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Congress Passes Prescription Drug Pricing Reform

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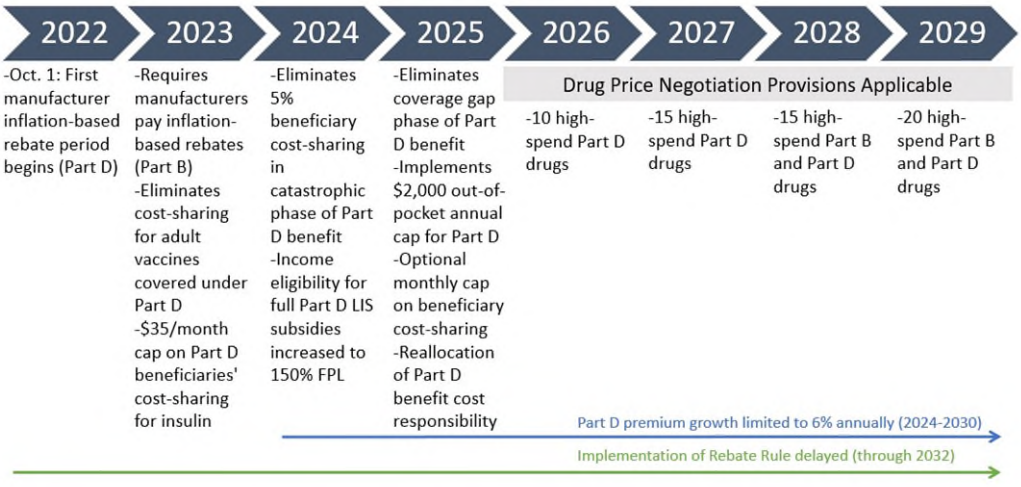
Public Policy, Health Care, Food, Drug, and Device

On Friday, August 12, 2022, the U.S. House of Representatives passed the Inflation Reduction Act ("IRA"), which includes provisions for "Prescription Drug Pricing Reform." Once implemented, these provisions will represent significant changes to how certain drug products are priced and paid for under Medicare, including by authorizing price-capped "negotiation" for certain high-spend drugs and mandating inflation-based rebates for Medicare utilization. The IRA also redesigns the Medicare Part D benefit to restructure manufacturer, federal government, and plan obligations, as well as set forth cost-sharing limits for patients, among other provisions.

The Prescription Drug Pricing Reform provisions in the IRA reflect, with meaningful modifications, prior proposals dating back to the House-passed bills, H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, and the Build Back Better Act ("BBBA"), as well as drug pricing reform bills released by the Senate Finance Committee. This client alert summarizes the provisions in the IRA related to Prescription Drug Pricing Reform: Part 1—Drug Price Negotiation; Part 2—Prescription Drug Inflation Rebates; Part 3—Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries; Part 4—Continued Delay of Implementation of Prescription Drug Rebate Rule; and Part 5—Miscellaneous.

Implementation Timeline of Prescription Drug Pricing Reform Provisions in the Inflation Reduction Act



I. Prescription Drug Pricing Reform Provisions

Part 1: Drug Price Negotiation

Part 1 of the Prescription Drug Pricing Reform provisions adds a new Part E to Title XI of the Social Security Act ("SSA"), providing for a "Price Negotiation Program to Lower Prices for Certain High-Priced Single Source Drugs" to set the price for certain Medicare Part B and Part D drugs by "negotiation." Under this new program, the Secretary of the U.S. Department of Health and Human Services ("HHS") would be required to (i) publish lists of selected drugs; (ii) enter into agreements with manufacturers regarding the negotiation and renegotiation process and access to the negotiated maximum fair price; (iii) negotiate maximum fair prices for selected drugs; and (iv) carry out applicable publication and administrative duties and compliance monitoring for the program.

The IRA sets the first initial price applicability year as 2026 for high-spend Part D products and 2028 for high-spend Part B products. The negotiation timeline for selected Part D and Part B drugs will proceed as follows:

	Initial Price Applicability Year 2026 **(Part D Only)**	**Initial Price Applicability Year 2027** **(Part D Only)**	**Initial Price Applicability Year 2028** **(Parts B and D)[1]**
HHS announces selected drugs[2]	Sept. 1, 2023	Feb. 1, 2025	Feb. 1, 2026
Manufacturers enter into negotiation agreements	Oct. 1, 2023	Feb. 28, 2025	Feb. 28, 2026
Negotiation period concludes	Aug. 1, 2024	Nov. 1, 2025	Nov. 1, 2026
HHS publishes maximum fair price	Sept. 1, 2024	Nov. 30, 2025	Nov. 30, 2026
HHS publishes explanation for the maximum fair price	Mar. 1, 2025	Mar. 1, 2026	Mar. 1, 2027
Maximum fair price effective	Jan. 1, 2026	Jan. 1, 2027	Jan. 1, 2028

[1] These relative timeframes hold for 2029 onward (e.g., HHS will announce selected drugs February 1 of the year that is two years before the Initial Price Applicability Year, et cetera).

[2] For certain biologics, if the Secretary determines there is a high likelihood of biosimilar launch prior to publishing the list of selected drugs, the Secretary may "pause" selection of the biologic.

The negotiation program includes the following provisions:

- Selection: The Secretary generally must rank negotiation-eligible drugs based on the total expenditures under Part B and Part D during the 12-month period ending on October 31 of the preceding year. The Secretary must select from among the negotiation-eligible drugs, which are the those qualifying single source drugs (discussed below) that are among the top 50 in Part B or Part D spending. The Secretary will select 10 negotiation-eligible Part D drugs in 2026 and 15 negotiation-eligible Part D drugs in 2027 based on Part D expenditures. Starting in 2028, Part B drugs are included in the selection, and the Secretary must select a total of 15 negotiation-eligible drugs in 2028 and 20 negotiation-eligible drugs in 2029 and each subsequent year.
- Eligibility: To be eligible for selection, a product must be a qualifying single source drug, meaning: (i) for drug products, the drug is approved under Section 505(c) of the FDCA, at least 7 years have elapsed since the date of such approval, and the drug is not the listed drug for a generic approved and marketed under Section 505(j); or (ii) for biologic products, the biologic is licensed under Section 351(a) of the PHSA, 11 years have elapsed since licensure, and the biologic is not the reference product for a biosimilar approved and marketed under Section 351(k). The IRA exempts certain small biotech drugs, low-spend drugs, orphan drugs, and plasma-derived products from the negotiation process.
- Negotiation: While the IRA provides for "negotiation" of a maximum fair price for selected drugs, the negotiated maximum fair price is subject to a ceiling. Specifically, the maximum fair price may not exceed the lower of:

    (i) The "applicable percent" of the non-FAMP for 2021, adjusted for inflation (for 2027 and subsequent years, if the non-FAMP for the year before the selected drug publication date is lower than the inflation-adjusted non-FAMP, that non-FAMP would apply); or

    (ii) Medicare payment rates (i.e., for Part D drugs, the average negotiated price under Part D plans net of all price concessions received by such plans or pharmacy benefit managers ("PBMs") on behalf of such plans for the drug under Part D for the most recent year for which data are available; for Part B drugs, the payment amount under SSA § 1847A(b)(4) for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug).

    The "applicable percent" used in determining the maximum fair price ceiling varies based on how much time has elapsed between the approval of the drug and the year in which the maximum fair price is to take effect, as follows:

    (i) "Short-monopoly drugs" (9 to <12 years elapsed since approval, in addition to vaccines) would be 75 percent of the non-FAMP.

    (ii) "Extended-monopoly drugs" (12 to <16 years elapsed since approval or selected drugs with a negotiation agreement in place for an initial price applicability year before 2030), would be 65 percent of the non-FAMP.

    (iii) "Long-monopoly drugs" (≥16 years elapsed since approval) would be 40 percent of the non-FAMP.

    HHS must make offers and counteroffers based on statutorily enumerated factors.

- Exit Based on Generic/Biosimilar Launch: A drug's status as a selected drug will be affected by the launch of a generic or biosimilar product. If the Secretary determines that a generic or biosimilar product has launched during the negotiation period, the product exits the negotiation program. Otherwise, a drug is a selected drug for the initial price applicability year and "each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary" determines entry of a generic or biosimilar product. Accordingly, the timing of the generic or biosimilar launch (as determined by the Secretary) will affect whether and when a drug may exit the program. If the launch occurs after the negotiation period, the innovator product will be selected and have a maximum fair price in place for at least the initial price applicability year. If the launch occurs prior to or within the first 3 months of the initial price applicability year (i.e., at least 9 months prior to the subsequent year), the innovator product will exit the program the subsequent year. If the launch occurs within 9 months of the start of the subsequent year, the innovator product will exit the program the year after the subsequent year.
- "Pause" Provisions: For certain biologics that are considered extended-monopoly drugs, the Secretary may "pause" selection of a reference biological product, upon request from a biosimilar manufacturer. The Secretary may authorize an initial one-year pause for such products if there is a high likelihood of biosimilar launch in the subsequent two years. If the biosimilar is not licensed and marketed over the course of the year, the Secretary may defer selection of the reference product for an additional year if the Secretary determines that "there is a high likelihood" of biosimilar launch within that year and, based on "clear and convincing evidence," the manufacturer of such biosimilar has made "a significant amount of progress" toward launch. If biosimilar launch does not occur during the pause, the reference product will become a selected drug and its sponsor must pay a rebate based on the maximum fair price that would have applied had the biologic gone through negotiation. Certain limitations would render the pause provisions inapplicable, including: (i) where a biosimilar has been licensed for more than one year without launch; (ii) where the biosimilar and reference product have the same manufacturer; or (iii) where the biosimilar manufacturer has entered into an agreement with the reference product manufacturer that requires or incentivizes the biosimilar manufacturer to submit a request for a pause, or that "directly or indirectly" restricts the quantity of biosimilar products that may be sold in the U.S. over a specified period of time.
- Price Reporting: The IRA requires that maximum fair prices be included in best price calculations and excluded from average manufacturer price calculations. The IRA also provides for non-duplication with 340B ceiling prices, meaning that manufacturers "shall be required to provide access to the maximum fair price" to 340B covered entities where the maximum fair price is below the 340B ceiling price. The bill does not address whether the maximum fair price is considered in the calculation of average sales price.
- Excise Tax: The IRA imposes an escalating excise tax on manufacturers, producers, and importers for sales of a "designated drug" on any day of non-compliance with the negotiation process (i.e., failure to enter a negotiation agreement, to negotiate or renegotiate a maximum fair price, or to provide required information). A "designated drug" is one included on the Secretary's list of drugs selected for negotiation and which is manufactured or produced in the U.S. or entered into the U.S. for consumption, use, or warehousing. The tax on each sale of the drug during a period of non-compliance is calculated based on the specified "applicable percentage" for a particular day of non-

compliance. For sales on a day during the non-compliance period, the tax levied is in an amount such that the relevant applicable percentage equals (1) the tax, divided by (2) the sum of the tax and the "price for which" the drug was "sold". The applicable percentage starts at 65 percent for the first 90 days of non-compliance and increases by 10 percent every 90 days to a maximum of 95 percent. Resulting daily tax rates on sales during a particular period range from 186% to 1900% of the sales price. The tax is suspended for sales during a period when the manufacturer has filed notices of termination of all "applicable agreements" with HHS (i.e., Medicaid Drug Rebate Program agreements, as well as Medicare Coverage Gap and Manufacturer Discount Program agreements), *and* when no drugs of the manufacturer are "covered by" a Medicare Coverage Gap or Manufacturer Discount Program agreement, thus essentially requiring the manufacturer to cease participation in Medicare Part D and Medicaid in order to suspend the tax. However, given the notice requirements for terminating a discount agreement, it could take significant time for a suspension to take effect. The IRA also sets forth an anti-abuse rule that allows the Secretary discretion to deem a sale timed to avoid the excise tax as having occurred during the noncompliance period (and thus as subject to the tax).

- Other Provisions: The IRA also sets forth administrative duties and compliance monitoring, civil monetary penalties, funding, and certain limitations on administrative or judicial review.

Beyond the negotiation program, "selected drug" status may change the application of other Prescription Drug Pricing Reform provisions in the IRA. For example, manufacturers may not owe rebates for selected drugs for the years in which the negotiation program is in effect. For selected drugs that exit the negotiation program, inflation-based rebates would be benchmarked to the maximum fair price from the last year of the price applicability period under the negotiation program. With respect to the Part D redesign provisions, selected drugs would not be subject to discount obligations under the new manufacturer discount program; instead, the government would subsidize the obligations selected drug manufacturers otherwise would have owed under the program.

Part 2: Prescription Drug Inflation Rebates

Part 2 of the Prescription Drug Pricing Reform provisions requires manufacturers to pay inflation-based rebates for Part B and Part D utilization of certain drugs and biologics with price increases higher than inflation. The IRA implements these provisions for years beginning October 1, 2022, for Part D utilization, and for quarters beginning January 1, 2023, for Part B utilization. Although the House-passed BBBA had contemplated inflation-based rebates for all Medicare and commercial (i.e., non-Medicaid) utilization, application to commercial utilization was removed from the bill following the parliamentarian's determination that the provision violated the Byrd Rule. Accordingly, under the IRA, the inflation-based rebates apply only to Medicare utilization.

The provisions set forth special considerations for drugs that are listed on the Food and Drug Administration's ("FDA's") shortage list, biosimilar products in the event of supply chain disruptions, drugs recently approved or licensed by FDA, and selected drugs that have exited the negotiation program. Manufacturers that fail to make the required inflation rebate payments would be subject to civil penalties of "at least " 125 percent of the Part B rebate owed or "equal to" 125% of the Part D rebate owed. The IRA sets forth limitations on administrative and judicial review with respect to the determination of whether a drug is a Part B or Part D rebatable drug,

the calculation of the rebate amount, and the determination of units of the Part B or Part D rebatable drug.

Part 3: Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries

Part 3 of the Prescription Drug Pricing Reform provisions implements certain changes to the Medicare Part D benefit, including redesigning the Part D benefit and giving beneficiaries the option of a monthly cap on cost-sharing. The IRA modifies "standard" Part D benefit as follows:

- Eliminates the Coverage Gap: Once a Part D beneficiary meets the deductible, the beneficiary is eligible for coverage with a 25 percent coinsurance until the beneficiary has incurred costs meeting the annual out-of-pocket threshold. This provision thus effectively eliminates the coverage gap. This provision is effective in 2025.
- Establishes Lower Annual Out-of-Pocket Threshold: Effective in 2025, the annual out-of-pocket threshold for beneficiaries will be $2,000, subject to annual percentage increases. Once a beneficiary reaches this $2,000 threshold, the beneficiary enters the catastrophic phase.
- Eliminates Beneficiary Cost-Sharing in the Catastrophic Phase: Previously, once a Part D beneficiary entered the catastrophic phase, the beneficiary was responsible for cost-sharing of up to five percent. The IRA eliminates beneficiary cost-sharing in the catastrophic phase, starting in 2024.
- Reallocates Cost Responsibility: The IRA reallocates responsibility for costs in the catastrophic phase. Plans' responsibility rises from 15 percent to 60 percent. The remaining 40 percent will be the responsibility of Medicare (for drugs not subject to the new manufacturer discount program) or will be split evenly between Medicare and manufacturers for drugs subject to the discount program. This is effective in 2025.
- Stabilizes Premiums: The annual beneficiary premium cannot increase by more than six percent each year from 2024 to 2030.
- Requires Plans to Offer a Monthly Cap on Beneficiary Cost-Sharing: The IRA permits beneficiaries to pay cost-sharing in monthly installments, thus allowing the beneficiary to spread outstanding costs evenly across the remaining months in the plan. This is effective in 2025.

Part 4: Continued Delay of Implementation of Prescription Drug Rebate Rule

Part 4 of the Prescription Drug Pricing Reform provisions delays until January 1, 2032, the implementation of the "Rebate Rule," which would revise the discount safe harbor to eliminate protection for discounts from manufacturers to Part D plan sponsors and PBMs acting on sponsors' behalf. The discount safe harbor would continue to protect discounts offered to other entities, such as wholesalers, hospitals, physicians, pharmacies, and third-party payers in other federal health care programs, and new protections would be available for discounts offered by manufacturers on prescription drugs at the point of sale.

The Rebate Rule has been subject to legal challenge and regulatory implementation delays. In 2021, Congress delayed the implementation date to January 1, 2026, as part of the Infrastructure Investment and Jobs Act. In 2022, Congress delayed the implementation date to January 1, 2027, as part of the Bipartisan Safer Communities Act. Although the BBBA had

proposed repealing the Rebate Rule altogether, the IRA provides for a further implementation delay.

Part 5: Miscellaneous

Part 5 of the Prescription Drug Pricing Reform provisions sets forth miscellaneous provisions related to: (i) coverage of adult vaccines recommended by the Advisory Committee on Immunization Practices under Part D; (ii) payment for biosimilars under Part B during the initial period when average sales price data are unavailable; (iii) a temporary increase in payment under Part B for certain biosimilars; (iv) expanding eligibility for low-income subsidies under Part D; (iv) improving access to adult vaccines under Medicaid and the Children's Health Insurance Program; and (v) limiting cost-sharing for covered insulin products for Medicare beneficiaries, and providing a safe harbor for high deductible health plans that fail to have a deductible for certain insulin products.

With respect to the insulin cost-sharing provisions, effective in 2023, the IRA caps insulin cost-sharing at $35 per month for Medicare beneficiaries. The IRA originally included a proposal to cap cost-sharing for insulin products at $35 for both Medicare and commercial beneficiaries, but the Senate parliamentarian determined that the cap for commercial beneficiaries violated the Byrd Rule.

II. Implementation

While the IRA effects potentially significant changes to Medicare reimbursement for drug products, the full effect of the new provisions will depend in meaningful part on the details of HHS's implementation. Many provisions will require HHS rulemaking, and the rulemaking process will provide opportunities for stakeholders to weigh in on the nuances of implementation. Additionally, certain provisions may be the subject of legal challenges.

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