

*Prepared by the New Zealand Embassy in Washington DC.*

## Summary

- New legislation will require the US federal government for the first time to negotiate directly with drug manufacturers over the price for some of its top-selling pharmaceuticals for the 64 million Americans covered by Medicare.
- Drug manufacturers will also be required pay rebates on pharmaceuticals used by Medicare beneficiaries if their prices rise faster than inflation.
- While much will depend on how the new legislation is implemented, the Congressional Budget Office has estimated these two changes will save the US government US\$170 billion over 10 years.

## Report

- The Inflation Reduction Act (IRA) signed into law in August 2022 by US President Joe Biden contained historic new powers to lower US prescription drug costs and reduce government pharmaceutical spending. The changes specifically relate to the federal Medicare health insurance programme covering 64 million American seniors and people with disabilities. Yet it is expected to have wider implications given Medicare's roughly US\$180 billion annual pharmaceutical budget accounts for more than a third of the country's total pharmaceutical spending.
- A key change is for the federal government to negotiate prices for some drugs covered under Medicare. To be eligible for negotiation, drugs must be among the 100 products costing Medicare the most money the year prior, have been on the market at least nine – or in some cases 13 - years, and lack generic or biosimilar competition. At the moment this would include blood thinning medications like Eliquis and Xarelto, that Medicare spent US\$10 billion on in 2020, cancer treatment Revlimid (\$5.4 billion), and diabetes drug Januvia (US\$4 billion).
- The change will be phased in. Medicare will announce its first 10 targets in September 2023 and the prices negotiated for those pharmaceuticals will take effect in 2026. The law allows Medicare to target additional pharmaceuticals each year thereafter, growing to as many as 60 overall by 2029. The agreed price will be published once negotiations are complete.
- A tax will be levied on companies that do not comply with the negotiation process. The excise tax starts at 65 percent of a product's sales in the US and increases by 10 percent every quarter to a maximum of 95 percent. As an alternative to paying the tax, manufacturers can choose to withdraw all of their drugs from coverage under Medicare and Medicaid.
- Another change is to require companies that increase their pharmaceutical prices higher than inflation to pay the difference in the form of a rebate to Medicare. Price changes will be measured based on the average sales price for Part B drugs and the average manufacturer price for Part D drugs. It takes effect in 2023. This would align it with the Medicaid programme which covers 82 million low-income Americans and

has used its inflation rebate power for 30 years.

- Some studies have found that half the pharmaceuticals in the Medicare programme have increased their prices faster than inflation in 2019. While a US Department of Health and Human Services (HHS) analysis highlights that if this provision had been in place from July 2021 to July 2022, then more than 1,200 pharmaceuticals would have been subject to the rebate for exceeding the 8.5 percent inflation rate during that period. The average price increase for this set of pharmaceuticals was 31.6 percent.
  - Under the IRA, vaccines for those on Medicaid will be free starting next year. For many vaccines, such as those needed to treat an injury or exposure to a disease such as rabies or tetanus, Medicare had only covered 80 percent of the cost. This included the vaccine to prevent shingles which 3.6 million Americans received through Medicaid in 2020. The change means that coverage will be consistent with fully-covered vaccines such as for influenza, pneumococcal pneumonia, hepatitis B, and COVID-19.
  - The IRA will also cap how much those with Medicare must spend on insulin to US\$35 a month. Since 2007, the number of Medicare beneficiaries using insulin has doubled with around 3.3 million older Americans now using insulin to control their diabetes. Studies show that one in four of them have skimped on insulin because of its cost. A RAND research report found the average list price for a vial of insulin in the United States is US\$98.70. The monthly cap on insulin cost sharing in Medicare takes effect in 2023.
  - Although the IRA is now law, many of its details still need to be determined through rulemaking and guidance. The magnitude of savings to the government will also depend on the price reductions that can be achieved through the negotiations process relative to what prices would otherwise be.
  - Nonetheless, the Congressional Budget Office (CBO) has released estimates that the drug pricing provisions in the IRA will reduce the federal deficit by US\$237 billion over 10 years (2022-2031). This included US\$98.5 billion in savings from the drug negotiation provisions, and a further US\$63.2 billion from the requirement that companies pay back Medicare for price rises higher than inflation.
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## External links

- The following links may provide useful information to businesses:

[Remarks by President Biden on Medicare and the Inflation Reduction Act](#)

[New HHS Reports Illustrate Potential Positive Impact of Inflation Reduction Act on Prescription Drug Prices](#)

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