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Congress Paves the Way for Drug Pricing Reforms with Passage of the Inflation Reduction Act of 2022

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On August 12, congressional Democrats capped off a years-long legislative campaign with the House of Representatives' passage of the Inflation Reduction Act of 2022 (the "IRA" or the "Bill").[1] The wide-ranging legislation, which passed the Senate earlier this month through the budget reconciliation process by way of a party-line vote, includes several major health care provisions related to drug pricing and the Affordable Care Act ("ACA"). The Bill now awaits the signature of President Joe Biden, whose administration claims the new law will lower the costs of prescription drugs, reduce federal health care spending, and lock in lower insurance premiums for millions of Americans.[2]

While the IRA generally incorporates many of the drug pricing concepts proposed in earlier reconciliation measures offered by congressional Democrats, including the Build Back Better Act last year, the Bill's actual provisions reflect a notably scaled-back version of prior iterations. The Bill's most important health care provisions include (1) establishing a new program for Medicare to directly negotiate prices with pharmaceutical manufacturers for certain high-spend Medicare drugs, with stiff penalties for companies that refuse; (2) requiring manufacturers to pay rebates on drugs reimbursed under Medicare Parts B or D for which average (i.e., net) prices increase faster than inflation; (3) revamping the Medicare Part D benefit, including establishing an annual out-of-pocket cap for beneficiary cost-sharing on prescription drugs and eliminating patient cost-sharing in the catastrophic phase; (4) delaying the effective date of the November 2020 Anti-Kickback Statute ("AKS") final rule removing safe harbor protection for prescription drug rebates until 2032; and (5) extending temporary expanded health insurance subsidies for ACA plans through 2025.

This Alert summarizes the Bill's key health care provisions and analyzes their implications for the life sciences and health care industries.

I. Drug Price Negotiation Program

The Bill establishes a Drug Price Negotiation Program ("Program") to be administered by the Secretary of Health and Human Services ("HHS").[3] This Program will seek to lower via government negotiation the prices of certain Medicare Part B and Part D drugs without competition, starting in 2026. Through this Program, the Secretary must (1) publish a list of selected drugs, (2) enter into agreements with manufacturers of those drugs, (3) negotiate and, where applicable, renegotiate "maximum fair prices" for selected drugs that will apply to Medicare Parts B and D, and (4) monitor and enforce compliance, including through new civil monetary penalties and excise taxes.

A. Selection of Negotiation-Eligible Drugs

Each year, starting in 2026, a new cohort of Medicare-covered drugs will be subject to a negotiated price. Specifically, the Secretary must select for negotiation 10 Part D drugs for the initial 2026 price applicability year, 15 Part D drugs for 2027, 15 Part B or Part D drugs for 2028, and 20 Part B or Part D drugs for 2029 and each subsequent year. These negotiation-eligible drugs must be selected from the 50 Part B drugs and 50 Part D drugs with the highest Medicare program expenditures over the preceding 12-month period. By September 1, 2023, the Secretary must publish the initial list of drugs that will be subject to negotiated prices in 2026. Subsequently, the list must be published by February 1 of the year that is two years before the price applicability year at issue (e.g., the Secretary will choose and publish the 15 Part B or Part D drugs to be subject to a maximum fair price in 2028 by February 1, 2026).

Generally, a negotiation-eligible drug means a single source pharmaceutical product that is either (1) an FDA-approved drug for which at least seven years have elapsed since the date of its approval and for which there is no generic on the market, or (2) an FDA-licensed biologic for which at least 11 years have elapsed since licensure and for which there is no biosimilar on the market. An authorized generic drug does not count as a generic or biosimilar on the market for the purposes of this definition. Further, the Bill excludes the following categories of products from being eligible for price

negotiation: (1) qualifying orphan drugs (i.e., designated as a drug for only one rare disease or condition and for which the only approved indication is for that disease or condition); (2) "low spend Medicare drugs"; (3) plasma-derived products; and (4) for 2026 through 2028, "small biotech drugs," which refer to drugs with total 2021 Part B or Part D expenditures that constitute (1) no more than 1% of the total 2021 expenditures for drugs of all manufacturers and (2) at least 80% of total 2021 expenditures for all drugs of a manufacturer, subject to certain exceptions.

B. Negotiation and Renegotiation Process

The negotiation timeline to determine a maximum fair price for the selected drugs is generally expected to last seven months and will occur two years prior to the year that the negotiated price goes into effect (except for the initial price applicability year of 2026, which will require a different schedule), as set forth below.

- February 1: As noted above, the Secretary will select and publish the list of drugs by February 1 of the year that is two years prior to the price applicability year (or by September 1, 2023 for 2026).
- February 28: Once the Secretary publishes the list, manufacturers of selected drugs are required to enter into an agreement to negotiate the price of the drug by February 28 (October 1, 2023 for 2026).
- March 1: During the negotiation period, the manufacturer must submit the product's non-Federal Average Manufacturer Price ("non-FAMP") and any "information that the Secretary requires to carry out the negotiation" by March 1 (October 2, 2023, for 2026).
- June 1: In response to information submitted by the manufacturer, the Secretary must provide a written initial offer by June 1 (February 1, 2024 for 2026). After receiving the initial offer, the manufacturer has 30 days to accept the proposed price or submit a counteroffer.
- November 1: All negotiations must conclude and a maximum fair price must be agreed to by November 1 (August 1, 2024 for 2026).[4] The Secretary ultimately will publish the agreed-upon maximum fair price for each drug.

In negotiating or renegotiating the maximum fair price, the Secretary must consider the following factors: (1) manufacturer research and development costs, including the extent to which such costs have been recouped and to which the manufacturer received federal financial support; (2) current unit costs of production and distribution; (3) information on pending and approved patents and FDA exclusivities; (4) market, revenue, and sales volume data; and (5) evidence regarding alternative treatments and comparative effectiveness. To the extent this information, or any non-FAMP data, includes proprietary information, the Bill requires that it be used only by the Secretary or disclosed to the Comptroller General for purposes of carrying out the Program.

The Secretary and the manufacturer ultimately must agree to a maximum fair price equal to or less than the statutorily defined ceiling price. For each product, the ceiling price will equal a defined percentage of the lowest of the following figures:

1. The product's average non-FAMP for 2021 (or, where there is no average non-FAMP available for 2021, for the first full year following market entry), as increased by the consumer price index for all urban consumers ("CPI-U") from September 2021 (or December of the first full year following market entry) to September of the year prior to the selected drug publication date (i.e., the year the drug is selected by the Secretary and negotiations begin);
2. For drugs with an initial price applicability year of 2027 or later, the average non-FAMP for the year prior to the selected drug publication date; or

3. An amount equal to:

    a. For Part D-covered products, the sum of the plan-specific enrollment weighted net negotiated price amounts for each prescription drug plan or Medicare Advantage prescription drug plan for the most recent year for which data is available; or

    b. For Part B-covered products, the lesser of the Average Sales Price ("ASP") or Wholesale Acquisition Cost ("WAC") for the year prior to the year of the selected drug publication date.

The applicable percentage noted above is determined based on how long the product has been on the market: (1) 40% for "long-monopoly drugs," which are products where more than 16 years have elapsed since the date of FDA approval; (2) 65% for "extended-monopoly drugs," where more than 12 but less than 16 years have elapsed since the date of FDA approval; and (3) 75% for "short-monopoly drugs," which includes all other products.[5]

There are several implications once a negotiated price is established. First, the maximum fair price will be adjusted and increased by CPI-U each year. Second, starting in 2028, the Secretary can select drugs for renegotiation. Renegotiation is mandatory if a selected drug graduates to extended-monopoly or long-monopoly drug status. The Secretary also has the option to commence renegotiations if a selected drug receives a new indication or there is a material change in the factors considered by the Secretary in setting the initial negotiated price. A selected drug's negotiated price (as renegotiated when applicable) will remain in place until a generic or biosimilar is launched, in which case the selected drug's maximum fair price would terminate at the start of the first year that begins nine months after the generic or biosimilar has entered the market.

C. Compliance and Enforcement Mechanisms

To drive manufacturers to the negotiating table and compel them to agree to maximum fair prices at or below the statutory price ceiling, the IRA imposes substantial excise taxes on manufacturers that do not (1) timely enter into negotiation, (2) timely submit the requisite information to the Secretary, or (3) timely agree to an initial or renegotiated maximum fair price at or under the applicable price ceiling. The excise tax equals a specified percentage of the price of all sales during the period of noncompliance. The applicable percentage equals 65% for the first 90 days of noncompliance, 75% for the 91st through 180th day, 85% for the 181st through 270th day, and 95% for all days thereafter. The tax does not apply during any period in which the manufacturer has terminated its Medicare Part D Coverage Gap Discount Program agreement (or, as discussed further in section III, the new Medicare Part D manufacturer discount program agreement starting in 2025) and its Medicaid Drug Rebate Program ("MDRP") agreement; however, manufacturers that terminate such agreements would lose any benefits of participation in those particular programs.

Further, the Secretary is charged with monitoring compliance by a manufacturer with the terms of the agreement and must establish a mechanism through which violations will be reported. Manufacturers may be subject to civil monetary penalties for (1) failing to offer the maximum fair price, (2) violating the terms of the negotiation agreement, and (3) knowingly providing false information. With respect to violations related to not offering the maximum fair price, civil monetary penalties will be equal to 10 times of: the product of (the number of units of the drugs furnished, dispensed, or administered during such year), and (the difference between the price of the drug made available for such year and the maximum fair price for the drug for such year).

D. Limitation on Administrative and Judicial Review

The Bill precludes administrative and judicial review of the Secretary's selection of drugs subject to the Program, the determination of maximum fair prices, and the determination of renegotiation-eligible drugs.

E. Implications for Federal Health Care Programs and Manufacturer Price Reporting Obligations

As a result of the Program, the payment amount under Part B for selected drugs will be 106% of the maximum fair price, while the negotiated price for Part D drugs will be no greater than the maximum fair price, plus any dispensing fee for such drug. Further, starting in 2026, all Part D plans must include in their formularies each covered Part D drug that is a selected drug – potentially limiting existing market competition within those therapeutic classes. With respect to the MDRP and government price reporting, a manufacturer will have to account for the maximum fair price in its calculations of Best Price, but not in its calculations of Average Manufacturer Price ("AMP").

II. Prescription Drug Inflation Rebates

The Bill also requires manufacturers to pay rebates for certain drugs paid under Medicare Parts B or D if their average prices increase faster than inflation.[6] While the original bill applied the rebate policy to drugs paid for through private insurance as well, the proposal was removed from the final Bill following a ruling by the Senate parliamentarian that it would violate budget reconciliation rules. Inflation rebates therefore will be based only on Medicare utilization, although it is possible that the existence of inflation rebates in Medicare could have spillover effects in other market segments.

A. Medicare Part B Rebate

The Bill requires rebates to be paid by manufacturers of certain drugs paid for under Medicare Part B that have price increases that outpace the rate of inflation. Not later than six months after the end of each calendar quarter beginning on or after January 1, 2023, the Secretary must, for each Part B rebatable drug, report to each manufacturer the total number of units paid during the relevant period, the excess increase in average sales price relative to the inflation rate, and the rebate amount due. Subsequently, no later than 30 days after the date of receipt, manufacturers must pay the specified quarterly rebate for any applicable Part B drug. To provide a transitional period to implement the program, the Bill allows the Secretary to delay reporting this information and collecting rebates for the first two years (2023 and 2024) until not later than September 30, 2025.

A Part B rebatable drug means a single source drug or biologic, as defined in Section 1847A(c)(6)(D) of the Social Security Act ("SSA"), including biosimilars (except for qualifying biosimilar biologic products, as defined in section 1847A(b)(8)(B)(iii) of the SSA), but excluding vaccines and low Medicare spend drugs. The rebate will be calculated as the total number of Medicare Part B units of the drug utilized in the rebate quarter, excluding 340B units, multiplied by the amount by which the rebate quarter Part B payment rate exceeds the inflation-adjusted benchmark quarter Part B payment rate. The inflation-adjusted payment amount for a Part B rebatable drug for a calendar quarter is the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter, increased by the percentage by which the rebate period CPI-U exceeds the CPI-U for January 2021. For drugs approved by the FDA after December 1, 2020, the manufacturer rebate requirement begins to apply on the later of the sixth full calendar quarter after the day on which the drug was first marketed or January 1, 2023.

The Secretary may establish a civil monetary penalty for manufacturer noncompliance equal to at least 125% of the applicable rebate. The Bill precludes administrative and judicial review of the determination of rebate units, rebate calculations, or whether a drug qualifies as a Part B rebatable drug.

Part B rebates are excluded from manufacturer calculations of ASP, Best Price and AMP.

B. Medicare Part D Rebate

The Bill also requires rebates for certain Part D drugs with average price increases that exceed the rate of inflation. Whereas Part B rebates are calculated and paid on a quarterly basis, the Part D rebates are calculated and paid on an

annual basis, with the applicable period each year measured from October 1 to September 30. Not later than nine months after the end of each applicable period, starting with the one-year period that begins on October 1, 2022, the Secretary must, for each Part D rebatable drug, report to manufacturers the amount of any excess annual price increase for each dosage form and strength and the rebate amount due for qualifying drugs. Subsequently, no later than 30 days after the date of receipt from the Secretary, the manufacturer of each Part D rebatable drug must provide a rebate equal to the determined amount. As with the Part B rebates, the Part D provisions provide for a transition period. For each rebatable covered Part D drug, the Secretary may delay reporting this information and requiring payment of the rebate amounts due for the first two years (i.e., October 1, 2022 through September 30, 2024) until not later than December 31, 2025.

The inflation rebate requirements apply to single source drugs and biologics paid under Medicare Part D, but exclude low Medicare spend products. Rebates will be calculated as the total number of Medicare Part D units of the drug dispensed in the rebate year, excluding 340B units (beginning in 2026), multiplied by the amount by which the volume-weighted AMP for the rebate year exceeds the inflation-adjusted volume-weighted AMP for the benchmark year. For new drugs approved after October 1, 2021, the benchmark year for the payment amount would be the first calendar year after the drug is first marketed and the inflation benchmark month would be January of that first calendar year.

If a manufacturer of a Part D rebatable drug fails to comply with the requirements set forth here, the Secretary may establish a civil monetary penalty for noncompliance equal to at least 125% of the applicable rebate. The Bill precludes administrative and judicial review of the determination of rebate units, rebate calculations, or whether a drug qualifies as a Part D rebatable drugs.

As is the case for the Part B rebates, the Part D rebates also will be excluded from ASP, Best Price, and AMP calculations.

III. Part D Benefit Redesign

Along with the provisions detailed above, the IRA also makes a number of changes to restructure the Medicare Part D benefit. Specifically, among other things, the Bill:

- Eliminates in 2024 the 5% beneficiary coinsurance requirement that currently applies in the catastrophic stage of the benefit and establishes an annual out-of-pocket cap of $2,000, beginning in 2025, beyond which beneficiaries will not bear any cost-sharing obligations;
- Permits beneficiaries to "smooth" out-of-pocket costs across the year on a monthly basis once the $2,000 cap goes into effect in 2025;
- Removes the coverage gap stage in 2025, leaving a Part D benefit that consists of an initial coverage phase (after the deductible is met) and a catastrophic phase;
- Creates a new manufacturer drug discount program to replace the current Coverage Gap Discount Program as of 2025 (under this new program, manufacturers must enter into agreements with Medicare to offer discounts of 10% in the initial coverage phase and 20% in the catastrophic phase on branded drugs, biologics, and biosimilars);
- Limits increases to beneficiary premiums from 2024 to 2030 to no more than 6% per year;
- Requires Part D plans to cover with no beneficiary cost-sharing all Part D-covered vaccines recommended by the Advisory Committee on Immunization Practices ("ACIP"), beginning in 2023 (vaccines covered by Medicare Part B, including those for influenza and COVID, are not affected by this change); and

- Caps Medicare beneficiaries' cost-sharing for approved insulin products at $35 per month, starting in 2023 (a similar provision to limit cost-sharing for insulin in commercial plans was stricken from the bill under the reasoning that it did not comply with budget reconciliation rules).

IV. Other Notable Health Care Provisions

Although more limited in scope with respect to health care issues than Democrats' prior proposed reconciliation legislation (e.g., the Build Back Better Act), the IRA nonetheless includes a handful of other notable health care provisions, including those summarized below.

- ***The AKS Rebate Rule***: The IRA further delays implementation of the AKS prescription drug rebate safe harbor final rule until January 1, 2032. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager ("PBM") service fees.[7] It originally was set to go into effect on January 1, 2022, but most recently had been delayed by Congress to January 1, 2027. This delay is likely to generate additional savings for the purposes of the IRA.

- ***Affordable Care Act Subsidies***: The Bill extends the temporary expanded health insurance subsidies through 2025 for individuals who buy health insurance through an ACA marketplace, including for taxpayers whose household income exceeds 400% of the Federal Poverty Level. Enacted as part of the American Rescue Plan Act, the enhanced subsidies otherwise would have expired at the end of 2022, likely resulting in premium increases in the individual insurance market.

- ***Vaccines***: In addition to the Medicare Part D vaccine reforms discussed above, the Bill also expands access to vaccines for adults in the Medicaid program by eliminating cost-sharing and offering a temporary 1% increase in federal Medicaid matching funds for states that already cover adult vaccine administration without cost sharing.

- ***Enhanced Payments for Biosimilars***: To incentivize the development and use of biosimilars, the Bill will temporarily increase the Medicare Part B add-on payment for certain biosimilars from 6% to 8% of the reference product's ASP from October 1, 2022 through the end of 2027. Additionally, for new biosimilars furnished on or after July 1, 2024, the Bill changes the initial period payment rate to be the lesser of the biosimilar's WAC plus 3% or 106% of the reference product's ASP.

- ***Medicare Low Income Subsidy ("LIS")***: Another provision expands low-income subsidies to Medicare beneficiaries below 150% of the Federal Poverty Level, beginning in 2024, increasing the current threshold from 135%.

V. Conclusion

The enactment of the IRA is poised to reshape drug pricing policy and the Medicare program as a whole in the years to come. While the effects of the Bill are yet to be seen, nonpartisan projections estimate the IRA may lower drug prices for some of the top-spending drugs covered by Medicare and produce savings for the Medicare program.[8] Although the Bill's drug pricing provisions do not directly impact non-Medicare market segments, these changes may have spillover effects to the commercial market (and potentially to drugs not directly subject to government negotiation requirements). As federal agencies begin to implement the law, they will need to undertake certain rulemaking, and issue subregulatory guidance, both of which are likely to introduce new legal, operational, and compliance challenges for pharmaceutical manufacturers and other parties to navigate.

Ropes & Gray will continue to analyze the implications of the new law and monitor the political and regulatory developments that will affect its implementation. If you have any questions, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

1. Inflation Reduction Act of 2022, H.R. 5376, 117th Cong. (2022), *available at* https://www.congress.gov/bill/117th-congress/house-bill/5376/text.
2. Office of Management and Budget, Statement of Administration Policy: H.R. 5376 – Inflation Reduction Act of 2022 (Aug. 6, 2022), *available at* https://www.whitehouse.gov/wp-content/uploads/2022/08/SAP-H.R.-5376.pdf.
3. The Drug Price Negotiation Program provisions are set to be codified and incorporated in federal statute after section 1184 of the SSA (42 U.S.C. 1320e-3).
4. The IRA allows the Secretary to delay negotiations, at its discretion, for a biologic that otherwise would have been selected for negotiation for one or two years where a biosimilar is expected to enter the market if (1) more than 12 but less than 16 years have elapsed since the biologic was approved by the FDA; (2) the biosimilar manufacturer requests such a delay from the Secretary; and (3) the Secretary determines that there is a high likelihood that the biosimilar will be licensed and marketed within two years after the biologic's selected drug publication date.
5. Additionally, for qualifying small biotech drugs with a first initial price applicability year of 2029 or 2030, the IRA establishes a temporary floor for the maximum fair price, which may not be less than 66% of the non-FAMP for 2021 (or, where there is no non-FAMP available for 2021, for the first full year following market entry).
6. The Prescription Drug Inflation Rebates provisions relating to Medicare Part B rebates will be inserted as a new subsection (i) within section 1847A of the SSA (42 U.S.C. 1395w-3a); the provisions relating to Medicare Part D rebates will be inserted after section 1860D-14A (42 U.S.C. 1395w-114a) as section 1860D-14B.
7. *See* Ropes & Gray's earlier alert on the safe harbor final rule: Ropes & Gray, Alert, *Cutting Out the Middleman? HHS Resurrects Anti-Rebate Rule for Medicare Part D* (Dec. 9, 2020), https://www.ropesgray.com/en/newsroom/alerts/2020/12/Cutting-Out-the-Middleman-HHS-Resurrects-Anti-Rebate-Rule-For-Medicare-Part-D.
8. *See, e.g.,* Juliette Cubanski, Nolan Sroczynski, and Tricia Neuman, Kaiser Family Foundation, "Simulating the Impact of the Drug Price Negotiation Proposal in the Build Back Better Act" (Jan. 27, 2022), *available at* https://www.kff.org/medicare/issue-brief/simulating-the-impact-of-the-drug-price-negotiation-proposal-in-the-build-back-better-act/ (finding that the IRA's predecessor bill could help to lower drug prices for some of the top-spending drugs covered under Medicare Parts B and D).