Vizient Office of Public Policy and Government Relations

Legislative Summary of Health Care Provisions in The Inflation Reduction Act

August 16, 2022

Background & Summary

On August 16, 2022, President Biden will sign the *Inflation Reduction Act* (IRA) into law, after passage by the Senate and the House of Representatives on August 7th and 12th, respectively. The IRA includes several key health provisions, particularly related to prescription drug pricing measures, including giving the Department of Health and Human Services (HHS) the authority to negotiate prices of certain prescription drugs in the Medicare program. The IRA also creates a new rebate program in Medicare Parts B and D for drug prices that increase faster than the rate of inflation, redesigns the Medicare Part D prescription drug program, temporarily increases Medicare reimbursement for biosimilars and places caps on insulin costs for Medicare beneficiaries. Outside of these drug pricing proposals, the IRA extends the enhanced marketplace subsidies authorized through the *American Rescue Plan Act* in 2021 set to expire at the end of this year and provides significant environmental investments and funding opportunities.

Drug Proposals

Medicare Drug Pricing Negotiations

Beginning in 2024 the HHS Secretary must begin negotiating a "maximum fair price" (MFP) for ten single-source, Part D drugs outside of their exclusivity period, with negotiated prices taking effect in 2026. As shown in the table below, that number grows to 15 in 2027, and incorporates Part B drugs beginning in 2028, until reaching a total of 20 products in 2029. Of note, the number of drugs selected is cumulative.

The products selected for negotiation will include products that represent the highest cost to the Medicare program in a specified 12-month period. Drugs that are fewer than 9 (small molecule) or 13 (biologics) years from their approval date are exempt from negotiation. The legislation also exempts certain "small biotech drugs" from price negotiation until 2028 and includes a provision that will allow HHS to postpone negotiations on a biologic for up to two years if it believes a biosimilar medication may soon become available. Certain products, including orphan drugs, plasma-derived products and low Medicare spend drugs — defined as drugs with a total initial spend below $200 million to be indexed for inflation in the future — are excluded from these negotiations. The HHS Secretary will publish the initial list of drugs selected for negotiation on September 1, 2023, with the list published for the following years on February 1st two years prior to the price applicability year.

Price Applicability Year	Number of Drugs	Eligible Drug Categories	Selected Drug Publication Deadline	Negotiated Maximum Fair Price Deadline
2026	10	Part D	Sept. 1, 2023	Aug. 1, 2024
2027	15	Part D	Feb 1. 2025	Nov. 1, 2025
2028	15	Part B and D	Feb 1, 2026	Nov. 1, 2026
2029	20	Part B and D	Feb 1, 2027	Nov. 1, 2027

For drugs subject to negotiation, the IRA establishes specific ceiling prices that negotiations would be expected to achieve. Additional details on the maximum fair price formula will be determined

during the rulemaking process; however, the IRA outlines that the MFP will be capped at a specific percentage of the non-federal average manufacturers' price (NFAMP) or an amount reflecting an average market price.

The MFP generally may not exceed the lower of:

- A specified percentage of NFAMP for 2021 (or the average of NFAMP for the first full year following market entry if there is no NFAMP for 2021), adjusted by an inflation factor;
- A specified percentage of average NFAMP for the year prior to the selected drug publication date (except for initial price applicability year 2026); or
- For Part B drugs: an amount determined for the year prior to the year of the selected drug publication date according to the lower of the average sales price or wholesale acquisition cost;
- For Part D drugs: A plan-specific amount that is the sum of the enrollment weighted net negotiated prices of the drug under prescription drug plans.

The length of time a drug has been on the market determines its specified percentage, as outlined below:

- 75% of NFAMP for short-monopoly drugs (more than 7 years but less than 12 years),
- 65% NFAMP for extended-monopoly drugs (more than 12 years but less than 16 years),
- 40% of NFAMP for long-monopoly drugs (approved for longer than 16 years).

In negotiating the price, the Secretary is required to consider, and manufacturers are required to submit, various factors, including R&D costs, costs of production and distribution, market and sales data and data on pending and approved patents. Evidence about alternative treatments is also considered. A drug would no longer be subject to the maximum fair price beginning the year that starts at least 9 months following a generic or biosimilar entering the market.

The legislation details penalties for manufacturers that are not in compliance with the negotiation process and MFP including civil monetary penalties (CMPs) and an excise tax penalty. Under the IRA, such manufacturers would face an escalating excise tax penalty of 65 percent of the sales of the drug, which increases up to 95 percent once the manufacturer is out of compliance for more than 270 days. Alternatively, the manufacturer may choose to withdraw the drug from Medicare and Medicaid to avoid the penalty. Manufacturers that do not offer a price equal to or lower than the MFP would be subject to a CMP of 10 times the difference between the offered price and the MFP for all applicable units.

Covered entities in the 340B drug pricing program may continue to purchase certain drugs at the 340B price or adopt the new negotiated price, whichever is lower. In addition, the reimbursement amount for negotiated drugs under Part B would continue to be 106 percent of the MFP. Medicare prescription drug plans would be required to include negotiated drugs on their formularies.

Inflation Rebates

The IRA also imposes penalties on drug manufacturers who increase prices faster than the rate of inflation. The inflationary increase in the legislation is based on the Consumer Price Index-Urban (CPI-U), which is typically lower than the Consumer Price Index-Medical (CPI-M). The inflation rebate provision will be implemented beginning in 2023 and will use the third quarter of 2021 as the base year for determining price changes relative to inflation in the coming years — acceptable price increases will be judged according to the rate of inflation from two quarters prior to the quarter in question. These provisions apply to all Part D products, but only single source Part B products. Additionally, vaccines, low spend (defined as under $100 per year per individual) and some biosimilars are excluded. For new products, inflationary rebates will be based on the third full quarter after the drug is initially marketed. Drugs on the FDA drug shortage list, generics or

biosimilars subject to supply chain disruptions and other generics subject to reduced access (as determined by the Secretary of HHS) are exempt from these provisions.

An earlier iteration of the IRA extended the inflationary caps to commercial health plans as well, however, these provisions were later dropped after being ruled non-germane by the Senate Parliamentarian.

Average Sales Price (ASP) Reimbursement for Biosimilars

The legislation includes a 5-year reimbursement increase for health care providers participating in Medicare Part B who use biosimilars, increasing their reimbursement rate from ASP plus 6% of the reference biologic to ASP plus 8%. For existing biosimilars already on the market and priced below the ASP of the reference biologic, the enhanced reimbursement will begin on October 1, 2022. For new biosimilars, entering the market between October 1, 2022 and December 31, 2027, the enhanced reimbursement rate will begin the quarter they enter the market and continue for five years, so long as ASP is below the reference biologic.

Part D Reforms

Effective in 2024, Medicare Part D beneficiaries will no longer have cost-sharing above the catastrophic threshold. In 2025, a $2,000 cap will be imposed on out-of-pocket spending — the new catastrophic threshold. Additionally, the Coverage Gap or "donut hole" is effectively eliminated. Cost-sharing obligations may be spread over the course of the plan year and vaccines recommended by the Advisory Committee on Immunization Practices must be covered without cost-sharing.

The IRA also includes a six percent cap on premium increases on a year-to-year basis through 2029 to ensure stability through the transition to the new benefit design.

Insulin Caps

The bill includes a provision capping out-of-pocket insulin costs at $35 per month under the Medicare program. Specifically, cost-sharing for Part D plans will be capped at $35 for approved insulin products starting with plan years 2023 through 2025. Beyond 2025, the price will be capped at the lesser of $35; 25 percent of the established maximum fair price; or 25 percent of the negotiated price. A similar provision related to commercial health plans was removed by the Senate Parliamentarian.

Extension of Enhanced ACA Marketplace Subsidies

Another significant component of the IRA is the three-year extension of enhanced insurance marketplace subsidies previously adopted under the *American Rescue Plan Act* (ARPA). ARPA substantially increased *Affordable Care Act* (ACA) premium tax credits (PTCs) and further extended tax credits to many Americans with an income level over 400 percent of the federal poverty line. These enhanced subsidies were scheduled to expire at the end of 2022. The IRA extends these enhanced PTCs through 2025 – a provision that Vizient and other hospital groups strongly supported.

Energy and Climate Investments and Tax Credits

The IRA relies heavily on the tax code to advance the deployment of clean energy technologies and combat climate change. It provides tax credits to support clean energy production, carbon capture and sequestration technologies, energy efficient manufacturing, energy efficient commercial building construction, as well as provides tax credits to support the purchase of commercial and individual electric vehicles. While the IRA does not make targeted investments in the health care provider

community and its carbon footprint, there are several potential areas where providers may be eligible for grants or where funding may support community health, including:

- $27 billion in funding to the EPA for a Greenhouse Gas Reduction Fund to help leverage private investments in projects that combat climate change. Over 40 percent of these investments will go to low-income and disadvantaged communities for clean energy projects that reduce greenhouse gas emissions.
- $4.75 billion in funding for EPA Climate Pollution Reduction Grants that would be provided through competitive grants to implement greenhouse gas air pollution reduction plans. Eligible applicants would be required to demonstrate the projected reduction of greenhouse gasses, as well as the plan's potential impact on low-income and disadvantaged communities.
- $3 billion in funding for Environmental and Climate Justice Block Grants that would be used to support activities including community-led air pollution monitoring, mitigating climate and health risks from urban heat islands, climate resiliency and adaptation, reducing indoor toxics and indoor air pollution and other efforts to mitigate the impacts of climate change.
- $3 billion in funding for Federal Highway Administration Neighborhood Access and Equity Grant Program that will support efforts to reconnect neighborhoods separated by existing highway infrastructure to support greater walkability and mitigate impact of construction projects on disadvantaged communities. While not oriented toward hospital funding, such investments could have a meaningful impact on Social Determinants of Health in affected communities.

Many of the specific details and eligibility for programs and grant funding will be made clearer once the federal agencies responsible for deploying the resources establish processes and parameters for awarding funding to states, cities, tribal governments and other stakeholders. Vizient will monitor those efforts and highlight opportunities that may become available for providers and other health care stakeholders.

What's Next?

Vizient's Office of Public Policy and Government Relations will continue to monitor the policy implications for providers that will result from the *Inflation Reduction Act*. We encourage you to reach out to our office if you have any questions regarding any aspects of the IRA. Please direct your feedback to our Government Relations Team in Vizient's Washington, D.C. office.