name drug's period of exclusivity (i.e., before other manufacturers can produce a generic version). If the drug is only available as the brand-name and authorized generic drug, then it is treated as the same qualifying single source drug.

The term qualifying single source drug excludes plasma-derived biological products, certain orphan drugs (those for which the only approved indication(s) is to treat only one rare disease or condition), and low spend Medicare drugs. Low spend Medicare drugs are those with total expenditures under Medicare Part B and Part D of less than the following:

- For initial price applicability year 2026, \$200 million;
- For initial price applicability year 2027, the prior-year amount (\$200 million) indexed for inflation;⁴ and
- For subsequent years, the prior-year amount indexed for inflation.⁵

The Medicare Part B and Part D expenditure data for determining low spend Medicare drugs are the same as the first row in Table 1, as follows:

- For initial price applicability year 2026, expenditure data from June 1, 2022 to May 31, 2023;
- For initial price applicability year 2027, expenditure data from the most recent 12 months ending no later than October 31, 2024; and
- For subsequent years, expenditure data from the most recent 12 months ending no later than October 31 of the year prior to the year of the drug publication date.

¹ Approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act.

² Licensed under section 351(a) of Public Health Service Act (PHSA).

³ An authorized generic drug is one that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

⁴ Using CPI-U from June 1, 2023 to September 30, 2024.

⁵ Using CPI-U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date.

Negotiation-eligible Drug generally refers to a **qualifying single source drug** that is either:

- Among the 50 covered part D drugs with the highest total expenditures under Medicare Part D, beginning with the initial price applicability year of 2026; or
- Among the 50 Part B drugs with the highest total expenditures under Medicare Part B, beginning with the initial price applicability year of 2028.

As shown above in the first row of Table 1, to calculate Part B and Part D total expenditures, data are generally for the 12-month period that ends before October 31 of the year prior to the selected drug publication date for the following year.⁶ Data must be aggregated across dosage forms and strengths; the determination may not be made on the specific formulation or package size or type of the drug.

In determining which drugs are determined negotiation-eligible drugs for a year, the Secretary may not consider or count any drug that is already a selected drug.

Small biotech drugs are excluded from the definition of negotiation-eligible drugs for the first three years. For initial price applicability years of 2026, 2027 and 2028, Part B and Part D qualifying sole source drugs are not considered to be negotiation-eligible drugs if they meet the following criteria:

- Expenditures for the drug in 2021 do not exceed 1 percent of the total expenditures under Part B or Part D (respectively) for all Part B drugs or covered Part D drugs (respectively); and
- Expenditures for the drug in 2021 equal at least 80 percent of the total expenditures for all Part B drugs or all covered Part D drugs (respectively) of the manufacturer.

This exception does not apply to new formulations of the qualifying single source drug. There are special aggregation rules and acquisition rules for manufacturers in applying this exception.

Selected Drugs. From the drugs identified as negotiation-eligible drugs for each initial price applicability year, the Secretary must do the following:

- Rank (from high to low) the combined list of negotiation-eligible drugs for a year by total expenditures under Medicare Parts B and D; and
- Select the drugs with the highest rankings. However, because Part B drugs are excluded from the Program during the 2026 and 2027 initial price applicability years, the ranking for those years only applies with respect to total expenditures for Part D drugs.

As previously stated, the number of selected drugs for each initial price applicability year is as follows:

- For 2026, up to 10 Part D drugs;
- For 2027, up to 15 additional Part D drugs;
- For 2028, up to 15 additional Part D or Part B drugs; and
- For 2029 and subsequent years, up to 20 additional Part D or Part B drugs.

⁶ The exception is for the initial price applicability year of 2026, for which the data must be from the period of June 1, 2022 to May 31, 2023.

Selected drugs are subject to negotiation during the negotiation period for the initial price applicability year (and to renegotiation during subsequent years during the price applicability period), with the following exception. The manufacturer of a selected drug that becomes subject to competition before or during the negotiation period applicable to the selected drug for an initial price applicability year will not be required to negotiate prices under the Program for that selected drug. Nonetheless, the drug will continue to be considered a selected drug under the Program for purposes of the number of negotiation-eligible drugs published on the list for that initial price applicability year.

A drug is no longer considered a selected drug with respect to a year when there is at least one competitor product on the market.

As noted above, in determining which drugs are determined negotiation eligible for an initial price applicability year, the Secretary may not consider or count any drug that is already a selected drug. Thus, a qualifying single source drug that is a selected drug for an initial price applicability year may not be included in the list of negotiation-eligible drugs for another initial price applicability year. The intention appears to be to avoid counting a previously selected drug toward the maximum number of negotiation eligible drugs that may be selected for a subsequent year, thereby increasing over time the number of drugs selected for negotiation under the Program.

“Sec. 1193. Manufacturer Agreements

The Secretary must enter into an agreement with each manufacturer of a selected drug for a price applicability period fairly quickly (i.e., within approximately a month of the selected drug publication date). Each agreement will require the parties to negotiate a maximum fair price (MFP) for the drug during the initial price applicability year under the process established under section 1194. The agreement and its MFP will continue unless the drug is no longer a selected drug (i.e., until there is competition on the market for the selected drug) or if the drug meets criteria for the renegotiation of its MFP under the process established under section 1194(f). Under the agreement, manufacturers must provide access to the MFP for a selected drug to MFP eligible individuals who are MA-PD or Part D plan enrollees at the point-of-sale (i.e., either at the pharmacy, through mail order or other prescribers) and to hospitals, physicians and other providers and suppliers with respect to MFP eligible individuals during the price applicability period.

Manufacturers must submit information on the drug’s non-Federal average manufacturer price (non-FAMP), which is the average price wholesalers pay for drugs distributed to purchasers outside the federal government,⁷ as well as “information that the Secretary requires to carry out the negotiation (or renegotiation process)”.

⁷ At 38 USC 8126(h)(5), the term “non-Federal average manufacturer price” means, with respect to a covered drug and a period of time (as determined by the Secretary [of Veterans Affairs]), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.

Information submitted to the Secretary pursuant to a manufacturer agreement is considered proprietary information and may only be used for purposes of the Program; the Secretary may disclose that information to GAO but only for purposes of carrying out the Program. Manufacturers must comply with requirements imposed by the Secretary.

To prevent duplication with 340B, when the 340B ceiling price is lower than the maximum fair price, the manufacturer is not required to provide the maximum fair price for maximum fair price eligible individuals who are also eligible for the drug through a 340B covered entity. On the other hand, when the maximum fair price is lower than the 340B ceiling price, the manufacturer is required to provide access to the maximum fair price in a nonduplicated amount for maximum fair price eligible individuals who are also eligible for the drug through a 340B covered entity.

“Sec. 1194. Negotiation and Renegotiation Process

As noted above, a manufacturer of a selected drug and the Secretary must negotiate (and renegotiate as applicable) the MFP for the drug during the price applicability period. The Secretary will establish a consistent methodology for those negotiations that aims to achieve the lowest MFP for a selected drug.

Negotiation Process. For the initial price applicability year for a selected drug, the elements of the negotiation are as follows (with timing shown in Table 1 above):

- Manufacturer submission of information. A manufacturer must submit to the Secretary information on the non-FAMP for the drug and year and all other information required by the Secretary to carry out the negotiation process.
- Initial offer by Secretary. The Secretary makes an initial written MFP offer which shall include a concise justification of the following factors used to develop the MFP offer.
- Factors. The Secretary must consider the following factors, as applicable to the drug, for determining offers and counteroffers:
 - Manufacturer-specific data:
 - Research and development costs of the drug and the extent to which those costs have been recouped;
 - Current unit costs of production and distribution;
 - Prior federal financial support;
 - Data on patents; and
 - National sales data
 - Evidence about alternative treatments:
 - The extent to which the drug represents a therapeutic advance as compared to existing alternatives (and their costs);
 - Prescribing information of the drug and therapeutic alternatives;
 - Comparative effectiveness of the drug and therapeutic alternatives (taking into account effects on subpopulations such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations);⁸

⁸ The Secretary may not use evidence on comparative effectiveness in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than an individual who is younger, nondisabled, or not terminally ill.

- The extent to which the drug and therapeutic alternatives address unmet medical needs.
- Manufacturer response to initial offer. The manufacturer has 30 days to respond (either accept or make a counteroffer that must be in writing and be justified also based on the factors above). The Secretary must respond in writing to a counteroffer; except for initial price applicability year 2026, all negotiations must conclude before November 1 of that year.

The Secretary is not permitted to agree to an MFP that exceeds the ceiling or is less than the floor for the selected drug and year involved, as described below.

MFP Ceiling. Price ceilings are based on the lower of what the statute calls the Subparagraph (B) amount and the Subparagraph (C) amount. Those terms are defined as follows:

- Subparagraph (B) amount:
 - For Part D drugs, the sum of the plan specific enrollment weighted amounts for each PDP or MP-PD plan. This is essentially the national average price⁹ paid by all Part D and MA-PD plans taking into account each plan’s enrollment.
 - For Part B drugs or biologicals, the lesser of the volume-weighted average sales price (ASP) and the wholesale acquisition cost (WAC) for the year prior to the selected drug publication date.
- Subparagraph (C) amount is based on the non-FAMP multiplied by one of the following percentages:
 - 75% for “Short-Monopoly Drugs and Vaccines” (i.e., drugs that are neither extended-monopoly drugs nor long-monopoly drugs);
 - 65% for “Extended-Monopoly Drugs” (i.e., drugs that are on the market for at least 12 and less than 16 years—other than vaccines licensed under section 351 of the PHSA and selected drugs before initial price applicability year 2030); and
 - 40% for “Long-Monopoly Drugs” (i.e., drugs that are on the market for more than 16 years—other than vaccines licensed under section 351 of the PHSA).

For 2026, the non-FAMP is based on 2021, increased by CPI-U to the year ending before the selected drug publication date (i.e., 2025). For 2027 and subsequent years, the non-FAMP is the lesser of (i) the non-FAMP for such drug in 2021 increased by CPI-U to the year ending before the selected drug publication date or (ii) the non-FAMP for the drug for the year ending before the selected drug publication date.

Temporary Floor for Small Biotech Drugs. For a small biotech drug for which the first initial price applicability year of a price applicability period is 2029 or 2030, the MFP may not be less than 66 percent of the non-FAMP for the drug in 2021 increased by CPI-U to the year ending before the selected drug publication date. (As described above, small biotech drugs are excluded from the definition of negotiation-eligible drugs altogether for initial price applicability years of 2026, 2027 and 2028.)

⁹ The negotiated price net of all price concessions received by the plan or the pharmacy benefit manager (PBM) on behalf of the plan.

Renegotiation Process. Beginning with 2028, the Secretary must establish a renegotiation process for a renegotiation-eligible drug during the price applicability period for that selected drug. A renegotiation-eligible drug is a selected drug (i) that has a new indication added; (ii) that was not an extended or long-monopoly drug but becomes an extended-monopoly drug; (iii) that becomes a long-monopoly drug, or (iv) for which there is a material change (based on any of the factors described earlier).

Each year, the Secretary must renegotiate the MFP for renegotiation-eligible drugs that:

- Become extended-monopoly drugs,
- Become long-monopoly drugs, and
- Other drugs (i.e., those with new indications or a material change in factors) for which the renegotiation will likely result in significant changes in the MFP.

The renegotiation process must be consistent with the negotiation process described above, including the application of the ceiling and floor for the MFP. If a generic drug or biosimilar product for a selected drug is approved or licensed before or during the renegotiation process, the selected drug is no longer subject to the renegotiation process.¹⁰

“Sec. 1195. Publication of Maximum Fair Prices

As shown in Table 1, the Secretary must publish the MFP for a selected drug by November 30 of the year that is two years before the initial price applicability year (e.g., November 30, 2025 for the 2027 initial price applicability year)—except for the 2026 initial price applicability year, when the MFP must be published by September 1, 2024.

The Secretary must publish an explanation for the MFP negotiated for a selected drug by March 1 of the year that precedes the initial price applicability year (e.g., March 1, 2025 for the 2026 initial price applicability year).

For subsequent years, the Secretary will publish the MFP for the selected drug either as adjusted for inflation by the CPI-U or as renegotiated. The date of publication is not later than November 30 of the year that is two years before the subsequent year (e.g., November 30, 2025 for 2027).

If the MFP for a selected drug is determined after the regular date of publication of the MFPs for selected drugs, the MFP must be published within 30 days of its determination.

“Sec. 1196. Administrative Duties; Coordination Provisions

This section requires the establishment of procedures for the following purposes:

- To apply the MFP before any discounts or coverage (or financial assistance) for prescription drug coverage for MFP eligible individuals;
- To compute the MFP across different strengths and dosage forms;
- To apply the Program for the benefit of MFP eligible individuals;

¹⁰ Section 1194(g) attempts to describe when the MFP for a selected drug, as negotiated or renegotiated, takes effect. However, the content and cross-references in this provision do not appear to clearly correspond to any of the other provisions in section 1194. It may have been intended to be part of another section. This will likely be clarified in rulemaking.

- To establish the negotiation and renegotiation processes;
- To establish a process for manufacturers to submit information to the Secretary;
- To share information with the Treasury for purposes of applying any excise tax for noncompliance (see below); and
- To establish procedures for the special aggregation rules and acquisition rules for manufacturers in applying the exception for small biotech drugs during 2026, 2027, and 2028.

The Secretary must monitor manufacturers' compliance under the agreement and establish a mechanism for reports of noncompliance. Any violations are subject to enforcement under the Internal Revenue Code (IRC) excise tax provisions (i.e., new §5000D of the Internal Revenue Code, described below) or civil monetary penalties under section 1197.

“Sec. 1197. Civil Monetary Penalty

Civil monetary penalties (CMP) may be imposed on a manufacturer of a selected drug subject to a manufacturer agreement for violating the requirement to provide access to the selected drug at or below the MFP for the year involved to MFP eligible individuals or to providers of services (including hospitals) and suppliers (including physicians) with respect to those individuals. The CMP will be determined by—

- multiplying the number of units of the selected drug furnished, dispensed or administered during the year involved by the difference between (i) the price at which the selected drug was made available by the manufacturer for the year involved to the individual, provider of services or supplier and (ii) the MFP for that drug and year; and
- multiplying that product by ten.

Additionally, a CMP of up to \$1 million for each day of a violation may be imposed for failure to comply with administrative requirements, including the provision of information, to carry out the Program.

A CMP may also be imposed on a manufacturer for knowingly providing false information for purposes of the special aggregation rules and acquisition rules for manufacturers in applying the exception for small biotech drugs during 2026, 2027, and 2028. This CMP is equal to \$100,000,000 for each item of false information.

“Sec. 1198. Limitation on Administrative and Judicial Review

Administrative and judicial review are prohibited for the determination of the following:

- A unit, with respect to a drug or biological product;
- Selected drugs;
- Negotiation-eligible drugs;
- Qualifying single source drugs;
- Maximum fair price; and
- Renegotiation-eligible drugs.

Section 11001(b) of the IRA makes a number of conforming amendments to the Medicare and Medicaid statutes, as follows.

Medicare Part B Average Sales Price (ASP) Methodology: Substitutes the MFP for a selected drug during the price applicability period that is payable under section 1847A (ASP Methodology) in lieu of ASP (or WAC) for that drug or biological.

Medicare Advantage (MA): Prohibits MA plans from charging cost-sharing for selected drugs in excess of the amount of cost-sharing for those selected drugs that would apply under Medicare Part B based off the MFP for the selected drug. Also requires MA plans to provide information, including price information, to the Secretary on selected drugs covered under the plan for purposes of the negotiation and renegotiation processes under the Program.

Medicare Part D: Waives the noninterference clause with respect to selected drugs, and requires that negotiated prices for payment of selected drugs may not exceed the sum of the MFP during the price applicability period and any dispensing fees. Also requires coverage under the plan of each selected drug that is a covered Part D drug during the price applicability period for the plan year, although the plan is not prohibited from removing the selected drug from a formulary (if permitted under current regulations). Further requires plan sponsors to provide information, including price information, to the Secretary on selected drugs covered under the plan for purposes of the negotiation and renegotiation processes under the Program.

Exemptions for Essential Drugs: Under current law, manufacturers of drugs treated by the Secretary as being essential to the health of beneficiaries are exempt from certain requirements under Part D, Part B, and Medicaid. Those exemptions will not apply if the manufacturer is subject to the new excise tax under 5000D of the Internal Revenue Code for compliance violations of the Drug Price Negotiation Program.

Medicaid Drug Rebate Program: Requires the MFP for a selected drug during the price applicability period to be taken into account in calculating the best price for the drug under the Medicaid rebate program and for purposes of other provisions of law that refer to the Medicaid best price definition, including prices negotiated for the selected drug under MA-PD and Part D PDP plans. However, any reduction in price for the MFP would not be reflected in average manufacturer price (AMP).

Section 11001(c) of the IRA states that the Secretary shall implement this section 11001—including amendments made by this section for 2026, 2027, and 2028—by program instruction or other forms of program guidance.

Sec. 11002. Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry.

This section makes changes to the Drug Price Negotiation Program established in the prior section by adding a new subparagraph (f) to section 1192. Under this special rule, the Secretary may delay—by no more than 2 years—a biological from having an MFP set under the Program if the Secretary determines there is a high likelihood that a biosimilar biological product (“biosimilar” for purposes of this summary) will be both licensed (approved by the FDA) and marketed (sold in the marketplace) within 2 years. This section details how a manufacturer may request the delay under this special rule, the conditions that must be met for the Secretary to make a determination that the biological qualifies, the effects of the delay, and what happens if the Secretary finds there is no longer a high likelihood of a biosimilar being licensed and marketed within the required time period.

Application for Special Rule

A biological product may qualify for this special rule if:

- It is an extended-monopoly drug;¹¹
- In the absence of this rule, it would be a selected drug under the Program; and
- The Secretary determines there is a high likelihood that a biosimilar will be both licensed and marketed within 2 years of the selected drug publication date.

The special rule’s initial 1-year delay can only be applied if that delay is requested of the Secretary by a manufacturer of a biosimilar prior to the selected drug publication date in which the biological product would have been included. The special rule’s second (and final) 1-year delay can only be applied if that delay is also requested of the Secretary by a manufacturer of a biosimilar biological product—prior to the 1-year anniversary of the selected drug publication date in which the biological product would have been included.

The request(s) must be submitted at a time and in a form specified by the Secretary, and must contain the following:

- Information necessary for the Secretary to make the determination, as specified by the Secretary and including the following (to the extent available):
 - The manufacturing schedule for the biosimilar as submitted to the FDA for its review of the biosimilar application;
 - Disclosures in certain required filings with the Securities and Exchange Commission (SEC) about capital investment, revenue expectations and actions taken by the manufacturer that are typical of the normal course of business in the year (or two) before marketing the biosimilar that pertain to such marketing or comparable documentation distributed to the shareholders of privately held companies;

¹¹ An extended-monopoly drug is a drug that has been on the market for at least 12 and less than 16 years—excluding vaccines licensed under section 351 of the PHSA and selected drugs before initial price applicability year 2030.

- Agreements between the manufacturers of the reference product and the biosimilar relating to the licensing of the biosimilar that are required to be filed with the Federal Trade Commission (FTC) or the Assistant Attorney General; and
- Any follow-up information requested by the Secretary.

Implementation of Special Rule

The Secretary may delay a biological from having an MFP set under the Program if the Secretary determines there is a high likelihood that a biosimilar will be licensed and marketed within 2 years of the otherwise applicable selected drug publication date. There is a **high likelihood** if the Secretary finds that:

- An application for biosimilar licensure has been accepted for review or approved by the FDA; and
- The information submitted to the Secretary (described above) provides clear and convincing evidence that such biosimilar will be marketed within the 2-year period of the special rule's delay (or within the remaining 1-year period, in the case of a possible extension of the delay for the second 1-year period).

If the Secretary makes the high-likelihood determination, a 1-year delay applies for the reference biological from being a selected drug. After that initial 1-year delay, if the biosimilar has not been licensed and marketed, the Secretary will (at the request of the biosimilar manufacturer):

- Reevaluate whether or not there is a high likelihood that the biosimilar will be licensed and marketed during the remainder of the 2-year period; and
- Evaluate whether, on the basis of clear and convincing evidence, the manufacturer has made significant progress (as determined by the Secretary) toward both licensure and marketing of the biosimilar, based on updated information provided to the Secretary regarding agreements related to the biosimilar filed with the FTC or the Assistant Attorney General, or additional information and documents requested by the Secretary necessary to make such determination.

After that initial 1-year delay, if the Secretary determines there is not a high likelihood that the biosimilar will be licensed and marketed within the remaining timeframe, or that there has not been significant progress toward such licensing and marketing, then the reference biologic will be a selected product for the next year (that is, it only obtained a 1-year delay from being a selected drug) and will be required to pay a rebate (described below) related to that 1-year delay.

On the other hand, if after that initial 1-year delay the Secretary determines there is a high likelihood that the biosimilar will be licensed and marketed within the remaining timeframe and that there has been significant progress toward such licensing and marketing, then the reference biologic will not be a selected product for the next year (that is, it obtains the entire 2-year delay from being a selected drug). If during that entire 2-year period a biosimilar was neither licensed nor marketed, not only will the reference biological become a selected drug after the two-year delay, but the manufacturer must also pay a rebate for the 2-year delay, described below.

The language then reiterates that in no case shall the Secretary delay for more than 2 years the inclusion of a biological from being on the published list of selected drugs. Other limitations on delays include the following:

- If a reference biological was delayed from the list by one year and, if it would have been on the list, its status would have changed to a long-monopoly drug (that is, on the market for more than 16 years), the Secretary in no case may provide a second 1-year delay.
- No delay is permitted for a biological for which more than 1 year has elapsed since the biosimilar was licensed but still has not begun marketing.
- No delay is permitted if the Secretary determines that the manufacturer of the biosimilar either (I) is the same as the manufacturer of the reference biological, or (II) based on information provided to the Secretary regarding agreements related to the biosimilar filed with the FTC or the Assistant Attorney General, has entered into an agreement with the manufacturer of the reference product that requires or incentivizes the biosimilar manufacturer to submit a delay request or restricts the quantity of the biosimilar that may be sold in the United States over a specified period of time.

Rebate

If a manufacturer's reference biological was delayed from being a selected drug but that delay ended with no biosimilar being approved and marketed (or the Secretary did not extend the delay beyond the first 1-year delay for the reasons described earlier), the manufacturer of the reference biological must pay a rebate to the federal government for the period of the delay. The rebate will be paid at such time and in such manner as determined by the Secretary.

The amount of the rebate will be the following estimated amount:

- For Part D, 75 percent of the amount by which the AMP for the biological exceeds the MFP that would have been negotiated (increased by CPI-U for the second year, if applicable), for the number of units dispensed under Part D—determined for each calendar quarter during such price applicability period; and
- For Part B, 80 percent of the amount by which the otherwise applicable Part B payment for the biologic (under the Medicare average sales price payment methodology under section 1847A(b)) exceeds the MFP that would have been negotiated (increased by CPI-U for the second year, if applicable), for the number of units administered and furnished under Part B¹²—determined for each calendar quarter during such price applicability period.

If a biologic for which a rebate must be paid becomes a long-monopoly drug at the time of its inclusion on the published list of selected drugs, the following calculation will be used in place of the MFP in calculating the rebate owed: 65 percent of the average non-FAMP generally for 2021, increased by CPI-U from September 2021 to September of the year prior to the selected drug publication date that would have applied if not for the delay.

¹² The number of units under Part B here excludes units that are packaged into the payment amount for an item or service and are not separately payable under Part B.

These rebates for Part B and Part D biologics will be deposited into the (Part B) Federal Supplementary Medical Insurance Trust Fund and the (Part D) Medicare Prescription Drug Account, respectively.

Any manufacturer that fails to comply with these rebate requirements will be subject to CMPs of 10 times the amount of the rebate the manufacturer failed to pay.

Section 11002(c) of the IRA states that the Secretary shall implement this section 11002—including amendments made by this section for 2026, 2027, and 2028—by program instruction or other forms of program guidance.

Sec. 11003. Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods.

If a manufacturer refuses to enter into negotiations (or renegotiations) after being selected by the Secretary or if the manufacturer leaves the negotiation (or renegotiations) before a maximum fair price is agreed to, then the manufacturer will be assessed an excise tax levied on its annual gross sales for the drug based on the number of days out of compliance. The excise tax— created in a new section 5000D of the Internal Revenue Code—will also apply for failure by the manufacturer to submit information required by the Secretary by the due date; the excise tax will apply for each day after the Secretary certified the information is overdue and will end on the date the information is submitted.

For days that would otherwise count in the noncompliance period, the tax is suspended beginning when the Secretary has received notice of terminations of all applicable agreements¹³ of the manufacturer and when none of the drugs of the manufacturer are covered by a Part D agreement.¹⁴

The assessment begins at 65 percent and increases by 10 percentage points every quarter the manufacturer is out of compliance to a maximum of 95 percent.

Sec. 11004. Funding.

Appropriates \$3,000,000,000 to CMS for fiscal years 2022 to carry out the provisions of this part, including the Drug Price Negotiation Program, the enforcement provisions, and the conforming amendments to the Medicare and Medicaid statute. Funds are available until expended.

¹³ Specifically, the Medicare coverage gap discount program under section 1860D-14A, the new manufacturer discount program created by the IRA as a new section 1860D-14C of the Social Security Act, and the Medicaid rebate program.

¹⁴ Specifically, the Medicare coverage gap discount program under section 1860D-14A and the new manufacturer discount program in section 1860D-14C.

PART 2—PRESCRIPTION DRUG INFLATION REBATES

Sec. 11101. Medicare Part B Rebate by Manufacturers

This section establishes a mandatory rebate program for all manufacturers of “Part B rebatable drugs” if the manufacturer has raised the price of the drug above the rate of inflation since July 2021. This rebate program begins with the first calendar quarter of 2023.

Part B Rebatable Drugs

A Part B rebatable drug is defined to mean any single source drug or biological (including most biosimilars) that is paid under Part B. However, the following drugs and biologicals are excluded from the definition and are not subject to mandatory rebate program:

1. Vaccines.
2. Drugs with low average Medicare Part B total allowed charges (i.e., less than \$100 in 2023).
3. Qualifying biosimilar biological products.

The \$100 threshold in 2023 for drugs with low average Medicare Part B total allowed charges is increased each year for inflation by the percentage increase in the CPI-U¹⁵ for the 12-month period ending in June of the previous year. Amounts are rounded to the closest \$10.

Special temporary 5-year payment rules for qualifying biosimilar biological products (or qualifying biosimilars) are established by amendments made in section 11403 of the IRA, which is described below. These are biosimilars that, during the temporary 5-year period involved, have an average sales price that is less than the reference biological product.

Information Reported by the Secretary

For each calendar quarter, beginning with the 1st quarter of 2023, the Secretary has six months after the end of the quarter to report to manufacturers the rebate amount that the manufacturer must pay for Part B rebatable drugs furnished during the quarter with price increases above the rate of inflation. The information reported to the manufacturer must also include the total number of units and billing codes for the drug and calendar quarter, and the amount by which the payment rate for the drug furnished during that quarter exceeded the rate of inflation. The total number of units excludes 340B units and packaged units (i.e., units packaged into payment for an item or service that are not separately payable).

For calendar quarters in 2023 and 2024, the Secretary may delay reports to manufacturers for those calendar quarters until September 30, 2025.

¹⁵ The consumer price index for all urban consumers (United States city average).

Rebate Payment

Upon receipt of a report from the Secretary for a calendar quarter, the manufacturer must pay a rebate based on the difference between the growth in the average sales price (ASP) and CPI-U for its Part B rebatable drugs furnished to Medicare beneficiaries during that quarter.

Specifically, the rebate payment amount is calculated as the product of the following:

- The total number of Medicare Part B units of the drug in the relevant quarter (other than 340B units and packaged units); and
- The amount which the payment rate for the drug during the quarter exceeds the inflation-adjusted payment amount.

The inflation-adjusted payment amount for a quarter is equal to the payment amount for the drug in the 3rd quarter of 2021 (referred to as the payment amount benchmark quarter) increased by the percentage growth, if any, between the rebate period CPI-U and the benchmark period CPI-U. The benchmark period CPI-U is the CPI-U for January 1, 2021. The rebate period CPI-U is the greater of:

- The benchmark period CPI-U; and
- The CPI-U for the first month of the calendar quarter that is two calendar quarters before the calendar quarter involved.

The Secretary must either reduce or waive entirely the rebate amount for a calendar quarter for a Part B rebatable drug that is either a drug on the FDA's drug shortage list at any point during that quarter or a biosimilar with respect to which the Secretary determines there is a severe supply chain disruption during the quarter.

Special Rules for Certain Drugs

For Part B rebatable drugs that are first approved or licensed after December 1, 2020, to determine whether a rebate is owed by a manufacturer for a calendar quarter, the payment amount benchmark quarter will be the 3rd full calendar quarter after the first day on which the drug is first marketed, and the benchmark period CPI-U will be the CPI-U for the first month of the first full calendar quarter after the first day on which the drug is first marketed. Manufacturer rebates for these new drugs would apply as of the later of January 1, 2023 or the sixth full calendar quarter after the first day on which the drug is first marketed.

Selected drugs under the Drug Price Negotiation Program are not subject to the rebate program during the price applicability period for that selected drug. Once the price applicability period for a selected drug terminates, it becomes subject to the mandatory rebate program. To determine whether a rebate is owed by a manufacturer for a calendar quarter after the end of the Drug Price Negotiation Program's price applicability period, the payment amount benchmark quarter will be the 1st calendar quarter of the last year of the price applicability period, and the benchmark period CPI-U will be the CPI-U for July of the year preceding the last year of the price applicability period.

Beneficiary Coinsurance

Beginning April 1, 2023, beneficiary coinsurance for a Part B rebatable drug that is subject to a rebate is capped at 20 percent of the inflation-adjusted benchmark quarter Part B payment amount. Conforming amendments are made to the ambulatory surgery center payment system and the hospital outpatient prospective payment system to provide the same beneficiary coinsurance protection for Part B rebatable drugs payable separately under those systems and subject to a rebate under this program.

Other Provisions

Civil Money Penalties CMPs. Each manufacturer that does not pay any required rebate amount for a calendar quarter is subject to CMPs of not less than 125 percent of the rebate amount.

Exclusion from Certain Calculations. Rebate amounts are excluded from the calculation of ASP, Best Price, and average manufacturer price.

Waiver of Administrative or Judicial Review. The statute prohibits administrative or judicial review of the determinations of rebate units, whether a drug is a Part B rebatable drug, the rebate calculations, or the calculation of beneficiary coinsurance.

Rebate Deposits. Rebates are deposited in the Medicare Part B Trust Fund.

Funding. A total of \$80 million is made available to CMS in FY 2022 to implement the program, of which \$12.5 million is allocated for FY 2022 and \$7.5 million is allocated for each of FYs 2023 through 2031. Funds remain available until expended.

Sec. 11102. Medicare Part D Rebate by Manufacturers

This section establishes a mandatory rebate program for all manufacturers of covered Part D drugs if the prices charged by a manufacturer for a covered Part D drug increase at a rate in excess of inflation compared to the first three quarters of 2021. If the average manufacturer price (AMP) for a Part D rebatable drug increases faster than the CPI-U, the manufacturer must pay a rebate based on the difference between the AMP and CPI-U. This rebate program is similar to the Part B rebate program in structure; differences include the drugs subject to the rebate program (all covered Part D drugs other than low-cost drugs are subject to rebates), the periods used to compare drug prices (a 12-month period beginning in October of a year) and to determine rebates, the periodicity of rebate payments (annual), the deadline for the first report to manufacturers, and the absence of any specific rule for beneficiary cost-sharing for covered Part D drugs subject to a Part D rebate.

Part D Rebatable Drugs

A Part D rebatable drug is any covered Part D drug with one exception—a drug or biological with an average total Part D cost of less than \$100 per individual who uses the drug during the 12-month period beginning on October 1, 2022 (referred to as an applicable period). The \$100

threshold is increased for each subsequent applicable period for inflation by the percentage increase in the CPI-U for the 12-month period beginning with October of the previous applicable period. Amounts are rounded to the closest \$10.

Information Reported by the Secretary

For each applicable period (i.e., a 12-month period beginning in October), beginning with the applicable period starting in 2022, the Secretary has 9 months after the end of the period to report to manufacturers the amount of the price that exceeded the rate of inflation for Part D rebatable drugs during that period and the rebate amount that the manufacturer must pay for those drugs.

For the two applicable periods beginning on October 1, 2022 and October 1, 2023, the Secretary may delay reports to manufacturers for those calendar quarters until December 31, 2025.

Rebate Payment

Upon receipt of a report from the Secretary for an applicable period, the manufacturer must pay a rebate based on the difference between the AMP (as defined under the Medicaid drug rebate program) and inflation-adjusted payment amount for each dosage form and strength of its Part D rebatable drugs furnished during that applicable period. Specifically, the rebate payment amount is calculated as the product of the following:

- The total number of units of the Part D rebatable drug in the applicable period (other than 340B units) for each dosage form and strength; and
- The amount which the AMP paid for the dosage form and strength for the drug during that period exceeds the inflation-adjusted payment amount.

A unit is defined as the lowest dispensable amount of the part D rebatable drug as reported under the Medicaid drug rebate program. The exclusion of 340B units applies for plan years beginning in 2026 and thereafter.

Using information required to be reported under the Medicaid drug rebate program, the Secretary determines the volume-weighted average AMP for each dosage form and strength of a Part D rebatable drug and applicable period. The Secretary also calculates the benchmark period manufacturer price, which is the volume-weighted average AMP for each dosage form and strength of a Part D rebatable drug for the first three quarters of 2021 (referred to as the payment amount benchmark period).

The inflation-adjusted payment amount for an applicable period for a dosage form and strength for a Part D rebatable drug is equal to benchmark period manufacturer price for each dosage form and strength for the drug increased by the percentage by which the CPI-U for the first month of the applicable period involved (referred to as the applicable period CPI-U) exceeds the CPI-U for January 2021 (referred to as the benchmark period CPI-U).

The Secretary must either reduce or waive entirely the rebate amount for an applicable period for a Part D rebatable drug under the following circumstances:

- A brand drug is placed on the FDA’s drug shortage list at any point during that period.
- A generic drug or biosimilar for which the Secretary determines there is a severe supply chain disruption during the applicable period.
- A generic drug that the Secretary determines would be placed on the FDA’s drug shortage list at any point during the subsequent period absent a reduction or waiver.

Special Rules for Certain Drugs

For Part D rebatable drugs that are first approved or licensed after October 1, 2021, to determine whether a rebate is owed by a manufacturer for an applicable period, the payment amount benchmark period will be the first calendar year after the day on which the drug is first marketed, and the benchmark period CPI-U will be the CPI-U for January of the first year that begins after the date on which the drug is first marketed. In the case of a new formulation (or line extension) of a Part D rebatable drug, the Secretary must establish a formula consistent with the formula used under the Medicaid drug rebate program to determine rebates for these new formulations. A new formulation includes an extended-release formulation, but excludes an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended-release formulation.

Selected drugs under the Drug Price Negotiation Program are not subject to the rebate program during the price applicability period for that selected drug. Once the price applicability period for a selected drug terminates, it becomes subject to the mandatory rebate program. To determine whether a rebate is owed by a manufacturer for an applicable period under the Part D rebate program after the end of the price applicability period under the Drug Price Negotiation Program, the payment amount benchmark period will be the last year of the price applicability period, and the benchmark period CPI-U will be the CPI-U January of the last year of the price applicability period for the selected drug.

Reconciliation

The Secretary must establish a process to reconcile amounts paid as rebates by a manufacturer for a Part D rebatable drug and applicable period where a PDP or MA-PD sponsor revises a report to the Secretary on the number of units dispensed of that covered Part D drug during the applicable period. Underpayments of rebates must be made no later than 30 days after the receipt of the reconciliation notice. The statute is silent on the issue of timing for overpayments.

Other Provisions

Civil Money Penalties CMPs. Each manufacturer that does not pay any required rebate amount for an applicable period is subject to CMPs of not less than 125 percent of the rebate amount.

Information. The Secretary will use information reported by manufacturers and states under the Medicaid drug rebate program as well as data submitted by sponsors of PDP and MA-PD plans.

Exclusion from Certain Calculations. Rebate amounts are excluded from the calculation of ASP, Best Price, and average manufacturer price.

Waiver of Administrative or Judicial Review. The statute prohibits administrative or judicial review of the determinations of units, whether a drug is a Part D rebatable drug, or the calculation of rebates.

Rebate Deposits. Rebates are deposited in the Prescription Drug Account of the Medicare Part B Trust Fund.

Implementation. For 2022, 2023 and 2024, the Secretary is to implement the program using program instructions or other guidance.

Funding. A total of \$80 million is made available to CMS in FY 2022 to implement the Part D rebate program, of which \$12.5 million is allocated for FY 2022 and \$7.5 million is allocated for each of FYs 2023 through 2031. Funds remain available until expended.

PART 3—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

Sec. 11201. Medicare Part D Benefit Redesign

The following table shows the Part D benefit under current law and as modified by the IRA:

	Current Law	2024 under IRA	2025 under IRA
Deductible			
Beneficiary	Amount based on last year’s amount increased by drug spending growth (\$480 in 2022)	No change (Amount updated for drug spending growth)	
Initial Benefit Phase: Above the Deductible up to the Initial Coverage Limit			
Initial Benefit Phase	Above \$480 deductible up to \$4,430 initial coverage limit (in 2022)	No change (amounts updated for spending growth)	Above deductible up to \$2,000 annual out-of-pocket threshold
Beneficiary	25%	25%	25%
Plan	75%	75%	65%
Manufacturer	0	0	10% discount (brand)*
Federal Government	0	0	10% subsidy (brand)**
Coverage Gap Above the Initial Coverage Limit up to the Out-Of-Pocket Threshold			
Coverage gap	Above \$4,430 up to \$10,012*** (in 2022)	No change (amounts updated for spending growth)	Eliminated
Beneficiary	25%	25%	
Plan	75% (generic) 5% (brand)	75% (generic) 5% (brand)	
Manufacturer	70% (brand)	70% (brand)	
Federal Government	0	0	
Catastrophic Range Above the annual out-of-pocket threshold			
Annual Out-of-pocket threshold	\$10,012*** (in 2022). Increased by drug spending growth for subsequent years	No change (amount updated for drug spending growth)	\$2,000. Increased by drug spending growth for subsequent years
Beneficiary	5%	0	0
Plan	15%	20%	60%
Manufacturer Discount	0	0	20% discount (brand)*
Federal Government Reinsurance	80%	80%	20% (brand) 40% (generic)
Base Beneficiary Premium			
Beneficiary	25.5% of national average monthly bid	Premium growth is capped at 6%	

Eliminating the Initial Coverage Limit

Beginning in 2025, the IRA replaces the initial coverage limit—or the upper threshold of the initial benefit phase—with the out-of-pocket limit. Before the IRA, the initial benefit phase begins once a beneficiary has paid the deductible and ends once a beneficiary has incurred costs equal the initial coverage limit. That amount, equal to \$4,430 for 2022, is set by increasing the prior year’s initial coverage limit by a measure of drug price spending growth.

In 2025, the IRA sets the out-of-pocket limit at \$2,000. This eliminates the coverage gap and lowers the out-of-pocket limit for the catastrophic phase of the benefit. For 2026 and thereafter, the upper threshold of the initial benefit phase will be calculated by increasing the prior year’s amount by the same measure of covered part D drug price spending growth as under present law.

Changes in the Catastrophic Range

Beginning in 2024, beneficiary co-insurance in the catastrophic range is eliminated. (It is equal to 5 percent under current law.)

Beginning in 2025, in combination with reducing the out-of-pocket limit for the catastrophic phase of the benefit, the IRA establishes a cap on copayments for Part D and MA-PD beneficiaries. As noted above, that amount is set at \$2,000 for 2025. For 2026 and thereafter, the upper threshold of the initial benefit phase is the prior year’s amount increased by the same measure of drug price spending growth as under present law.

Elimination of Coverage Gap

Under the IRA, the coverage gap is eliminated starting in 2025. Because the IRA changes the initial benefit phase to end at \$2,000 for 2025 (or, for subsequent years, the prior year’s amount increased by drug price spending growth) and the catastrophic phase begins at that same figure, there is no longer any coverage gap. The coverage gap provisions of the statute sunset as of January 1, 2025.

Reinsurance

Under existing law, Medicare subsidizes 80 percent of total drug spending incurred by Part D enrollees with drug spending above the catastrophic coverage threshold. Under the IRA, starting in 2025, Medicare will subsidize an amount equal to the sum of 20 percent of the costs of *applicable drugs* incurred after an individual has exceeded the annual out-of-pocket threshold plus 40 percent of the costs incurred after an individual has exceeded the annual out-of-pocket threshold of the costs of *non-applicable drugs*.

- Applicable drugs are defined as those approved under new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or a biologic licensed under section 351 of the PHSA and are included on a Part D or MA-PD plan formulary (or, if the sponsor does not use a formulary, then drugs for which benefits are available under the plan) as well as those covered through an exception or appeal. Effectively these are brand name drugs that are not subject to the Drug Price Negotiation Program summarized above.
- Non-applicable drugs are those selected drugs under the Drug Price Negotiation Program summarized above.

New Manufacturer Discount Program

Beginning on January 1, 2025, new section 1860D-14C establishes a manufacturer discount program for Part D enrollees who have incurred costs in excess of the annual deductible and who are not enrolled in a qualified retiree prescription drug plan. The discount program applies to brand name drugs (those originally approved under a new drug application or a biologic licensed under section 351 of the PHSA) that are on the formulary of the sponsor, or if there is no formulary, drugs for which coverage is provided, as well as those drugs covered through an exception or appeal. It does not apply to those drugs selected for negotiation under the Drug Price Negotiation Program summarized above.

Discount Agreements. Under the program, manufacturers enter into an agreement with the Secretary to provide discounts for these drugs dispensed to Part D beneficiaries. For plan year 2025, the agreement must be entered into by March 1, 2024. For subsequent plan years, the Secretary will set the deadline, which may be on a quarterly or semi-annual basis. Agreements are not less than 12 months in length and are renewed automatically unless terminated by one of the parties. The Secretary may terminate an agreement for willful violations of its requirements or other good cause. If requested, the Secretary must provide for a hearing to review such terminations. A manufacturer terminating an agreement must do so before January 31 for the succeeding plan year. If it terminates after January 31, it can only terminate for the second succeeding plan year.

General Rule for Discounts. Unless a manufacturer qualifies for a phased-in discount as described below, manufacturers must provide a discounted price, beginning in 2025, equal to:

- 90 percent of the negotiated price for those beneficiaries who have not yet exceeded their annual out-of-pocket threshold; and
- 80 percent of the negotiated price for those beneficiaries who have exceeded the annual out-of-pocket threshold.

Discounts provided under the Manufacturer Discount Program do not impact the liability of a beneficiary for any required copayments or coinsurance, nor the ability of a beneficiary to purchase a covered drug that is not an applicable drug or a drug that is not on the formulary of their plan.

Phased-In Discounts for LIS Beneficiaries. For certain manufacturers and with respect to drugs provided to LIS beneficiaries, the discounts would be phased in such that manufacturers would be required to provide a discounted price—determined by multiplying the negotiated price by the applicable percentage for the year involved, shown in the following schedule:

	For those LIS beneficiaries who have not yet exceeded their annual out-of-pocket threshold	For those LIS beneficiaries who have exceeded their annual out-of-pocket threshold
2025	99 percent	99 percent
2026	98 percent	98 percent
2027	95 percent	95 percent
2028	92 percent	92 percent
2029	90 percent	90 percent

2030	(For 2029 and thereafter)	85 percent
2031		80 percent (For 2031 and thereafter)

Manufacturers permitted to phase in discounts applicable to LIS beneficiaries are those that had a coverage gap discount agreement under section 1860D-14A in effect in 2021 and for which:

- Total spending for all of the Part D drugs of the manufacturer covered by that agreement was less than 1 percent of the total Part D spending during 2021; and
- Total spending for all of the drugs of the manufacturer that are single source drugs and biological products covered under Part B during 2021 was less than 1 percent of the total Part B spending for all drugs or biological products covered during 2021.

Phased-In Discounts for “Specified Small Manufacturers.” The same phase-in schedule established for drugs for LIS beneficiaries also applies to certain “Specified Small Manufacturers.” These are manufacturers that have a coverage gap discount agreement under section 1860D-14A in effect in 2021 and that have total spending under Part D for any one of their drugs covered by the coverage gap discount agreement equal to more than 80 percent of the total Part D spending for all drugs of that manufacturer.

Both phase-in schedules apply to drugs of qualifying manufacturers that are produced, prepared, propagated, compounded, converted, or processed by the manufacturer. All persons treated as a single employer under the Internal Revenue Code are considered to be a single manufacturer for this purpose. A manufacturer acquired by another manufacturer that is not a Specified Small Manufacturer is not included as a Specified Small Manufacturer for the purpose of applicability of the phased-in discount schedule.

Total spending with respect to Part D for the purpose of determining eligibility for phase-in discounts includes ingredient costs, dispensing fees, sales tax, and if applicable, vaccine administration fees. Total spending with respect to Part B for the purpose of determining eligibility for phase-in discounts excludes spending for a drug or biological that is bundled or packed into payment for another service.

Discounts for Claims that Cross Phases of the Part D Benefit. When the negotiated price of a claim for an applicable drug that is subject to a discount under the Manufacturer Discount Program falls only in part above the annual deductible, the manufacturer provides the discounted price on only the portion of the negotiated price that falls above the deductible. Likewise, where the amount of the negotiated price of an individual claim for the drug falls in part above and in part below the annual out-of-pocket threshold, the manufacturer provides the 10 percent discount applicable to the portion of the claim below the annual out-of-pocket threshold plus the 20 percent discount applicable to the portion of the claim that falls above that threshold.

Administering Discounts. The Secretary will establish policies to (i) determine the discounted prices for applicable drugs; (ii) establish procedures to ensure that a pharmacy or mail order service is reimbursed for the negotiated price less the discount within 14 days for electronic claims and 30 days for other claims; (iii) ensure that discounts are provided before other coverage or financial assistance is applied; and (iv) establish a dispute mechanism to resolve

disagreements between manufacturers, beneficiaries and a third-party contractor administering the program on behalf of the Secretary. The Secretary must also monitor compliance with the discount program and may collect appropriate data from Part D and MA-PD plans for the purposes of providing discounted prices.

The Secretary may not receive or distribute funds of a manufacturer in administering the program.

Manufacturer Duties and Enforcement. Manufacturers must collect and have available such data as the Secretary determines is needed to demonstrate compliance with the agreements. Unlike the Build Back Better Act (BBBA) as passed by the House of Representatives in 2021, the IRA does not specify that manufacturers must subject to periodic audits by the Secretary. However, the IRA does subject manufacturers to civil money penalties of 125 percent of the amount of the discounts for failure to provide the discounted prices.

The provision includes several definitions:

- *Manufacturer.* A manufacturer under this section is defined as an entity engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly. Such term does not include a wholesale distributor of such drugs or a retail pharmacy licensed under state law.
- *Negotiated Price.* Refers to the definition of negotiated price in 42 CFR 423.100 (existing Part D regulations) and would include any dispensing fee and vaccine administration fee, if applicable.

Discounted prices under this section will be incorporated in the actuarial valuation of Part D bids.

New Selected Drug Subsidy Program

New section 1860D-14D requires the federal government to provide plan sponsors a 10 percent subsidy toward the negotiated price for those covered Part D drugs selected for negotiation under the new Drug Price Negotiation Program dispensed to Part D and MA-PD enrollees who have incurred costs above the deductible but below the annual out-of-pocket threshold.

Stabilizing the Beneficiary Premium

Under current law, a beneficiary is required to contribute 25.5 percent toward the premium cost of standard drug coverage under Part D. Under the BBBA, the premium percentage would have been reduced to 23.5 percent beginning in 2024.

The IRA adopts a different policy. For each of the 2024 through 2029 plan years, it caps the amount by which the monthly base premium may grow by 6 percent. For each of those plan years, the base beneficiary premium for a month will be the lesser of (i) the base beneficiary premium for the previous year increased by 6 percent or (ii) the base beneficiary premium that would be calculated if the 6 percent cap is not applied. The 6 percent cap does not apply in 2030 and subsequent years.

However, starting with the 2030 plan year, the beneficiary premium contribution toward standard drug coverage of 25.5 percent shall be modified by the Secretary by whatever percentage point adjustment is necessary to ensure that the base beneficiary premium for a month in 2030 is equal to the lesser of the following:

- 106 percent of the base beneficiary premium for a month in 2029; or
- The base beneficiary premium calculated for a month in 2030 using the 25.5 percent beneficiary contribution under existing law.

In no case may the beneficiary contribution be less than 20 percent.

Waiver of Rulemaking Requirements

Requirements for rulemaking to carry out the many provisions of this section during 2024, 2025 and 2026 are waived; they may be implemented through program instruction or otherwise.

Implementation Funding

The IRA provides funding to CMS to implement the Part D Benefit Redesign provisions as follows:

- For fiscal year (FY) 2022, \$341 million, including \$20 million for FY 2022 and \$65 million for FY 2023; and
- For each of FYs 2024 through 2031, \$32 million.

Funds remain available until expended.

Sec. 11202. Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug Plans and MA-PD Plans.

For plan years beginning on or after January 1, 2025, PDPs and MA-PD plan sponsors must permit an enrollee, including an LIS enrollee, to opt to spread their payments for certain cost sharing amounts over a period of time as described below. A beneficiary may make an election prior to a plan year or in any month during the plan year.

If the beneficiary elects to spread out their cost-sharing, the plan sponsor bills the beneficiary a monthly amount which is subject to a ceiling. The ceiling for a month is calculated as follows:

- For the first month after the election, the annual out-of-pocket threshold (\$2,000 in 2025) minus the incurred costs divided by the number of months remaining in the plan year;
- For each subsequent month, the sum of any remaining out-of-pocket costs owed divided by the number of months remaining in the plan year.

Examples of Maximum Monthly Cap on Cost Sharing Payments with 6 Months Remaining in the Plan Year

	Beneficiary A incurs \$1,800 in out-of-pocket costs*	Beneficiary B incurs \$800 in out-of-pocket costs*
Month 1	$(\$2,000 - \$1,800)/6$ =\$33.33	$(\$2,000 - \$800)/6$ =\$200
Month 2	$(\$1,800 - \$33.33)$ or $\$1,767/5$	$(\$800 - \$200)/5$ or $\$600/5$

	\$353	\$120
Month 3	1767-353/4 or 1414/4 \$353	(\$600-\$120)/4 or \$480/4 \$120
Month 4	1414-354/3 or 1060/3 \$353	(\$480-\$120)/3 or \$360/2 \$120
Month 5	1060-353/2 or 707/2 \$353	(\$360-\$120)/2 or \$240/2 \$120
Month 6	\$353	\$120

*Figures are rounded and may not sum to totals because of rounding.

The Secretary of HHS must provide information to Part D eligible individuals regarding the option. PDP and MA-PD sponsors must:

- Notify prospective enrollees, prior to the start of the plan year, regarding the option and include information on the option in educational materials;
- Have a mechanism in place to notify a pharmacy during a plan year when an enrollee incurs out-of-pocket costs that the enrollee may benefit from the election;
- Provide that the pharmacy informs the beneficiary of such option after it receives such a notification;
- Ensure that an election under this option does not impact payments (or the timing of payments) to a pharmacy; and
- Have a financial reconciliation process to correct inaccuracies in payments made by an enrollee electing the option.

PDP and MA-PD sponsors may not limit the option for an enrollee to make such an election to certain covered part D drugs.

An election under this provision will be terminated if an enrollee fails to pay the billed monthly amounts, and the PDP sponsor or MA organization may preclude the enrollee from making such an election in a subsequent plan year.

Nothing under this provision prevents a PDP or MA-PD sponsor from billing enrollees for past due amounts. Unsettled balances of amounts owed under this provision are treated as plan losses; the Secretary is not liable for those amounts outside of those assumed as losses estimated in plan bids.

This section waives requirements for rulemaking to carry out provisions during 2025; they may be implemented through program instruction or otherwise. Funding for CMS to carry out this section is provided: \$10 million is made available to CMS for FY 2023, which remains available until expended.

PART 4—CONTINUED DELAY OF IMPLEMENTATION OF PRESCRIPTION DRUG REBATE RULE

Sec. 11301. Extension of Moratorium of Implementation of Rule Relating to Eliminating the Anti-Kickback Statute Safe Harbor Protection for Prescription Drug Rebates.

On November 30, 2020, the HHS Office of the Inspector General (OIG) published a final rule titled, “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” ([87 FR 76666](#)). Section 11301 of the IRA prohibits the Secretary from implementing, administering or enforcing the provisions of that rule prior to January 1, 2032.

The rule eliminated safe harbor protections for drug rebates negotiated by pharmacy benefit managers (PBMs) in order to offer those protections to discounts provided directly to consumers. Specifically, the rule amended the safe harbor that protects from federal anti-kickback requirements certain price discounts provided to individuals and entities, including health care providers, who solicit or receive price reductions, and the individuals and entities who offer to pay them. The final rule eliminated from that safe harbor the rebates provided from a manufacturer to a Part D plan sponsor (including a Medicare Advantage plan offering drug coverage). The rule also established two new safe harbors. One protects discounts provided by manufacturers to Part D plan sponsors and Medicaid managed care plans if they are given at point-of-sale. The second protects flat fee service payments that manufacturers make to PBMs for specific activities.

[Judicial, administrative and congressional action](#) pushed back the rule’s implementation multiple times—for example, until January 1, 2026, in the Infrastructure Investment and Jobs Act,¹⁶ and until January 1, 2027, in the Bipartisan Safer Communities Act.¹⁷ This section of the IRA prohibits implementation before January 1, 2032, a 5-year extension.

¹⁶ P.L. 117-58, enacted November 15, 2021

¹⁷ P.L. 117-159, enacted June 25, 2022

PART 5—MISCELLANEOUS

Sec. 11401. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D.

For coverage beginning January 1, 2023, PDPs and MA-PDs may not charge any cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

Because PDPs and MA-PDs submitted their 2023 bids prior to the enactment of this provision (and thus those bids did not account for these costs), the IRA provides a temporary retrospective subsidy to PDPs and MA-PDs to cover these costs for 2023. The Secretary is required to provide this subsidy for the aggregate reduction in cost sharing and deductibles for 2023 by no later than 18 months following the end of the applicable plan year (i.e., by June 30, 2025).

Section 11401(d) states that this provision does not limit coverage under Part D for vaccines that are *not* recommended by ACIP. Section 11401(e) states that the Secretary shall implement this section—including amendments made by this section for 2023, 2024, and 2025—by program instruction or other forms of program guidance.

Sec. 11402. Payment for Biosimilar Biological Products During Initial Period.

Section 1847A of the Social Security Act specifies the calculation for payments of drugs and biologics under Medicare Part B using a methodology generally relying on average sales price (ASP). For biosimilars, the Part B payment is generally the biosimilar's ASP plus 6 percent of the reference product's ASP. However, in cases where ASP is not available during the first quarter of sales for the new biosimilar, CMS has been using 103 percent of wholesale acquisition cost (WAC).

Under this section of the IRA, on or after July 1, 2024, where ASP is not available during the first quarter of sales for the new biosimilar, the Part B payment will be the lesser of the price Medicare pays for the biosimilar's reference product or 103 percent of the biosimilar's WAC.

Sec. 11403. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products.

For biosimilars, the Part B payment is generally the biosimilar's ASP plus 6 percent of the reference product's ASP. This section of the IRA increases the percentage to 8 percent for the applicable 5-year period for qualifying biosimilars.

Applicable 5-year period means:

- For a biosimilar for which Part B payments were made as of September 30, 2022, the 5-year period beginning October 1, 2022; and

- For a biosimilar for which Part B payments were made after September 30, 2022, the 5-year period beginning on the first day of the quarter during which a Part B payment is first made.

Qualifying biosimilar biological product means a biosimilar with an ASP lower than that of the reference biological product, determined on a quarterly basis during the applicable 5-year period. Thus, the biosimilar would not qualify for the 2 percentage point increase for any quarter during the applicable 5-year period in which the biosimilar’s ASP exceeds that of the reference product.

Sec. 11404. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program.

Under current law, the Part D low-income subsidy (LIS) program provides assistance with the costs of Part D premiums and cost-sharing (including deductibles) to Part D enrollees with incomes up to 150 percent of the federal poverty level (FPL). However, the degree of assistance varies based on income. Part D enrollees with incomes up to 135 percent of the FPL and lower resources receive full LIS benefits whereas those with income between 135-150 percent of the FPL and higher resources receive partial benefits.

Beginning with plan year 2024, full LIS benefits will be available to Part D enrollees with income between 135-150 percent of the FPL and higher resources, and the partial LIS benefit will be eliminated.

Sec. 11405. Improving Access to Adult Vaccines Under Medicaid and CHIP.

This section adds a mandatory Medicaid benefit with no cost sharing for approved adult vaccines (and their administration) recommended by ACIP. This mandatory benefit is also added to the State Children’s Health Insurance Program (CHIP) for individuals age 19 or older.¹⁸

The Medicaid and CHIP changes made by this section will take effect on October 1, 2023.

Since 2013, such vaccines were an optional Medicaid benefit for which states could obtain a 1 percentage point increase in their federal Medicaid matching rate—that is, the federal medical assistance percentage (FMAP). States that had implemented this optional Medicaid benefit with no cost sharing as of August 16, 2022, will continue to receive the 1 percent FMAP increase for another 8 fiscal quarters once the mandatory requirement begins (i.e., October 1, 2023, through September 30, 2025). Otherwise, the state’s regular FMAP applies.

¹⁸ Adults age 19 and older may be eligible for CHIP-funded coverage in a state covering pregnant women under either the state plan option for targeted low-income pregnant women (§2112) or through continuation of an existing 1115 waiver.

Sec. 11406. Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D.

Insulin and related supplies are covered under Part D with the exception of insulin that is administered through an infusion or inhalation pump, which is covered under Part B. Insulin covered under Part D is subject to the Part D deductible and applicable cost-sharing.

Starting with the 2023 plan year and for subsequent plan years, the deductible is waived for covered insulin products under Part D.

Also starting in 2023 and for succeeding years, cost-sharing for Part D covered insulin products will be capped. This will apply notwithstanding the Part D benefit redesign summarized in Part 3 above. For plan years 2023, 2024, and 2025, the monthly cost-sharing that may be charged to Part D enrollees for covered insulin products is capped at \$35. For plan years beginning after 2025, the monthly cost-sharing will be capped at the lowest of the following:

- \$35;
- 25 percent of the maximum fair price under the Drug Price Negotiation Program; or
- 25 percent of the negotiated price under the PDP or MA-PD plan.

For the first three months of 2023, the PDP or MA-PD plan must reimburse a Part D enrollee for monthly cost-sharing charged in excess of \$35 for the month's supply at the point of sale. The cost-sharing caps also apply under the LIS benefits program.

The federal government will provide a temporary, retrospective subsidy to plans for 2023 to offset aggregate reductions in cost-sharing and deductibles by reason of these changes. The subsidy payment will be made no later than 18 months after the end of the plan year (i.e., by June 30, 2025).

Implementation for plan years 2023, 2024, and 2025 will be done by program instruction or other program guidance. For fiscal year 2022, \$1.5 million is appropriated to carry out the policy, which remains available until expended.

Sec. 11407. Limitation on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment.

As noted in the previous section, insulin that is administered through an item of durable medical equipment (i.e., an infusion or inhalation pump) is covered under Part B. This insulin is subject to applicable cost-sharing, namely the deductible and a 20 percent coinsurance of the payment amount determined using the average sales price methodology.

Starting in July 2023, no deductible will apply to the costs of insulin furnished through covered durable medical equipment, and the beneficiary will not be required to pay more than \$35 for a month's supply of that insulin.

Payment amounts that would otherwise be made to suppliers will be adjusted to reflect the \$35 monthly cap on beneficiary cost-sharing.

Implementation for 2023 will be done by program instruction or other program guidance.

Sec. 11408. Safe Harbor for Absence of Deductible for Insulin.

Section 223 of the Internal Revenue Code of 1986 permits an income tax deduction for contributions to a health savings account with respect to high deductible health plans. The definition of high deductible health plan is amended to ensure that not applying the deductible with respect to insulin under the plan will not disqualify the plan from being treated as a high deductible health plan. This rule (referred to as a safe harbor) is similar to the special treatment for the nonapplication of the deductible for preventive care or for health care services furnished through telehealth or other remote care during the COVID-19 public health emergency under high deductible health plans.

Insulin is defined as any dosage form (such as vial, pump, or inhaler dosage forms) of any different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin.

The safe harbor applies for plan year 2023 and each subsequent plan year.

Subtitle C—Affordable Care Act Subsidies

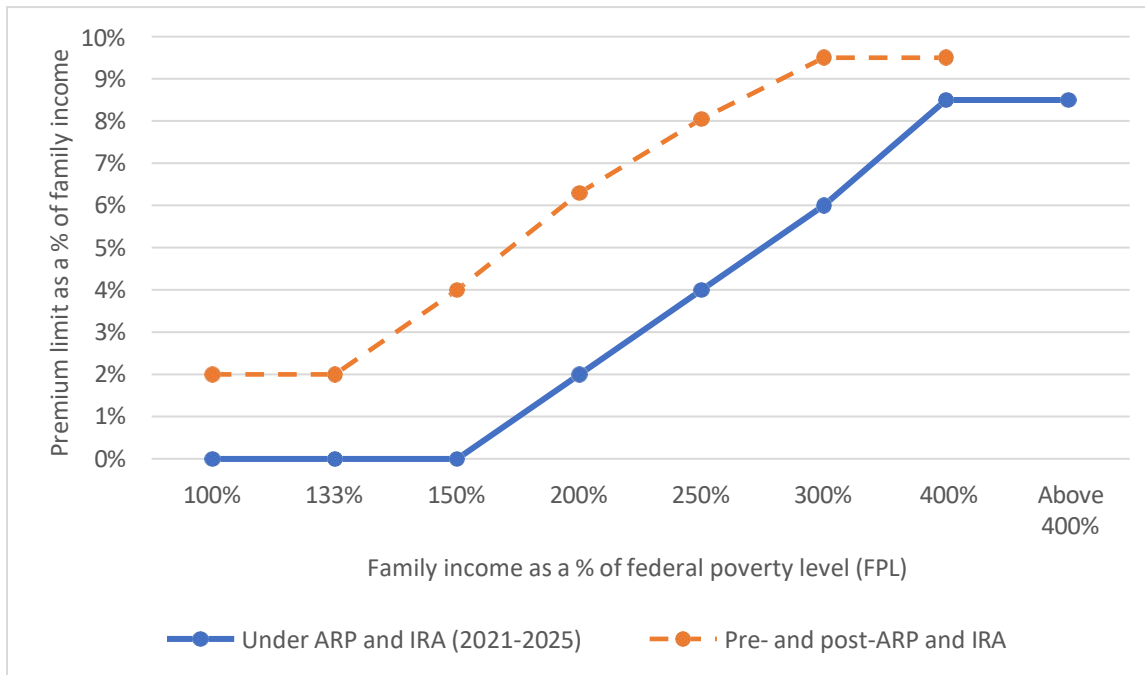
Sec. 12001. Improve Affordability and Reduce Premium Cost of Health Insurance for Consumers.

The American Rescue Plan Act of 2021 (ARP, P.L. 117-2) was signed into law on March 11, 2021, and temporarily increased the premium assistance for individuals purchasing health insurance coverage through health insurance Exchanges for taxable years 2021 and 2022:

- The amount of premium tax credit was increased for individuals with income below 400 percent of the federal poverty level (FPL).
 - For example, those with income between 300 and 400 percent FPL qualify for premium subsidies that limit their premiums to between 6 and 8.5 percent of income (respectively) for the second lowest cost silver metal-level plan available in their area, rather than 9 percent of income.
 - Those with income below 150 percent FPL qualify for premium subsidies that cover the full amount of the second lowest cost silver metal-level plan available in their area, rather than between 2 percent and 3 percent of income, depending on their income.
- Premium tax credits were made available for the first time for individuals with income above 400 percent FPL—to the extent that their health insurance premium for the second lowest cost silver metal-level plan exceeds 8.5 percent of their income. Previously premium tax credits were not available for individuals with income above 400 percent FPL.

The IRA extends these ARP premium-subsidy provisions (Figure 1) for 3 additional years, through tax year 2025.

Figure 1. Maximum out-of-pocket premium payment for second lowest cost silver plan in a health insurance Exchange, by family income as percentage of federal poverty level (FPL)



Source: HPA analysis of 36B of the Internal Revenue Code, including as amended by the American Rescue Plan Act of 2021 (ARP) and the Inflation Reduction Act of 2022 (IRA).

Note: In the 48 contiguous states in 2022, 100% FPL is \$13,590 for an individual and \$4,720 for each additional person.