THORN RUN PARTNERS
GOVERNMENT RELATIONS

Memorandum *November 23, 2022*

TRP SPECIAL REPORT: HEALTH CARE PROVISIONS IN THE INFLATION REDUCTION ACT

On August 7, the **Senate clinched final passage of their long-sought reconciliation bill**, the Inflation Reduction Act (text), sending the measure to the House for a final vote later this week. The Senate Parliamentarian's "Byrd bath" rulings — along with the marathon "vote-a-rama" amendment process — resulted in a pair of key changes to the drug pricing policies, originally included in the text, within the filibuster-proof measure: (1) the **removal** of a provision that would have **required drug companies to provide rebates if the cost of the products they sold to private insurers exceeded inflation**; and (2) **nixing a proposed price cap for insulin in the private marketplace**. Notably, the Senate-passed legislation includes provisions that would: (1) allow Medicare to negotiate drug prices; (2) redesign the Medicare Part D benefit to lower out-of-pocket costs for beneficiaries; (3) cap the monthly out-of-pocket cost of insulin to $35 for Medicare beneficiaries; and (4) extend the Affordable Care Act (ACA) subsidies for households with income exceeding 400 percent of the federal poverty level until 2025.

A key policy included in the Senate-passed bill would allow Medicare to negotiate drug prices under Medicare Parts B and D. Under the bill, the **initial negotiated prices would be applicable starting in 2026** with negotiations for eligible drugs beginning in 2023. Notably **Part D drugs are eligible for negotiation beginning in 2026; however, Part B drugs will not be eligible until 2028.** For the purposes of negotiation, **insulin is no longer treated as a separate class** as it was in the prior iteration of the provision. In addition to these policies, the legislation would also cap Medicare Part D **beneficiary catastrophic spending** before 2024, delay implementation of the **Trump-era rebate rule** until to January 1, 2032, and implement **inflationary rebates** in Medicare for manufacturers who raise the price of drugs faster than inflation.

- **What's Next?** House lawmakers will return on Friday to consider the Inflation Reduction Act. Passage of the bill — which is highly likely as the Democratic caucus appears to be unified at the moment — would send the roughly $740 billion measure to President Joe Biden's desk for signature. This will mark the end of a busy summer work period for both chambers, with the Senate breaking until Tuesday, September 6, and the House until Tuesday, September 13.

Key health care provisions contained within the Senate passed IRA include:

Drug Price Negotiation — This section of the bill would require the Secretary of HHS to establish a Drug Price Negotiation Program, allowing Medicare to negotiate drug prices under Parts B and D for single-source drugs outside of their initial exclusivity periods. Under the bill, the **initial price applicability year is 2026 rather than 2025** as proposed in prior versions of the legislation, resulting in negotiated prices taking effect an additional year later. Also of note, the **initial year of negotiation is now 2023** rather than 2024.

- *Eligibility* — Under the Drug Price Negotiation Program, the Secretary of HHS would be required to create a ranked, combined list of the 50 highest-priced, single-source, brand-name drugs from Parts B and D, respectively, according to the total expenditures for such drugs under Parts B and

D. **The Secretary is required to select from such ranked drugs the negotiation-eligible drugs with the highest rankings**. The bill text defines the term 'total expenditures' to include, with respect to Part D**, the total gross covered prescription drug costs**. Notably, the term "total expenditures" excludes, in the case of expenditures with respect to Part B, expenditures for a drug or biological that are bundled or packaged into the payment for another service.

- *Criteria for Negotiation* — Subsequently, the Secretary of HHS would then select drugs each year from this list to be negotiated. HHS will begin to compile this list of negotiable drugs in 2023; therefore, a drug product — approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act — seven years passed launch of small molecule drugs at this time is considered to be a qualifying single-source drug. Qualifying single-source drugs also include a biological product — licensed under section 351(a) of the Public Health Service Act — that is 11 years passed its licensure.

  The bill text establishes parameters for the number of drugs to be negotiated each year, for which the negotiated price would apply, including: (1) **10 Part D drugs in 2026**; (2) **15 additional Part D drugs in 2027**; (3) **15 additional Part D or Part B drugs in 2028**; and (4) **20 additional Part D or Part B drugs in 2029 and beyond**. If fewer than the number of drugs specified for each year are eligible for negotiation, the **Secretary is required to include all drugs eligible for negotiation in that year**. Under the Senate-passed text, the Secretary will be required to negotiate a specific number of drugs each year in contrast to a maximum number of drugs as was the case in previous iterations of the package. This clarification in language aims to remove Secretarial discretion in the number of drugs to be negotiated each year to ensure that drug price negotiation remains steadfast regardless of the priorities of any given administration. For the purposes of negotiation, insulin is no longer treated as a separate class as it was in the prior iteration of the provision.

  Moreover, the bill text stipulates that each negotiation-eligible drug included on the list with respect to an initial price applicability year will be referred to as a 'selected drug' with respect to such year and each subsequent year beginning before the first year that begins at least nine months after the date on which the Secretary determines at least one drug or biological product matches specified criteria — a stipulation included in prior Senate language, though the House had allotted for an additional three months.

  A drug's negotiation period begins on the sooner of either: (1) the date on which the manufacturer and the Secretary enter into an agreement with respect to such drug; or (2) February 28 following the selected drug publication date. The negotiation period is to end on November 1 of the year that begins two years prior to the initial price applicability year. **With regard to drugs with an initial price applicability year of 2026, the negotiation period is to begin on October 1, 2023, and end on August 1, 2024.**

- *Exceptions* — The bill exempts drugs manufactured by small biotech companies until 2029. A small biotech company is defined as a company which manufactures one drug that makes up 80 percent of its Part B or Part D revenue, but constitutes less than one percent of total Part B or Part D expenditures. The bill text also stipulates that drugs that are a new formulation, such as an extended-release formulation, of a qualifying single, are not considered small biotech drugs.

  Additionally, the bill also excludes from negotiation: (1) certain orphan drugs — a drug that is designated as a drug for only one rare disease or condition under the Food, Drug, and Cosmetic Act and for which the only approved use is for such disease or condition; (2) low spend Medicare drugs — those that contribute less than $200 million in Medicare spending beginning in 2021 and adjusted for increases in the consumer price index (CPI) as of **September** for each subsequent

year; and (3) **plasma-derived products** — biological products derived from human whole blood or plasma. Notably, this bill defines "low spend Medicare drugs" as drugs that, for 2026, contribute less than $200,000,000 of Medicare spending between June 1, 2022, and May 31, 2023. For the price applicability year beginning in 2027, a drug qualifies as a low spend Medicare drug if spending for the drug is less than $200,000,000 of Medicare spending between June 1, 2022, and May 31, 2023, adjusted for the annual percentage of CPI-U between June 1, 2023, and September 30, 2024. The legislation further describes how a drug will be considered a low spend Medicare drug for subsequent price applicability years.

- *Non-Duplication with 340B Ceiling Price* — The manufacturer of a drug selected for negotiation and under such an agreement with HHS would not be required to provide access to the maximum fair price (MFP) to a 340B-covered entity for its selected drug if such drug is subject to a 340B agreement and the ceiling price is lower than the MFP for the selected drug. Conversely, if the ceiling price for a selected drug under such an agreement is higher than the MFP, the manufacturer would be required to provide access to the MFP to a 340B covered entity.

- *Delay of Selection and Negotiation of Biologics for Biosimilar Market Entry* — The bill, if enacted, would allow the Secretary to delay the negotiation of a biologic drug for up to two years provided a biosimilar demonstrates "high likelihood" of entering the market before the negotiated price would take effect. The delay is limited to two years with no extensions. If the biosimilar has not been licensed and marketed within that period, the manufacturer of the biologic will owe a rebate in an amount specified under the bill. Additionally, the delay must be requested by the manufacturer, and it must submit documentation to the Secretary "necessary for the Secretary to make this determination." The Secretary is required to implement this section by program instruction or other forms of program guidance for 2026, 2027, and 2028.

- Ceiling for Maximum Fair Price — The Senate-passed language stipulates that a negotiated price cannot exceed a drug's 2021 non-federal average manufacturer price (AMP) in the following amounts: (1) 75 percent for drugs that are on the market between 9 and 12 years; (2) 65 percent for drugs that have been on the market for at least 12 years, but fewer than 16 years; and (3) 40 percent for drugs that have been on the market for at least 16 years. The bill **provides additional clarification as to the specifics of the calculation of the non-Federal AMP**. Additionally, under the legislation, a temporary floor of 66 percent of the non-federal AMP is provided for select small biotech companies in **2029 and 2030**.

- *Renegotiation Process* — In the case of a renegotiation-eligible drug, the Secretary will provide for a process of renegotiation — to begin in 2028 — of the MFP for a drug during its price applicability period. The Secretary is required to specify the process for renegotiation of MFPs with the manufacturer of a renegotiation-eligible drug selected for renegotiation. This process must, to the extent practicable, be consistent with the methodology and process established for the initial negotiation process. Drugs eligible for renegotiation include a selected drug: (1) for which a new indication is added to the drug; (2) that undergoes a change of status to a an **extended-monopoly** or long-monopoly drug; or (3) which the Secretary determines there has been a material change of factors.

- *Manufacturer Provided Information* — Under the Drug Price Negotiation Program, manufacturers would be required to provide HHS with specified data for the drug under consideration — to aid in negotiations for the MFP — related to: (1) research and development costs; (2) current cost of production and distribution; (3) prior Federal financial support for novel therapeutic discovery and development of the drug; (4) data on pending and approved patents and on existing and pending exclusivity; and (5) market and revenue sales data. **The legislation no longer calls for**

manufacturer-provided information on national sales data for the drug or information on clinical trials.

- *Civil Monetary Penalties and Excise Tax* —The bill establishes an excise tax to be levied against manufacturers during periods when the manufacturer is non-compliant with the requirements of the negotiation program. Specifically, the tax would begin at 65 percent of the sales for the first 90 days of non-compliance and would increase at regular intervals until reaching 95 percent for any period of non-compliance beyond 270 days. Further, the bill would also establish a civil monetary penalty (CMP) for manufacturers who fail to provide access to a price that is equal to or less than the MFP to eligible parties. The CMP under such circumstances would be equal to ten times the number of units of the drug dispensed multiplied by the difference between the price the manufacturer charged for such drug for such year and the MFP for such drug during such year. In addition, manufacturers would face a CMP equal to $1 million for each day of the manufacturer fails to provide HHS with the required information under the Drug Price Negotiation Program.

- *Limitation of Judicial Review* — Under the Senate-passed bill, administrative or judicial review for the following is prohibited: (1) the determination of a unit with respect to a drug or biological product; (2) the selection or determination of drugs eligible for negotiation; (3) the determination of a qualifying single source drug; (4) the determination of MFP; and (5) the determination and selection of renegotiation-eligible drugs.

- *Implementation through Program Instruction* — The Secretary is required to implement Section 11001 (the Drug Pricing Negotiation Program) for **2026, 2027, and 2028** by program instruction or other forms of program guidance. The Secretary is additionally required to implement Section 11002 (Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry) by program instruction or other forms of program guidance for 2026, 2027, and 2028.

- *Funding* — The legislation would appropriate **$3 billion** — a marked increase from the $300 million proposed by the House — for fiscal year (FY) 2022 **until expended** to carry out drug price negotiation provisions.

Inflationary Rebates — This section of the IRA would implement inflationary rebates. Specifically, manufacturers would be required to pay rebates if Part B and D drug prices rise faster than inflation based on CPI-U. Failure to pay the mandatory rebate would result in a 125 percent civil monetary penalty (CMP) of the rebatable amount for that quarter. Additionally, the proposal would appropriate a total of $160 million for FY 2022 through 2031 to CMS to implement the Parts B and D inflationary programs. Notably, the Parliamentarian ruled over the weekend that the **inflation rebate provision must be limited to drugs sold to Medicare patients**. As a result, the updated Senate passed text reflects this ruling by removing the incorporation of prices of drugs sold in the private sector market when applying inflationary rebates.

- *Part B Rebate* — Within six months of each calendar quarter beginning January 1, 2023, the Secretary of HHS would be required to inform manufacturers of their products' price increases in excess of the average sales price (ASP) and any rebates that are owed by a manufacturer. Under this proposal, the rebate amount a manufacturer must pay for a product during the calendar quarter would be equal to the total number of billing units — as defined by the legislation — multiplied by the amount by which the manufacturer price exceeds the inflation-adjusted payment amount — the cost during the quarter starting July 1, 2021, or upon launch trended by CPI-U for the applicable quarter. The Secretary of HHS may delay its reporting to manufacturers of required rebate amounts for 2023 and 2024 until 2025. Applicable drugs would include single-source drugs and biologics covered under Part B, and some biosimilars.

- *Part B Waivers* — Additionally, rebate amounts may be waived or reduced at the discretion of the Secretary if the FDA deems a drug to be in shortage. Beneficiary coinsurance would be 20 percent of the inflation-adjusted payment for a rebatable drug. Additionally, inflationary rebates paid for Part B drugs would be excluded from the Medicaid calculation of "best price" and AMP.

- *Part B Exclusions* — Vaccines (for pneumococcal, influenza, and hepatitis B), some biosimilars, and — at the Secretary's discretion — drugs that do not exceed $100 per year in allowable charges would not be subject to inflationary rebates. The $100 drug exclusion would be applicable in 2023, and future cost thresholds would be calculated as the $100 2023 baseline plus the CPI-U for the preceding year.

- *Part D Rebates* — Part D drugs that would be subject to inflationary rebates include drugs and biologics and would be based on whether the product price increases in excess of AMP. Inflationary rebates would be determined by the extent to which the applicable CPI-U for the applicable quarters exceeds the CPI-U from January 2021. Subsequently approved drugs — those licensed after October 1, 2021 — would be subject to inflation calculations with a benchmark based on the first calendar year in which the drug was marketed. HHS would also be tasked with determining rebate amounts for new formulations of a Part D rebatable drug, not including abuse deterrent formulations. For 2022 through 2024, HHS would implement Part D inflation rebates by program instruction or other guidance. The Secretary of HHS may delay its reporting to manufacturers of required rebate amounts for 2022 and 2023 until December 31, 2025, at which point manufacturers would need to comply with any applicable rebate requirements. **This program would be effective in October 2022.**

    - *Part D Waivers* — Similar to the Part B provisions, the Secretary would be permitted to reduce or waive inflationary rebates if a drug is in shortage. Additionally, inflationary rebates paid for Part D drugs would be excluded from the Medicaid calculation of "best price" and AMP.

    - *Part D Exclusions* — Drugs and biologics with an annual cost of under $100 to beneficiaries would be excluded from inflationary rebates. As with Part B inflationary rebates, future cost thresholds would be calculated as the $100 2023 baseline plus the CPI-U for the preceding year. However, generic drugs approved under an abbreviated pathway would be subject to inflationary rebates if the drug has no other therapeutically equivalent drug, the manufacturer is not a first applicant during the 180-day exclusivity period, and the manufacturer is not a first approved applicant.

Part D Redesign — This provision, if enacted, would implement a redesign of Medicare Part D which would include changes to out-of-pocket (OOP) costs, reinsurance amounts, and the current coverage gap discount program. The Part D redesign will not take effect until 2025, but beginning in 2024, beneficiaries would pay zero coinsurance in the catastrophic phase, as described in more detail below.

- *Maximum OOP Caps* — This provision would implement a $0 OOP spending cap for beneficiaries in the catastrophic phase starting in 2024. Beginning in 2025, this bill would establish a maximum $2,000 OOP cap for each beneficiary's Part D drug expenditures, and these costs would be payable by beneficiaries over the course of the plan year.

- *Premiums Stabilization* — This bill would cap premium growth under Part D plans at six percent per year through 2029 and beyond.

- *Beneficiary Premium Percentage Adjustment* — If enacted, the Secretary of HHS would be authorized to make a one-time adjustment to the beneficiary Part D premium percentage in 2030.

- *Reinsurance Amounts* — Under this bill the federal government's share of reinsurance for costs incurred by enrollees in the catastrophic phase of Part D would be reduced from 80 percent to 20 percent for applicable brand drugs and 40 percent for non-applicable drugs.

- *Coverage Gap Discount Program* — The current coverage gap discount program would be converted, requiring manufacturers of branded drugs to contribute to payments in both the initial (10 percent) and catastrophic (20 percent) phases of the benefit. The proposal would also allow for a discount phase-in for certain drug manufacturers.

Maximum Monthly Cap on Cost Sharing Payments Under Prescription Drug/MA-PD Plans — Each Medicare Part D (PD) plan sponsor offering a prescription drug plan and each Medicare Advantage (MA) organization offering an MA–PD plan must provide enrollees with the option to elect to pay cost sharing under the plan in monthly amounts that are capped in accordance with specified thresholds. This section also stipulates that, if an enrollee fails to pay the amount billed for a month as required, the PDP sponsor or MA organization may preclude the enrollee from making this election in a subsequent plan year. This provision would take effect on January 1, 2025.

- *Implementation through Program Instruction* — The Secretary is required to implement this Section for 2025 "by program instruction or otherwise."

- *Funding* — The language passed by the Senate will appropriate $10 million to CMS for FY 2023, to remain available until expended.

Further Delay of Rebate Rule Implementation— Most recently, the Bipartisan Safer Communities Act (S.2938)(TRP analysis) signed into law on June 25, 2022, delayed HHS implementation of the Trump-era rebate rule until January 1, 2027. This provision, if enacted, would explicitly prohibit HHS from implementing the rule before January 1, 2032.

Expanding Vaccine Coverage Under Medicare Part D — Vaccines recommended by the Advisory Committee on Immunization Practice would be required to be covered under Medicare Part D with zero coinsurance.

- *Implementation through Program Instruction* — The Secretary is required to implement this section for 2023, 2024, and 2025 "by program instruction or other forms of program guidance. This provision would take effect on or after **January 1, 2023**.

Payment for Biosimilar Products during the Initial Period — During the initial coverage period, biosimilars would be limited to ASP+6 percent or wholesale acquisition cost (WAC)+3 percent of the biological reference product, whichever is less expensive, for drugs furnished on or after July 1, 2024.

Temporary Increase in Part B Payment for Certain Biosimilar Products — This provision would provide a temporary payment increase from ASP+6 percent to ASP+8 percent under Medicare Part B during a biosimilar's first five years on the market from October 1, 2022, to December 31, 2027. These payments are not to exceed the total payment for the reference product.

Expanding Eligibility for Part D LIS— If enacted, this bill would expand the income threshold for eligibility for the Part D low-income subsidy (LIS) from 135 percent to 150 percent of the federal poverty level beginning January 1, 2024.

Limiting Cost-Sharing for Insulin Products under Medicare — This provision **would cap cost-sharing for insulin products furnished under Part D plans at $35** starting in plan year 2023 through

2025. During subsequent plans years, cost-sharing for insulin will be the lesser of $35, 25 percent of the established maximum fair price under the Drug Price Negotiation Program, or 25 percent of the negotiated price. In addition, this provision would prohibit the application of the deductible under Part D for insulin products beginning in plan year 2023. The IRA also includes a provision that would prohibit the application of the deductible under Part B for insulin products beginning in plan year 2023, as well as limit payments to suppliers of insulin furnished as durable medical equipment under Medicare Part B. **Notably, provisions that would apply cost-sharing limitations on insulin in the private market were stripped, as the Senate Parliamentarian ruled that this provision violated the chamber's reconciliation rules.**

Increasing Vaccine Access under Medicaid/CHIP — This section would require Medicaid and CHIP to cover adult vaccinations for beneficiaries and would prohibit cost-sharing for such vaccinations. This section would also increase the Federally Medical Assistance Percentage (FMAP) for adult vaccines and their administration by one percentage point for the first eight fiscal quarters beginning on or after the effective date of this section. The amendments made by this section would take effect on the first day of the first fiscal quarter that begins on or after the date that is one year after the date of enactment of this legislation.

Extension of Affordable Care Act Premium Tax Subsidies — Under current law, the expansion of the health insurance premium tax credits made available to households with income above 400 percent of the Federal Poverty Level under the American Rescue Plan Act is set to expire on December 31, 2022. If enacted, this provision would extend the availability of the premium tax credits to these households through the **end of 2025**.