NELSON HARDIMAN
HEALTHCARE LAWYERS

Client Alert: A Priority Legislation Update -The Inflation Reduction Act of 2022 & Healthcare

On August 12, 2022, House Democrats passed the Inflation Reduction Act (IRA), a sweeping package to combat climate change, lower healthcare costs, and reduce the federal deficit by raising taxes for some billion-dollar corporations. On Tuesda President Biden signed the legislation into law. Although the bill is projected to account for $485 billion in new government spending, it vastly scales back the Democratic Party's aspirational Build Back Better Act (BBB), which has been stalled in the Senate since last November. That bill, which included measures for cost-free community college and free childcare for childre under six, was expected to generate some $2.4 trillion in new spending and tax cuts. But as far as healthcare is concerned, th new, pared-down, legislation still manages to preserve several healthcare measures first introduced in the Build Back Better Act.

An ACA Extension
The bill extends for three years Affordable Care Act subsidies that Congress had passed last year in American Rescue Plan A . The plan reduces or eliminates insurance premiums for lower- and middle-income families enrolled in health insurance marketplaces. For example, a family of four making $90,000 could save up to $2,400 annually under the extension.

Expansion of Medicare Benefits
For individuals covered under Medicare Part D, the bill eliminates co-payments and cost-sharing for adult vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as those for shingles, measles, or influenz Meanwhile, for Medicare enrollees using insulin, there will be a monthly $35-dollar price cap. Both provisions take effect January 1, 2023.

In 2024, eligibility for Part D Low Income Subsidies (LIS) will be expanded. This program helps people on Medicare with very low incomes (particularly retirees) that need further assistance paying their premiums and deductibles. In addition, the bill will eliminate the 5% coinsurance requirement above the catastrophic threshold that is mandated under current law. Once implemented, beneficiaries will no longer need to pay 5% co-payments for costly anti-cancer or multiple-sclerosis drugs.

Lastly, beginning in 2025, there will be a $2,000 cap on out-of-pocket prescription drug costs. The Kaiser Foundation estimate that this measure alone would benefit 1.5 million Part D enrollees.

Negotiating Prescription Drug Prices
Starting next year, the bill requires drug companies to pay rebates when drug prices rise faster than inflation. These inflation-based refunds include prescription drugs covered under Medicare Part B, Medicare Part D, as well as private insurance.

The proposed legislation also establishes a "Drug Price Negotiation Program" for Medicare beginning in 2026. FDA-approved drugs that have been approved for at least 7 years and have no generic competition are eligible targets for negotiation. However, there are exclusions for "Orphan" drugs, new formulations, as well as medicines for which Medicare spends less tha $200 million annually. Manufacturers that refuse to enter a negotiated agreement may be subject to progressive excise fines extending from 65% to 95% of the designated drug's sales. The Kaiser Foundation identified 42 insulin therapeutics and 20 non-insulin drugs that might possibly qualify under the selection criteria for the Medicare negotiation program. Possible contenders include Xarelto (a blood thinner), Symbicort (asthma), Revlimid (cancer), and Humira (rheumatoid arthritis). Pharmaceutical companies may preemptively cut drug pricing in 2025 to avoid being selected in 2026.

Impact on Innovation?
While the Pharma lobby complained that the bill will curtail innovation and the development of new drugs and biologics, this contention has been hotly disputed. In a presentation at Dartmouth College earlier this year, the Congressional Budget Office (CBO) modeled that the new legislation may result in a 19% drop in global pharmaceutical revenue. However, CBO projects that the current average of 44 new drugs entering the market each year to be reduced by no more than 10% over the long-ter

Authored By:

Harry Nelson, Managing Partner, Nelson Hardiman

Yehuda Hausman, Law Clerk, Nelson Hardiman

Nelson Hardiman LLP, Healthcare Law for Tomorrow

Nelson Hardiman regularly advises clients on new healthcare law and compliance. We offer legal services to businesses at every point in the commercial stream of medicine, healthcare, and the life sciences. For more information, please contact us.

This article is provided for educational purposes only and is not offered as, and should not be relied on as, legal or medical advice. Any individual or entity reading this information should consult an attorney or doctor for their particular situation.