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Senate Approves Inflation Reduction Act Including Key Health Care Provisions

Includes three-year extension of enhanced ACA subsidies, the ability for Medicare to negotiate drug prices and $35 monthly insulin caps for Medicare, among other items

On Sunday (August 7), the Senate approved 51-50 the Inflation Reduction Act (IRA) of 2022 (H.R. 5376), on a party line vote with Vice President Harris breaking the tie to send the Democrat's long-pursued reconciliation bill to the House. The bill includes climate and energy provisions and an extension of enhanced Affordable Care Act (ACA) subsidies paid for by a 15% corporate alternative minimum tax (CAMT) on adjusted financial statement income for corporations with profits over $1 billion, a stock buyback tax, increased IRS enforcement funding, and prescription drug provisions including permitting Medicare to negotiate certain prescription drug prices. The House is planning to reconvene on Friday, August 12 to consider the Senate bill.

President Biden said in a statement after passage that "Senate Democrats sided with American families over special interests, voting to lower the cost of prescription drugs, health insurance, and everyday energy costs and reduce the deficit, while making the wealthiest corporations finally pay their fair share." U.S. Senate Republican Leader Mitch McConnell (R-KY) also issued a statement saying that "Democrats have proven over and over they simply do not care about middle-class families' priorities. They have spent 18 months proving that. They just spent hundreds of billions of dollars to prove it again." Congressional Democratic leaders, however, applauded the legislation and urged its quick passage in the House. Energy and Commerce Frank Pallone (D-NJ) called it "one of the most significant pieces of health care legislation to move through Congress in over a decade."

Prescription drug provisions in the bill include the establishment of a Drug Price Negotiation program within Medicare, prescription drug inflation rebates, a redesign of the Part D benefit, and a $35 monthly caps on out-of-pocket costs for insulin for Medicare beneficiaries. The bill also extends the enhanced ACA subsidies established in the American Rescue Plan Act (ARPA) for three years – through 2025. According to the Congressional Budget Office (CBO), extending the ARPA policy would result in about 4.8 million more people having marketplace coverage and is expected to cost $64 billion. The drug pricing provisions are projected to save $288 billion over a decade, however a provision struck by the Senate parliamentarian – which would have included the commercial market in the inflationary rebate calculation – could reduce the savings by around $40 billion. The CBO also predicted the bill will lead to higher drug launch prices to offset losses from inflation rebates and Medicare price negotiation.

Throughout the "vote-a-rama," a lengthy series of proposed amendments, Republicans were also able to strike from the final bill a provision that would have capped out-of-pocket insulin costs for individuals with private insurance, leaving the cap in place for just Medicare beneficiaries. The Senate parliamentarian ruled that the cap did not comply with the rules of reconciliation and thus would have needed 60 votes to keep it

in the bill. In several instances, Democratic leaders called for opposing Democratic amendments – including those addressing the Medicaid coverage gap and strengthening the Medicare price negotiation provision – in an effort to preserve the IRA and keep the deals reached with key Senators Joe Manchin (D-WV) and Kyrsten Sinema (D-AZ) intact.

Below is a high-level summary of key health care provisions; it is not exhaustive:

I. Prescription drugs (key provisions)

A) Medicare negotiation: The bill directs the Secretary of the Department of Health and Human Services (HHS) to establish a Drug Price Negotiation program to lower the prices of certain prescription drugs. The number and type of drugs subject to negotiation will increase over time from 10 to 20 drugs. The HHS Secretary will be required to select and publish a list of 10 "high spend," single-source Part D drugs for initial price applicability year 2026, increasing to 15 in 2027. In 2028, the 15 drugs can include both Part D and/or Part B drugs, increasing to 20 Part D and/or Part B drugs in 2029 and beyond. HHS will negotiate maximum fair prices (MFP) with manufacturers of selected drugs and impose an excise tax and other penalties for non-compliance.

- **Negotiation eligible drugs**: "High spend" drugs are those among the 50 single-source drugs with the highest total expenditures in the relevant category (i.e. Part D in 2026 and 2027 and Part D and B in 2028 and subsequent years) in the 12 months prior to the drug publication date. Drugs must have been licensed for at least 7 years without generic competition for small molecule drugs and 11 years without biosimilar competition for biologic products to be selected for negotiation (with the initial price applicability year being two years after selection). A drug selected for negotiation would continue to be included in the program until it is removed by the HHS Secretary.
    - **Exemptions and delays**: Certain orphan and plasma-derived drugs, drugs determined to be "low-spend," and vaccines will be exempted. Small biotech drugs are exempted from negotiation for 2026-2028. Additionally, if a biologic product is selected by HHS for negotiation, the drug maker may request a one-year delay from negotiation if it provides information that confirms market entry of a biosimilar competitor within that period.
- **Negotiated price**: The final MFP cannot exceed price ceilings set by the following:
    - **For Part D drugs**: The lower of, 1) the negotiated, net price of the drug weighted by enrollment for all Part D plans or, 2) A percentage of the non-Federal average manufacturer price (AMP) that varies based on category of drug: 75% for Short Monopoly Drugs (<12 years); 65% for Extended Monopoly Drugs (>12-<16 years) and a 40% for Long-Monopoly Drugs (>16 years) average manufacturer price (AMP).
    - **For Part B drugs**: The lower of, 1) the amount paid by Medicare for single source drugs and biologicals or, 2) An amount that varies based on category of drug (as seen in Part D above).
    - **Small biotech drugs**: Negotiated prices for small biotech drugs selected in 2029 or 2030 (i.e. the first years they are eligible) cannot be less than 66% of non-federal average AWP.
- **Excise tax**: An excise tax will be levied against manufacturers during periods of noncompliance, escalating over time:
    - **First 90 days**: 65%
    - **91-180 days:** 75%
    - **181-270 days**: 85%
    - **271 days and beyond**: 95%

Manufacturers that charge more than the negotiated maximum price would pay a civil monetary penalty of as much as 10 times the difference in prices. The penalty for providing false information would be $100 million. A manufacturer can instead choose to cease agreements with HHS for the designated drug (i.e. pull out of the Medicare market), in which case the tax is suspended.

- **Related provisions:**
    - Includes provisions designed to prevent nonduplication with 340B price discounts.
    - Requires plans to cover all selected drugs negotiated until removed from the annual list.
    - Negotiated drug prices under these provisions will be included in Medicaid "best price" rebate calculations, but MFPs will be exempt from national average wholesale price (AWP) reporting. Part B drugs subject to these negotiations will be paid at 106% of the MFP. Under Part D, the negotiated price used for payment can be no greater than the maximum fair price for such drug plus any dispensing fees.

B) Inflationary rebates: Beginning in 2023, if the price of a single-source Part B drug or biologic, or a Part D branded drug or biologic, increases more than the rate of inflation (using CPI-U as a benchmark), the manufacturer would be required to provide a rebate to the federal government. A civil monetary penalty of 125% of the rebate amount would be imposed if a manufacturer does not pay. The measure would allow for some reductions or waivers of rebates if it could result in a shortage during a severe supply chain disruption.

C) Part D redesign/coverage provisions:

- **Out-of-pocket limits:** Institutes a cap on beneficiary Part D out-of-pocket costs at $2,000 a year for MA and Part D plans starting in 2025. Starting in 2024, beneficiaries would pay nothing in the catastrophic phase.
- **Benefit and liability redesign**: Eliminates the Medicare Part D coverage gap phase effective 2025. Modifies the levels of liability in the following ways:
    - *Initial Coverage Phase*: 25% beneficiary; 65% plan; 10% manufacturer for brands and biologics
    - *Catastrophic Coverage Phase*: 0% beneficiary; 6% plan; 20% manufacturer for brands and biologics; 20% Medicare for brands/biologics and 40% for generics. Currently Medicare pays 80% of the costs in the catastrophic phase.
- **Premium stabilization**: Limits increases in Medicare Part D premiums exceeding 6%.
- **Smoothing:** Beginning in 2025, mandates that plans allow beneficiaries the option to spread payment of high out-of-pocket costs over the course of the plan year (known as "smoothing") via monthly caps.
- **LIS enhancement**: Extends the income eligibility threshold for the full Part D Low-Income Senior (LIS) from 135% to 150% of the federal poverty level effective 2024.

D) Cost-sharing for insulin products under Medicare: Excludes insulin products covered under Medicare Part D from applying to beneficiary deductibles, starting in 2023, and sets co-payment caps at no more than $35 a month starting in 2023. In 2026 and beyond, the co-payment would be set at the lesser of $35 a month or 25% of the price established through the new Medicare price negotiation program, if applicable. The measure would also limit the monthly coinsurance for insulin-related durable medical equipment to 80% of the established amount under Medicare Part B and waive deductibles for such equipment beginning July 1, 2023.

E) Other notable provisions:

- **Rebate rule**: Extension of the moratorium on the implementation of the rule relating to the Anti-kickback statute safe harbor protection for prescription drug rebates.
- **Vaccine coverage**: Beginning in 2023, Part D plans are required to cover all adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) without cost-sharing (other than vaccines covered under Part B). All adult vaccines recommended by the ACIP must also be covered without cost-sharing for Medicaid and CHIP enrollees, with a temporary increase in FMAP for vaccine costs.
- **Biosimilar provisions**: For purposes of calculating a biosimilar's average sales price (ASP) upon market entry on or after July 1, 2024 for the new Prescription Drug Negotiation Program, that price will be the lesser of 106% of a single source originator drug's ASP or Wholesale Acquisition Cost (WAC), or 103% of the biosimilar's WAC. Also provides, starting October 1, 2022, a 5-year increase in payments for certain Part B biosimilar products to ASP + 8% instead of ASP + 6%.

ACA subsidy extension

The package includes a three-year extension, through 2025, of enhanced ACA marketplace subsidies enacted under the American Rescue Plan. The enhanced credits removed a subsidy cliff at 400% of the federal poverty line (FPL) and lowered the final premium percentage to 8.5% of FPL, while also boosting credits for lower income levels. The subsidies are set to expire at the end of the year, which could result in premium payments skyrocketing for millions of enrollees.

For additional information or questions, please contact Heather Meade or Laura Dillon.