Congress approves major health care proposals but the work is just beginning for CMS and stakeholders

August 15, 2022

On August 7, 2022, the Senate passed the Inflation Reduction Act of 2022 (the IRA). The House approved the bill on August 12, and President Biden is expected to sign the IRA into law in the coming weeks.

The IRA addresses a range of policy topics across health care climate, energy, and taxation. Regarding health care, the IRA makes structural changes to the Medicare Part D prescription drug benefit and provides new authority for the Medicare program to address the pricing of prescription drugs in the Part B and Part D programs. The measure also extends the temporary enhanced assistance for health coverage purchased from Marketplaces, which was first approved in the American Rescue Plan Act (ARPA). In addition, the IRA updates vaccine coverage policies in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

While the IRA provides a critical framework for the structural changes to the nation's largest public health insurance programs, the U.S. Department of Health and Human Services will be responsible for building out the policy and operational components necessary to support implementation.

Notably, the Centers for Medicare and Medicaid Services (CMS) will lead implementation of the IRA's Medicare and Marketplace provisions. The changes to the Part D benefit and the development of entirely new processes and policies to support the IRA's drug pricing provisions require significant resources and consideration of direct as well as indirect impacts for the health care market. The agency can use a variety of regulatory tools to support implementation, including issuing standalone Requests for Information (RFIs), convening stakeholder engagement sessions, updating policy manuals, and undertaking notice and comment via the formal rulemaking process, among others.

CMS' strategic plan emphasizes the value of stakeholder engagement, and this is likely to lead to multiple opportunities for public input, particularly as CMS implements the new Medicare provisions of the IRA. For example, the agency must develop the policy parameters for reforming the Part D benefit design and is likely to seek input from Medicare Advantage (MA) and MA Prescription Drug Plans (MA-PDPs), providers, vendors, and consumer advocacy groups among others to inform its approach. CMS will also need input from the stakeholder community as it establishes the timelines, reporting, and negotiating mechanisms impacting Part B and D prescription drugs pricing and how it will implement the inflation penalty policies outlined in the IRA.

The IRA's extension of the American Rescue Plan Act's (ARPA) enhanced eligibility for premium assistance through 2025 provides more near certainty around eligibility and enrollment for this market. This may led to renewed momentum for CMS to engage with states and stakeholders on Marketplace policies and structures.

Many of the details around how the IRA's health care policies will be implemented are unknown at this time. Stakeholders will want to monitor CMS' progress and provide feedback with data-informed analysis and concrete and practical recommendations as these opportunities are announced.

An overview of many of the IRA's health care provisions follows. Our team of experts can provide tailored analysis and support to clients as they begin to unpack the full breadth of the IRA's policy changes and implications for Medicare Advantage and Part D plans, providers, vendors, consumer advocacy groups and other stakeholders.

- **Part B and Part D Drug Pricing.** Requires the Secretary of HHS to select a list of drugs eligible for negotiation, and enter into agreements with select manufacturers, negotiating a "maximum fair price" (MFP) for each selected

drug in the Medicare program. The Secretary is required to negotiate on a certain number of drugs per year, 10 drugs in 2026; 15 drugs in 2027 and 2028, and 20 drugs in 2029 and subsequent years. The number of drugs negotiated will accumulate over the years, such that up to 60 drugs could be negotiated by 2029. Manufacturers who are not in compliance will face an excise tax that could far exceed the cost of drugs sold over time and civil monetary penalties.

- **Prescription Drug Inflation Rebates.** Requires manufacturers to pay rebates for Medicare Part B and D drugs with prices rising faster than inflation. The rebate calculation would be based on units and pricing in Medicare and would determine an inflation-adjusted payment amount based on the percentage by which the price exceeds the inflation benchmark, as determined by the Consumer Price Index for All Urban Consumers (CPI-U). If a manufacturer fails to pay the rebate, then they would be subject to a civil monetary penalty either equal to or at least 125 percent of the rebate amount for the quarter.
  - The Part D inflation rebate takes effect October 2022 for Part D drugs and biologics.
  - The Part B inflation rebate begins January 2023 for single-source drugs or biologics and certain biosimilar products. The IRA also includes an inflation growth cap on beneficiary coinsurance in Part B, beginning April 2023.

- **Part B Payment for Biosimilar Biological Products**. Amends Medicare's Average Sales Price (ASP) payment methodology in cases where the ASP during the first quarter of sales is unavailable to establish a payment rate for biosimilars. The IRA also updates Medicare Part B reimbursement for certain biosimilar products for a five-year period beginning on October 1, 2022, by increasing the add-on payment from six percent of the reference product's ASP to eight percent of the reference product ASP.

- **Medicare Part D Assistance for Beneficiaries and Benefit Design.** Increases the qualifying income amount (federal poverty level (FPL)) for the full Low-Income Subsidies (LIS) under Part D, from 135 percent of the FPL to 150 percent of the FPL, starting in 2024. The IRA also adjusts the cost-sharing requirements in the Part D benefit by:
  - Eliminating cost sharing in the catastrophic phase of the benefit in 2024;
  - Setting an annual out-of-pocket (OOP) limit for enrollees at $2,000

beginning in 2025;
  - Capping monthly premium increases for a prescription drug plan in 2024 through 2029 at six percent per year. The Secretary may make a one-time adjustment to the beneficiary Part D premium contribution percentage in 2030 to ensure longer-term beneficiary premium reduction; and
  - Adjusting the benefit coverage liabilities for the initial coverage phase and catastrophic coverage phase.

- **Coverage for Insulin**. Requires Medicare to cover select insulin products and not apply a deductible or impose cost-sharing more than $35 or 25 percent of the negotiated price (including all discounts) for a 30-day supply. Beginning in July 2023, Medicare must exempt from beneficiary deductibles insulin provided through durable medical equipment (DME) and ensure that coinsurance for a month's supply of insulin administered through DME does not exceed $35. High-deductible health plans (HDHPs) will be able to cover selected insulin products with no deductible without impacting their status as a HDHP, starting in 2023.

- **Medicare, Medicaid, and CHIP Coverage for Vaccines**. Requires full coverage of Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines under Medicaid and CHIP without cost-sharing. The IRA also increases the Federal Medical Assistance Percentage (FMAP) by one percentage point, for adult medical assistance for such vaccines and their administration, during the first eight fiscal quarters on or after the date of the IRA's enactment.
  - Requires Medicare Part D provide full coverage without cost sharing of ACIP-recommended adult vaccines for plan years beginning on or after January 1, 2023.

- **Enhanced Temporary Assistance for Marketplace Coverage**. Extends the ARPA's expansion of Advanced Premium Tax Credit (APTC) eligibility and amounts through 2025. ARPA modified the affordability percentages used for the calculation of APTC to increase subsidy amounts for individuals eligible for assistance.

Experts from HMA and HMA companies are supporting clients as they begin to strategize and formulate initial recommendations for federal agencies and plan for

implementation. We will continue to monitor developments in this area and provide additional updates as more information becomes available.

Related blog posts:

- HHS Releases Blueprint to Address Prescription Drug Costs
- HMA Summary of Democratic Nominee Joe Biden's Healthcare Plan
- GAO 50-State Medicaid Survey on Federal Policy Challenges

< HMA Identifies Key Trends for Emerging Medicaid Section 1115 Demonstration Proposals

Meet the HMA blog contributors

Amy Bassano

Managing Director, Medicare

Washington, DC