Biden signs landmark bill with health care implications

By Jennifer L. Bragg, Esq., Avia M. Dunn, Esq., Maya P. Florence, Esq., and William McConagha, Esq., Skadden, Arps, Slate, Meagher & Flom LLP*

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On August 16, 2022, President Joe Biden signed the Inflation Reduction Act (the Act) into law, which is expected to have a significant impact on climate, tax and health care policy in the United States. The result of intense negotiations among Democrats including Sen. Joe Manchin, D-W.Va., and Senate Majority Leader Chuck Schumer, D-N.Y., the Act sets a goal of reducing carbon emissions in the U.S. by 40% by 2030 and includes parts of the Build Back Better Act (BBBA).

In a three-part series of articles, we provide an outline of the Act's major provisions, which are designed to spur clean energy, implement a 15% minimum tax on corporations and lower prescription drug prices.

The Act requires drug companies to pay rebates to Medicare if prices paid by Medicare increase at a rate that is faster than inflation.

To achieve its aim, the Act contains an array of grants, loans and tax credits for consumers and businesses — provisions that would affect industries ranging from automaking to utilities and energy. A provision to modify the treatment of carried interests was removed during negotiations with Sen. Kyrsten Sinema, D-Ariz., a moderate and key vote, and was replaced by a 1% excise tax on stock buybacks by U.S. public corporations.

Senate Democrats, who passed the measure through the budget reconciliation process on August 7, 2022, have said provisions in the Act will raise enough in revenue to balance out the new investments and reduce deficits over the next decade. Vice President Kamala Harris provided the tie-breaking vote to pass the bill following a marathon overnight session during which Republicans introduced a flurry of amendment votes. The House of Representatives passed the Act on August 12, 2022.

The key provisions outlined in this alert are related to health care.

The Act allows Medicare to negotiate certain prescription drug and biologics prices, caps the amount individuals must pay out of pocket for Medicare prescription drugs and continues Affordable Care Act (ACA) premium subsidies for another three years.

Given the complexity and magnitude of the proposed measures, please consult your Skadden contact for more information.

Health care

To help offset the costs of new subsidies, tax credits and other incentives, the Act includes several measures to reduce government and individual health care costs. The Act achieves these savings by imposing controls on Medicare drug and biologic spending and by continuing the provision of premium subsidies for individuals purchasing insurance made possible by the ACA.

Prescription drug pricing. The Act requires Medicare, for the first time, to negotiate prices for certain prescription drugs (Part D) and biologics (Part B). Medicare will negotiate the price of 10 Part D drugs in 2026, 15 Part D drugs in 2027, 15 Parts B and D drugs in 2028, and 20 Part B and D drugs in 2029. The products subject to negotiation include certain Part D drugs that received Food and Drug Administration (FDA) approval at least seven years prior (small molecule drugs) and Part B biologics that received FDA approval at least 11 years prior, and which are not subject to generic or biosimilar competition.

The Act also requires drug companies to pay rebates to Medicare if prices paid by Medicare increase at a rate that is faster than inflation. This represents a significant change from earlier versions of the proposed legislation, which had also required drug companies to pay rebates to Medicare if prices increased faster than inflation in the commercial market.

Medicare out-of-pocket costs. The Act also includes several provisions that protect against out-of-pocket costs for Medicare patients. In particular, the Act:

- caps Medicare prescription drug out-of-pocket spending at \$2,000 in 2025,
- eliminates the 5% co-insurance that Medicare prescription drug enrollees must pay after their drug costs qualify for catastrophic coverage, starting in 2024,
- limits Medicare prescription drug premium increases to no more than 6% annually through at least 2029, and
- adds new cost-sharing provisions for insulin products in 2023.

Additionally, the Act delays implementation of the Trump-era rebate rule, which would have excluded certain manufacturer



rebates paid to Medicare drug coverage plans from anti-kickback safe harbor protection, until 2032.

The Act imposes an excise tax and significant penalties for noncompliance, meaning that companies will not only have to maintain strong price reporting controls but also will have to contend with even greater overall scrutiny of drug prices.

Affordable Care Act subsidies. The Act extends through 2025 the expanded subsidies provided in the 2021 American Rescue Plan Act, which enables ACA participants to pay no more than 8.5% of their income toward health insurance premiums. Without the subsidies, ACA health care premiums are expected to rise, potentially causing many to drop their coverage or utilize fewer health care services.

About the authors









(L-R) Jennifer L. Bragg, head of Skadden, Arps, Slate, Meagher & Flom LLP's Washington, D.C., litigation practice, is a nationally recognized lawyer who advises Food and Drug Administration-regulated companies facing government investigations and related enforcement challenges. She can be reached at jennifer.bragg@skadden.com. Avia M. Dunn, a

partner in the firm's Washington, D.C., office, focuses her practice on internal and congressional investigations, health care regulatory enforcement actions and complex civil and criminal litigation. She can be reached at avia.dunn@skadden.com. **Maya P. Florence**, a partner in the firm's Boston office, advises life sciences industry companies, boards of directors, general counsel and other key executives. She has extensive experience advising on government enforcement matters, regulatory compliance, transactions and litigation. She can be reached at maya.florence@skadden.com. **William McConagha**, a partner in the firm's Washington, D.C., office, is a nationally recognized lawyer in FDA law with experience in enforcement, regulatory and legislative matters. He can be reached at william.mcconagha@skadden.com. A version of this article was originally published August 7, 2022, on the firm's website. Republished with permission.

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