The Inflation Reduction Act of 2022: Healthcare Provisions

After almost a year of negotiations among congressional Democrats and the White House, the Inflation Reduction Act of 2022 (IRA) was signed into law by President Biden on August 16, 2022. It passed in the US Senate by a vote of 50–50, with the vice president breaking the tie, on August 7, 2022. The bill passed the US House of Representatives August 12, 2022 by a party-line vote of 220-207.

The package was initially proposed as the Build Back Better Act, which passed in the House on November 19, 2021. Democrats hit roadblocks to passing the bill in the Senate, however. Senators Manchin (D-WV) and Sinema (D-AZ) expressed concerns regarding the size and cost of the package, especially considering rising inflation. After months of negotiations, Majority Leader Schumer (D-NY) and Senator Manchin reached a deal to reduce the federal deficit, reform prescription drug pricing, make several tax reforms, invest in energy and climate change, and extend the American Rescue Plan Act (ARPA) advanced premium tax credit (APTC) subsidy increases for health plans purchased through the Affordable Care Act (ACA) marketplaces for three years. The Manchin-Schumer deal was further modified to gain the support of Senator Sinema. None of the changes required to secure her vote impacted the healthcare provisions.

While the original vision for this reconciliation bill was substantially higher and included more provisions and dollars, the IRA is still a significant bill that achieves many of President Biden's initiatives on climate, taxes, energy and healthcare. The bill establishes a novel pathway for price negotiation, the first time such a process would be allowed in Medicare Part B and D, and is one of the most consequential pieces of healthcare legislation in the last 25 years.

Presuming the bill passes in the House, the process of implementing the prescription drug pricing provision will be long and potentially arduous. It will certainly be subject to legal challenge, as we have seen with most healthcare legislation in recent memory. While the changes to Part D may not be fully implemented for one or two plan years, the provision capping Medicare's out-of-pocket spending on prescription drugs is an extremely important and long-awaited beneficiary protection. The implementation process for the drug price negotiation provision will also take time and be subject to substantial advocacy. This bill will join other landmark legislation, such as the Medicare Modernization Act and the ACA, in heralding a significant departure from the preceding legislative framework.

The extension of the ACA tax credits will make coverage through the ACA more affordable. The additional subsidies through the tax credits enacted in ARPA have led to significant increases in coverage, and the maintenance of these subsidies is vital since millions of people will become ineligible for Medicaid once the public health emergency ends. These subsidies will help many individuals avoid becoming uninsured. These coverage gains will remain in jeopardy, however, because this measure is only a three-year extension rather than permanent policy. Finding a pathway to a permanent extension before the three-year window ends will be a political imperative.

The summary below focuses on the healthcare provisions of the IRA.

Prescription Drug Reform

Drug Price Negotiation Program

Background: Since the enactment of Medicare Part D, the US Department of Health and Human Services (HHS) Secretary has been prohibited from engaging in price negotiations between drug manufacturers and Part D Plan sponsors (PDPs). As a result, Medicare has been required to heavily subsidize the Part D program but has been barred from setting the price or establishing a fee schedule. Likewise, Medicare Part B includes no mechanisms for drug price negotiations.

Provision: The IRA would officially establish a Medicare Drug Price Negotiation Program. The bill directs the HHS Secretary to negotiate maximum fair prices for selected drugs for the Medicare program beginning with plan year 2026. This price negotiation arrangement is notably more narrow than the provision included in the Build Back Better Act, in which Democrats proposed an expansive Medicare price negotiation program modeled after the 2019 introduced bill, H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

The list of negotiation-eligible drugs would be determined according to which drugs have high expenditures under Medicare Part B or D, with the exception of small biotech drugs and certain orphan drugs (*i.e.*, drugs designated for only one rare disease indication). To be eligible for negotiation, drugs must be approved by the US Food and Drug Administration (FDA) and must have been on the market for a certain number of years—seven years for small molecule drugs, and 11 years for biologics. The final version of the bill includes vaccines as eligible for price negotiation.

The bill directs HHS to negotiate prices for 10 drugs in 2026, an additional 15 drugs in 2027 and 2028, and an additional 20 drugs per year in 2029 and beyond. Once negotiation concludes, the Secretary must publish the list of maximum fair prices (MFPs) for these drugs no later than November 30 two years prior to the price applicability year. The Secretary must also publish an explanation of the methodology and selection no later than March 1 of the year prior to the initial year of the negotiated price applicability. For years beginning with 2028, the Secretary must provide for a drug pricing renegotiation process under certain circumstances. These conditions include approval of new indications for the drug, change of status to either an extended-monopoly or long-monopoly drug, or material changes to the drug.

Drugs that would not be subject to negotiation include orphan drugs designated for only one orphan indication and new formulations of single source drugs. The bill also allows for a delay in negotiation of no more than two years for certain drugs likely to face biosimilar competition in the two years between selection and price applicability. For drugs included in the list of MFPs that warrant a delay, manufacturers would be required to pay a rebate. In cases where these

negotiated drug prices are lower than the 340B prices, manufacturers would be obligated to make the MFP available to covered entities, but "in a nonduplicated amount to the ceiling price."

As part of the negotiation process, manufacturers must submit information that includes research and development costs for the drug, market data for the drug, unit costs of production and distribution of the drug, prior federal financial support for development of the drug, FDA-approved patent applications and drug applications, revenue and sales volume data, and information on clinical trials for the drug.

The bill would impose a noncompliance tax on the manufacturer of a selected drug if the manufacturer delays the negotiation process or does not sell the drug at the negotiated price.

Inflationary Rebates

Background: According to AARP research, the price of prescription drugs widely used by older Americans has increased faster than inflation each year since at least 2006. Inflation-based rebates for both Medicare Part B and D were supported by the bipartisan Prescription Drug Pricing Reduction Act of 2019 from Senate Finance Committee leaders Senators Grassley (R-IA) and Wyden (D-OR). The Elijah E. Cummings Lower Drug Costs Now Act also included inflation-based rebates.

Provision: Under the IRA, beginning in July 2023, drug manufacturers would have to pay a rebate to the Federal Supplementary Medical Insurance Trust Fund for Part B and Part D drugs. Part B drug manufacturers would have to pay a rebate for single source drugs and biological and biosimilar products if the average increase in total allowed charges for a drug outpaces inflation increases each year. Similarly, drug manufacturers would have to pay a rebate for Part D drugs or biologicals if the average manufacturer price increased outpace inflation increases in a given year. Vaccines as well as drugs whose average sales price or average manufacturer price is lower than $100 annually would be excluded from the inflationary rebate requirement.

The rebate amount equals the amount by which the cost of a drug exceeds the consumer price index for all urban consumers inflation-adjusted payment amount for the calendar quarter. Manufacturers that fail to pay the required rebate would be assessed a civil monetary penalty at 125% of the rebate.

To meet the Byrd rule requirements, the final version of the IRA was modified to omit a provision that would have extended inflation rebates on drugs to commercial health insurance plans. Instead, this provision is only applicable in Medicare.

Cap on Insulin Costs

Background: Throughout the debate on drug pricing reforms, the price of insulin has become a central focus for many members on both sides of the aisle. Despite market competition among manufacturers, from 1999 to 2019 prices rose 1,000% for insulin—a drug that most individuals with diabetes need on a daily basis in order to live. A plethora of legislation has been introduced

in recent years to reduce insulin costs for patients, and many of these proposals have received bipartisan support. One of the most prominent proposals has been the establishment of a monthly cap on out-of-pocket costs, since diabetic patients require insulin on a chronic basis. Shortly before bringing the IRA to the floor, Democrats added a provision to cap insulin costs in Medicare and under private insurance. Republicans raised a point of order against the provision extending the cap to private insurance, and it was stricken from the bill.

Provision: Beginning in plan year 2023, the bill would impose a monthly cap on the cost of insulin furnished under Medicare Part D. The monthly cap during plan years 2023, 2024 and 2025 would be $35. Beginning in plan year 2026, the cap would be the lesser of $35, the MFP or the negotiated Medicare price. Covered insulin products are defined as any insulin products (inclusive of rapid-acting, short-acting, intermediate-acting, long-acting, ultra-long-acting and premixed forms of insulin) that are covered under Medicare Part D or Medicare Advantage Part D plans and have received FDA marketing approval and licensure. The bill would also remove deductibles and lower coinsurance for insulin provided through durable medical equipment in Medicare Part B. The bill directs the Secretary to implement these provisions through program instruction or other forms of program guidance.

Part D Benefit Redesign and Capping Out-of-Pocket Costs

Background: Under the current Part D program, there is no cap on annual out-of-pocket costs for beneficiaries. If beneficiaries spend enough on prescription drugs to reach the Part D "catastrophic coverage" phase, beneficiaries are only responsible for 5% of all drug costs for the remainder of the plan year, while Medicare covers 80% and plans cover the remaining 15%. Medicare program spending in catastrophic coverage has grown significantly in recent years. In 2020, 40% of all Medicare spending on Part D was for coverage in the catastrophic phase.

Provision: The bill would establish a $2,000 out-of-pocket cap for payments under PDPs and Medicare Advantage Part D plans in 2025 and beyond.

The bill would also institute a Part D redesign to modify the phases of coverage (*i.e.*, deductible, initial coverage, coverage gap and catastrophic coverage) and financial liability requirements for PDPs, drug manufacturers and the Medicare program. Beginning January 1, 2025, the bill would end the Medicare Coverage Gap Discount Program because of the new financial liability configuration under the redesign.

Pharmacy Benefit Manager Rebate Rule

Background: In the Part D program, drug manufacturers and PDPs negotiate discounts, also called rebates, for certain covered drugs. Rebates are often used to lower premiums for all Part D enrollees, rather than being passed along to the individual enrollee purchasing a drug subject to a rebate at the pharmacy. Approximately 40% of drugs covered by Part D have some form of discount negotiated between the drug manufacturer and the PDP.

In 2020, the Trump Administration issued a finalized version of a prescription drug rebate rule that would have eliminated the anti-kickback statute safe harbor protection for prescription drug rebates. This rule would have eliminated the safe harbor with a new protection requiring that all discounts be passed to the individual enrollee at the point of sale. Because these discounts would no longer be available to subsidize Part D premiums, insurance premiums would have increased for all enrollees. Given how heavily Medicare subsidizes Part D premiums, both the Centers for Medicare & Medicaid Services Office of the Actuary and the Congressional Budget Office (CBO) concluded that the rebate rule would cost Medicare between $180 billion and $200 billion over 10 years.

Because of this, CBO indicated that delaying the rebate rule would save money. HHS previously delayed the implementation date for the discount safe harbor revisions from January 1, 2022, to January 1, 2023. The Infrastructure Investment and Jobs Act further delayed implementation of the rule until January 2026. The Bipartisan Safer Communities Act, signed into law in June 2022, also included an additional one-year delay of the rebate rule through 2027.

Provision: The IRA would further delay the implementation of the rebate rule until 2032.

Other Items of Note

Additional provisions relevant to healthcare stakeholders include the following:

- Expanded Medicare Part D coverage of adult vaccines recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices.
- Revises Part B payment for new biosimilar biological products that launch on or after July 24, 2024, during the initial offering period. The initial offering period spans the first two calendar quarters of payment for the drug prior to availability of average sales price (ASP) price. This change aims to encourage provider use of lower cost biosimilar and biological products compared to brand name products.
- Temporary increases in Medicare Part B payment for certain biosimilar biological products in order to encourage provider use of lower cost biosimilar biological products compared to brand name products.
- Expanded eligibility for low-income subsidies under Part D of the Medicare Program from 135% of the federal poverty line (FPL) to 150% of the FPL beginning January 1, 2024.
- Improved access to adult vaccines under Medicare and Medicaid.

Marketplace Advanced Premium Tax Credits

Background: The ACA included APTCs to help individuals and families with incomes between 100% and 400% of the FPL purchase health insurance in the federal exchange marketplace. ARPA temporarily extended these tax credits to individuals with incomes above 400% of the FPL and made the subsidy more generous for those below 400%. For 2021 and 2022, ARPA also expanded the ACA requirement that a health plan premium not be more than 8.5% of an

individual's income to those with incomes above 400% of the FPL. The ARPA tax credits were originally set to expire on January 1, 2023.

Provision: The IRA would extend the expanded APTCs for three years through 2025. These tax credits are identical to those included in ARPA. This provision simply pushes the sunset date of the ARPA tax credits to January 1, 2026. (ARPA also provided enhanced marketplace subsidies for people who received or were approved to receive unemployment compensation for any week beginning in 2021. However, the IRA does not include an extension of this provision.)

Next Steps

Many healthcare provisions originally under consideration did not make it into the IRA. These items include provision of dental, vision and hearing benefits in Medicare; coverage of individuals in Medicaid non-expansion states; provision of additional investments in home and community based services providers; and improvements in Medicaid to help children and postpartum women maintain coverage. While these provisions are absent from the final bill, they remain significant issues that require policy solutions.

The ability to utilize the reconciliation process to achieve such broad policy goals may not arise again in the near term. Now that the IRA is signed into law, legislating in healthcare will return to a more regular order process in Congress. Moving legislation through the House and Senate will require compromises between both parties and several committees later this year, and probably in the next Congress as well if Republicans seize control of one or both chambers. Healthcare issues not addressed in the IRA may be on the table in September, during a lame duck session, or in 2023 and beyond.

In the short term, Congress will likely turn to behavioral health before this term ends. The lame duck session after the midterm elections may also provide opportunity for legislative action on behavioral health, telehealth, Medicare extenders, prior authorization and more. The productivity of a lame duck session is hard to predict this far in advance, but early indications suggest that at least these healthcare items will be in play.

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