Memorandum

August 8, 2022

# SENATE APPROVES INFLATION REDUCTION ACT ON SIMPLE MAJORITY

Over the weekend, the Senate approved the Inflation Reduction Act by a vote of 51-50, with Vice President Kamala Harris delivering the tie breaking vote (summaries). The bill largely retains the health-related provisions previously introduced at the end of July, including drug price negotiations, Part D redesign, and extending the Affordable Care Act (ACA) premium tax subsidies through 2025. In addition to these proposals, the full text version features the following changes:

- **Part B and Part D Inflation Rebates** – The Senate Parliamentarian ruled that the inflation rebate cannot be applicable to units sold in the commercial market. The rebate amount will now only be based on Medicare units.

- **Insulin Copay Cap** – Beginning January 1, 2023, Medicare beneficiaries' insulin cost sharing will be limited to $35 per 30-day supply and insulin coverage will not be subject to a deductible.

- **Rebate Rule** – In the new version, the Trump Administration rebate rule implementation is further delayed until 2032, rather than fully repealed as under previous versions.

The Congressional Budget Office released an updated score of each titles' impact on the deficit over the 2022 to 2032 period. Overall, the agency estimates that drug pricing and deficit reduction provisions would reduce the deficit by $1 billion.

In addition to the health-related provisions, the package features proposals to:

- Reduce carbon emissions by 40 percent by 2030 (summary of energy security and climate change investments);
- Support climate-smart agriculture and rural power and clean energy (summary of Committee on Agriculture, Nutrition, and Forestry provisions); and
- Address climate change and equity issues, including methane and greenhouse gas reduction(summary of Committee on Environment and Public Works provisions)

The bill now heads to the House side, where they are expected to vote on the package on Friday.

Our summary of Inflation Reduction Act health-related provisions follows:

**Title I – Committee on Finance**

**Subtitle A – Deficit Reduction (p.1)** The bill would generate an estimated $726 billion in revenue, which would be used to fund investments in energy security and climate change, as well as extend the Affordable Care Act (ACA) premium tax credit subsidies through 2025 (and which are set to expire this year). The remaining funding will be allocated towards deficit reduction. A further breakdown of these changes is below.

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The $726 billion is generated from the following savings:

- 15 percent corporate minimum task – $313 billion
- Drug pricing reform – $288 billion
- IRS tax enforcement – $124 billion

As stated, a portion of the generated savings will be invested in the following:

- Energy security and climate change – $369 billion
- ACA subsidy extensions – $64 billion

The remainder will be allocated towards deficit reduction. Additional details on the above-mentioned policy changes are included in the following sections of this summary.

**Subtitle B – Prescription Drug Pricing Reform**

***PART 1 – Lowering Prices Through Drug Price Negotiations***

- **Sec. 11001. Providing for Lower Prices for Certain High Priced Single Source Drugs -** This section calls for the establishment of a drug price negotiations program for certain high-prices single-source drugs, biological products, and insulin, with the first negotiated price applicability year being 2026. Additional details of the section follow.

    - **Negotiation-Eligible Drugs:** Drug eligible for negotiation include the 50 Part D and 50 Part B single source drugs with the highest total expenditures during the most recent 12 months. Qualifying single source drugs include the following:

        - Drugs that are approved under 505(c) of the Food, Drug, and Cosmetics (FD&C) Act for which 7 years have passed since the drug was first marketed, and is not listed a reference product for any generic product;

        - Biological products that are licensed under 351(a) of the Public Health Service Act for which at least 11 years have passed since the drug was first marketed, and is not listed a reference product for any biosimilar product.

      The section clarifies that qualifying single source drugs do not include: 1) orphan drugs designated for only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication if for such disease or condition; 2) single-source drugs in Part B and D with total expenditures that are less than $200 million, with respect to 2021, or with respect to subsequent years $200 million increase by the annual percentage increase in the consumer price index; and 3) biological products that are derived from human whole blood or plasma.

- **Exception for Small Biotech Drugs:** For 2026 through 2028, drugs that are exempt from the negotiations process include those whose account for 80 percent of a company's Medicare revenue, but less than 1 percent of Medicare drug spend.

- **Selection of Negotiation-Eligible Drugs as Selected Drugs:** The Secretary is required to publish the list of selected drugs on the following dates:

  - *For the 2026 price applicability year*, the Secretary must publish a list of 10 negotiation-eligible drugs by February 1, 2024;
  - *For the 2027 price applicability year*, the Secretary must publish a list of 15 negotiation-eligible drugs by February 1, 2025;
  - *For the 2028 price applicability year*, the Secretary must publish a list of 15 negotiation-eligible drugs by February 1, 2026; and
  - *For the 2029 price applicability year and subsequent years*, the Secretary must publish a list of 20 negotiation-eligible drugs by February 1, 2027.

  The bill clarifies that drug previously published as negotiation-eligible would be subject to the negotiation process.

- **Selection of Drugs:** With respect to the initial price applicability year (2026); the Secretary is required to rank the negotiation eligible drugs according to Part B and Part D expenditures during the most recent 12 months and select from the ranked drugs with the highest expenditures.

- **Negotiation Process:** The Secretary is required to develop and use a consistent methodology and process for negotiations to achieve the lowest the lowest maximum fair price. The bill clarifies that the Secretary must carry out the negotiations process. Such a process is to include the following:

  - By March 1 of the year of the selected drug publication date, manufacturers submit information on non-federal average manufacture price;
  - By June 1 of the year of the selected drug publication date, the HHS Secretary will make an initial maximum fair price offer. Manufactures have30 days to respond to the initial offer and either accept or propose a counter offer
  - By November 1 of the year of the selected drug publication date, all negotiations must be concluded;
  - By November 30 of the year of the selected drug publication date, the Secretary will publish in the Federal Register the maximum fair price negotiated for negotiation-eligible drugs.

When negotiating a maximum fair price, the Secretary is required to consider manufacturer specific information, including research and development costs; market data for the drug; unit costs of

production and distribution; prior federal support for novel therapeutic discovery; data on patents; national sales; and information on clinical trials and alternative treatments.

- **Ceiling for Maximum Fair Price:** HHS Secretary is directed to offer a maximum fair price that cannot exceed the lower of:

  - For 2026:
    - For Part D drugs, the sum of the plan specific enrollment weight amounts for each prescription drug plan, or for Part B drugs, the average sales price (ASP) of the drug or biological for the year prior to the year of the selected drug publication date; or

    - The applicable percentage for certain categories of drugs based of the 2021 non-federal average manufacturer price (non-FAMP) increased by the percentage increase in the consumer price index for all urban consumers:

      - *Short-monopoly drugs and vaccines***:** 75 percent of the non-federal average manufacturer price for short monopoly drugs (drugs on the market between 9 and 12 years);
      - *Extended-monopoly drugs:* 65 percent of the non-federal average manufacturer price for post-exclusivity drug (drugs on the market between 12 and 16 years); and
      - *Long-monopoly drugs:* 40 percent of the non-federal average manufacturer price for long-monopoly drugs (drugs on the market for more than 16 years).

  - For 2027 and subsequent years:
    - The applicable percentage for certain categories of drugs based of the 2021 non-federal average manufacturer price (non-FAMP) increased by the percentage increase in the consumer price index for all urban consumers:
      - *Short-monopoly drugs and vaccines***:** 75 percent of the non-federal average manufacturer price for short monopoly drugs (drugs on the market between 9 and 12 years);
      - *Extended-monopoly drugs:* 65 percent of the non-federal average manufacturer price for post-exclusivity drug (drugs on the market between 12 and 16 years);. and
      - *Long-monopoly drugs:* 40 percent of the non-federal average manufacturer price for long-monopoly drugs (drugs on the market for more than 16 years); or
    - The average non-FAMP manufacturer price for such drug for the year prior to the selected drug publication date.

  The plan specific enrollment weight amount is an amount equal to the product of the negotiated price of a drug net of all price concessions and a fraction of the total number of individuals enrolled in a plan divided by total of individuals enrolled in a Part D plan.

Additionally, vaccines are explicitly not included in the definition of extended monopoly or long-monopoly drugs.

The bill also provides a temporary floor for small biotech drugs in which the maximum fair price negotiated for years 2029 and 2030 may not be less than 66 percent of the average non-FAMP.

- **Nonduplication with 340B Ceiling Price:** The bill clarifies that manufacturers are required to provide the lower of either the negotiated maximum fair price or the 340B ceiling price to eligible 340B entities.

- **Sec. 11002 Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry –** The bill states for in cases of a biological products that would be an extended monopoly drug, the Secretary can delay the negotiation of maximum fair price if it determined there is a high likelihood that a biosimilar, that uses such biologic as a reference product, will be licensed and marketed before a date that is 2 years after the selected drug publication date.

- **Sec. 11003. Selected drug manufacturer excise tax imposed during noncompliance periods –** If a manufacturer does not provide access to the maximum fair price, or less, the manufacturer will be subject to a civil monetary penalty equal to 10 times the number of units sold during the year and the difference between the price made available and the maximum fair price.

- **Sec. 11004. Funding –** The bill provides $3 billion for fiscal year 2022 to implement this section.

***PART 2— Prescription Drug Inflation Rebates***

- **Sec. 11101. Medicare Part B Rebate by Manufacturers** – Beginning January 1, 2023, this section would require manufacturers of Part B rebatable drugs to provide a rebate to the HHS Secretary that is equal to the rate at which the price of the drug exceeds inflation. Specifically:

  - **Rebate amount:** the rebate amount would be equal to the amount by which the total number of Medicare units sold of the drug multiplied by payments for the drug exceeds the inflation-adjusted payment amount.

  - **Inflation-adjusted payment amount**: the inflation-adjusted payment amount is equal to the payment amount for a drug increased by the increase in CPI-U, benchmarked at January 2021.

  - **Rebatable drugs**: a Part B rebatable drug is defined as a single source drug or biologic (excluding certain biosimiars), except for drugs whose average total allowed charges are less than $100 for a year per individual, or for vaccines.

  - **Beneficiary coinsurance protection**: for Part B drugs furnished on or after April 1, 2023 whose payments exceed the inflation-adjusted payment established by the bill, any coinsurance

payments for a beneficiary would be equal to 20 percent of the inflation-adjusted payment amount for the drug.

- **Enforcement**: Manufacturers that do not comply with the Part B inflation rebate requirements will be subject to a civil monetary penalty amount of at least 125 percent of the original rebate amount.

- **Sec. 11102. Medicare Part D Rebate by Manufacturers** – Beginning in October 2022, this section would require manufacturers of Part D rebatable drugs to provide a rebate to the HHS Secretary that is equal to the rate at which the price of the drug exceeds inflation. Specifically:

  - **Rebate amount:** the rebate amount would be equal to the total number of units that are used to calculate the average manufacturer price for Part D drugs as reported by drug manufacturers multiplied by the amount by which the annual manufacturer price exceeds the inflation-adjusted payment amount. Note that certain units of Part D drugs would be excluded from this calculation, such as drugs for which payment was made by a state Medicaid program.

  - **Inflation-adjusted payment amount:** the inflation-adjusted payment amount is equal to the benchmark year manufacturer price increased by the percentage by which the applicable year CPI-U for the year exceeds the benchmark period CPI-U (the year beginning January 2021).

  - **Annual manufacturer price:** the benchmark year manufacturer price is the sum of the products of –

    - The average manufacturer price for each calendar quarter of the payment amount benchmark year; and
    - The ratio of the total number of units reported as covered outpatient drugs with respect to each calendar quarter of such payment amount benchmark year to the total number of units reported as covered outpatient drugs with respect to such payment amount benchmark year.

  - **Enforcement**: Manufacturers that do not comply with the Part D inflation rebate requirements will be subject to a civil monetary penalty amount of at least 125 percent of the original rebate amount.

  In the case of a drug that is a line extension of a Part D rebatable drug, HHS is directed to establish a formula for determining the rebate about and the inflation adjusted payment amount that is consistent with the formula applied used for inflation rebates in the Medicaid Drug Rebate Program.

***PART 3 – Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiarie***

- **Sec. 11201 Medicare Part D Benefit Redesign**

  - **Beneficiary Maximum Out-of-Pocket (OOP) Cap:** Beginning in 2024, beneficiaries would be responsible for $0 in the catastrophic phase, and a $2,000 OOP would be applicable in 2025.

- **Part D Benefit Design:** The bill includes the following Part D benefit structure for the different phases of the benefit beginning in 2025:

| Benefit Phase | Proposed Liability |
|---|---|
| Initial Coverage Phase | • Beneficiary – 23 percent<br>• Plan – 67 percent for brands and 77 percent for generics<br>• Manufacturer – 10 percent for brands and 0 percent for generics |
| Coverage Gap | Eliminated under redesign |
| Catastrophic Phase | • Beneficiary – 0 percent<br>• Plan – 60 percent<br>• Manufacturer – 20 percent for brands and 0 percent for generics<br>• Federal Government – 20 percent for brands and 40 percent for generics |

- **Manufacturer Discount Phase-in for Certain Drugs Dispensed to Low-Income Subsidy (LIS) Beneficiaries:** The bill establishes a manufacture discount phase-in for manufacturers with total expenditures for drugs that are dispensed to LIS beneficiaries and represent less than 1 percent of total Part D expenditures and less than 1 percent of Part B expenditures in 2021. The manufacturer discount would be phased-in the following way:

    - In the initial coverage phase:
        - 1 percent in 2025;
        - 2 percent in 2026;
        - 5 percent in 2027;
        - 8 percent in 2028; and
        - 10 percent in 2029 and subsequent years.

    - In the catastrophic coverage phase:
        - 1 percent in 2025;
        - 2 percent in 2026;
        - 5 percent in 2027;
        - 8 percent in 2028;
        - 10 percent in 2029;
        - 15 percent in 2030; and
        - 20 percent in 2031 and subsequent years.

- **Phase-in for Specific Small Manufacturers**: A small manufacturer is defined as a manufacturer whose total expenditures for single drug represent 80 percent of their Medicare revenue. For these manufacturers the manufacturer discount in phased-in in the following way:

- In the initial coverage phase:
  - 1 percent in 2025;
  - 2 percent in 2026;
  - 5 percent in 2027;
  - 8 percent in 2028; and
  - 10 percent in 2029 and subsequent years.

- In the catastrophic coverage phase:
  - 1 percent in 2025;
  - 2 percent in 2026;
  - 5 percent in 2027;
  - 8 percent in 2028;
  - 10 percent in 2029;
  - 15 percent in 2030; and
  - 20 percent in 2031 and subsequent years.

o **Medicare Part D Premium Stabilization:** For the years 2024 through 2029, Part D base premiums are limited to the lesser of a 6 percent increase from the previous year or the premium what would have been applied if the stabilization program was not established. In 2030 and subsequent years, the Secretary is authorized to make adjustment necessary to the base Part D premium to ensure that premium is increased by the less of 6 percent or what the or the premium what would have been applied if the stabilization program was not established.

o **Appropriations:** The bill provides $341 million in fiscal year 2022 to carry out these provisions.

- **Sec. 11203 Maximum Monthly Cap on Cost-Sharing Payments –** Beginning in 2025, prescription drug plan and MA-PD plans, must provide enrollees that are subsidy eligible the option to elect to pay cost-sharing in monthly amounts that are capped. The maximum monthly cap cannot exceed the annual out-of-pocket cap divided by the applicable number of months.

***PART 4 – Continued Delay of Implementation of Prescription Drug Rebate Rule***

- **Sec. 11301. Extension of Moratorium on Implementation of Rule Relating to Eliminating the Anti-Kickback Statute Safe Harbor Protection for Prescription Drug Rebates** – The bill further delays the implementation of the rule relating to eliminating the anti-kick-back statute safe harbor protection for prescription drug rebates beginning January 1, 2032.

***PART 5 – Miscellaneous***

- **Sec. 11401. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices (ACIP) under Medicare Part D:** Beginning in 2023, for ACIP recommended vaccines that are covered under Part D, no deductible or cost sharing shall apply.

- **Sec. 11402 Payment for Biosimilar Biological Products During the Initial Period:** This section would establish payments for biosimilars furnished on or after July 1, 2024 during the initial period at the amount that is the lesser of the following:

    - 103 percent of the wholesale acquisition cost (WAC); or
    - 106 percent of average sales price (ASP).

- **Sec. 11403. Temporary Increase in Part B Payment for Biosimilars:** The section provides a payment increase for biosimilars with average sales prices that are lower than the reference product for a 5-year period beginning on September 30, 2022.

- **Sec. 11404. Expanding Eligibility for LIS Under Part D:** The eligibility for LIS is expanded from 135 percent of the federal poverty level to 150 percent.

- **Sec. 11405. Improving Access to Adult Vaccines Under Medicaid and CHIP:** The section requires coverage of adult vaccines without any deductible or cost sharing. Additionally, the section increases FMAP for the administration of adult vaccines. These provisions are effective beginning one year after the date of enactment.

- **Sec. 11406. Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D** – For plan year 2023 and subsequent years, Medicare Advantage prescription drug plans (MA-PDs) and Part D plans (PDPs) are prohibited from applying a deductible for insulin coverage. For plan years 2023, 2024, and 2025, MA-PDs and PDPs must limit insulin cost-sharing to $35 per 30-day supply. For plan year 2026 and subsequent years, MA-PDs and PDPs must limit insulin cost sharing to the less of $35 per 30-day supply or 25 percent of the negotiated price of the selected insulin net of all price concessions.

- **Sec. 11407. Limitation on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment (DME)** – Beginning July 1, 2023, a deductible shall not apply to insulin coverage furnished through DME. Additionally, coinsurance amounts are limited to $35/

- **Sec. 11408. Safe Harbor for Absence of Deductible for Insulin** – The section establishes that a plan shall not fail to be treated as a high deductible health plan by failing to have a deductible for selected insulin products, beginning December 31, 2022.

**Subtitle C – ACA Subsidies**

- **Sec. 12001. Improve Affordability and Reduce Premium Costs of Health Insurance for Consumers -** This section would extend the ACA premium subsidies until January 1, 2026. The tax credits would apply for individuals with a household income over 400 percent of the federal poverty line (FPL) through 2025.