On August 7, 2022, after extensive deliberation, Senate Democrats passed their long-awaited reconciliation bill, the Inflation Reduction Act of 2022 (the Reconciliation Bill). In addition to climate and tax provisions, the Reconciliation Bill includes a revised drug pricing reform package that Democrats had approved last month. This drug pricing reform package was highly negotiated among Senate...
Democrats after Senator Joe Manchin’s lack of support stalled the $1.75 trillion Build Back Better Act that passed in the House late last year. In an attempt to lower prescription drug prices for seniors, the bill, among other things, does the following:

- Allows Medicare to negotiate for lower drug prices for a limited number of drugs;
- Institutes an “inflation rebate” that would require manufacturers to pay Medicare the difference if prices for certain drugs rise faster than inflation;
- Sets a cap on monthly Part D related cost-sharing amounts for Part D plans (including Medicare Advantage Prescription Drug Plans (MA-PDs)) and set a maximum out-of-pocket (MOOP) annual spend limit for beneficiary Part D prescription drug expenses;
- Repeals the Part D rebate rule released by the Trump administration; and
- Caps monthly out of pocket costs for insulin at $35 for Medicare beneficiaries.

Changes from the Build Back Better Act

The drug pricing reform package includes several scaled-down measures from what was originally proposed in the Build Back Better Act. For example, the Reconciliation Bill approves Medicare negotiation for lower drug prices but does not extend such negotiation to private health insurance. In addition, the Reconciliation Bill includes an inflation cap that does not reverse previous price hikes, which was a part of the former proposal.

Senate Democrats did vote to repeal the rebate rule, but other notable provisions from the Build Better Act, such as pharmacy benefit manager (PBM) transparency requirements, were spun into their own legislation.

Medicare Drug Price Negotiation

The Reconciliation Bill allows Medicare to negotiate prescription drug prices under a specific timeline. The Department of Health and Human Services (HHS) will select 10 drugs eligible for negotiation in 2025 and 15 drugs in 2026 and 2027. In 2028 and forward, HHS will select 20 drugs eligible for negotiation each year.

HHS will choose the drugs eligible for negotiation from the list of 50 drugs with the highest total Part D expenditures and the 50 drugs with the highest total Part B expenditures. The bill provides exemptions for certain drugs from being initially eligible for negotiation with Medicare. For example, smaller biotech drugs with low expenditures are exempt from being eligible for negotiation until 2028.

Drug Pricing-Related Caps

The bill creates the following drug pricing-related caps:

- Inflation Cap: Institutes a cap on price inflation by requiring manufacturers to pay an “inflation rebate” to Medicare if prices for certain drugs rise faster than
inflation.

- **Cap on Beneficiary Monthly Spend**: Requires Part D plans (including MA-PDs) to offer enrollees the option to elect to pay cost-sharing amounts under the plan in monthly-capped amounts. For beneficiaries who elect to participate, the plan would calculate the first month’s cap by subtracting costs incurred by the enrollee from the annual out-of-pocket threshold and dividing the remainder by the number of months remaining in the plan year. In subsequent months, the cap is calculated by dividing the sum of remaining out-of-pocket costs yet to be billed to the beneficiary (and any additional out of pocket costs) by the number of months in the remaining year.

- **Cap on Beneficiary MOOP Annual Spend**: Establishes a new Medicare beneficiary MOOP spend of $2,000 per year for out-of-pocket prescription drug expenses. Current procedures require patients to pay a percentage of the cost of expensive drugs with no limit on spending.

- **Cap on Insulin Prices**: Places a $35 cap on the monthly cost of insulin for Medicare beneficiaries. A parallel $35 cap on monthly out of pocket insulin costs for commercial health plans was removed based on reconciliation budget procedural concerns, despite the seven Republicans who voted alongside Democrats to waive budget rules in order to keep the cap for the commercial market in the bill.

**Repeal of Trump Administration Part D Rebate Rule**

The bill repeals the Part D rebate rule, which would have eliminated Federal Anti-Kickback Statute safe harbor protection for Part D drug rebates in favor of direct customer discounts.

**Temporary Increase in Medicare Part B Payments for Certain Biosimilar Products**

The bill temporarily increases Medicare Part B reimbursement for certain qualifying biosimilar biological products for which payment will be made between October 1, 2022 and December 21, 2022. The new reimbursement rate will be the average sales price (ASP) plus 8 percent; these products are currently reimbursed at ASP plus 6 percent.

**Expanded Aid to Lower-Income Seniors**

Currently, Medicare provides subsidies to seniors earning less than 135% of the federal poverty line. The bill eliminates partial subsidy status and expands premium and co-pay assistance for out-of-pocket drug costs under Part D for seniors with incomes below 150% of the federal poverty line.

**Next Steps for Reconciliation Bill**

The Reconciliation Bill now heads to the House, which will briefly return from August recess on Friday August 12, 2022 to take up the measure with the goal of
sending the bill to President Biden for his signature. We will be sure to keep you up
to date on the impact of the changes that will take place upon the law’s enactment.

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National Law Review, Volume XII, Number 222