The Inflation Reduction Act

New era for drug pricing in the US

On 1 October a new era in drug pricing began in the US. This was the start of a 12-month inflation period which will guide how Medicare, the government-run insurance programme for people aged 65 years and older, regulates drug prices in the future. As part of the *Inflation Reduction Act of 2022*, which was passed by the US Congress and signed into law by President Joe Biden on 16 August, pharma companies will be required to pay rebates to Medicare in the future if the prices for their drugs increase by more than the annual inflation rate. Under the same law, the federal government will also negotiate prices with manufacturers for a selection of high-cost drugs. This negotiation will be mandatory.

The legislation is the culmination of more than 70 years of political debate in the US over the merits of national health insurance starting with the administration of President Harry Truman in the late 1940s. Truman introduced several healthcare proposals to Congress, only to be rebuffed by legislators who didn't want to increase taxes. In addition, the American Medical Association lobbied hard against the healthcare plans, calling them "socialised medicine."[1]

The political climate shifted during the administration of President Lyndon Johnson when Congress enacted Medicare in 1965, covering the cost of hospital procedures as well as certain supplemental benefits for the elderly. It also enacted Medicaid, a health programme for low-income families which is funded jointly by states and the federal government. However an outpatient prescription drug benefit was dropped from the proposed legislation because of its potential cost.[1]

Introduction of a drug benefit

President George W Bush returned to the medical insurance issue shortly after his election in 2000 with the *Medicare Modernization Act of 2003*. This introduced a drug benefit called Part D. Under this feature, drug benefits were provided by private insurers which received premiums from patients and the government. Part D became the newest segment of Medicare, supplementing Part A which is hospital insurance and Part B which covers doctors' bills. Under this legislation, the amount of money patients had to pay for medicines was a function of the retail cost of the drug and the rules of their particular insurance plans. The legislation did not allow the US government to negotiate Part D drug prices directly with manufacturers. In support of this approach, the Bush Administration said that drug prices should be the outcome of competition among the private drug plans.[2]

The administration of President Barack Obama restructured healthcare further in 2010 with *The Patient Protection and Affordable Care Act* which made private and public insurance plans for people of all ages more accessible. But it stopped short of overseeing the prices of drugs. This was due to concerns that drug price regulation would disrupt the development of new medicines.[3]

Since the enactment of the *Affordable Care Act* however, the rate of increase in drug prices has accelerated. According to a report by the Office of Health Policy issued on 30 September, US prescription drug prices, in the year 2018, were 2.56 times higher than those in 32 comparable countries. In the year to July 2022, the prices of 1,216 products in the US increased faster than the rate of inflation.

The *Inflation Reduction Act* addresses these issues in three ways. First, it *requires* the Secretary of Health and Human Services to negotiate prescription drug prices with the manufacturers of certain single-source chemical drugs and biological products covered by Medicare. Second, it introduces an inflationary rebate, requiring manufacturers to refund Medicare if their prices rise above a certain threshold. As stated earlier, this threshold, which came into effect on 1 October, is set annually. Third, it restructures the standard benefit for participants, limiting a patient's out-of-pocket costs. The legislation covers drugs under Medicare Part B, which are physician-administered drugs, and Part D, which are retail prescription drugs.

The cost of prescription drugs

According to the Kaiser Family Foundation, the US public has become increasingly concerned about the cost of prescription drugs. A survey conducted in April of this year showed that 83% of American adults thought the cost of prescription drugs was unreasonable. Some 29% of respondents said they had not taken their medicines as prescribed because of the cost. And 26% said it was very difficult for them to afford their medicines.

The government's new negotiating power is focused on proprietary drugs that have been on the market for several years but do not yet face generic or biosimilar competition. Price negotiations for small molecule drugs will start nine years after their market launch, and negotiations for biologics at 13 years. The selection of these drugs however starts two years earlier. The programme focuses on drugs produced by a single manufacturer which face limited market competition. During the talks, the government is required to take into account a company's cost of production as well as its investment in research and development. At the end of the process, a maximum fair price will be established.[4]

The process is set to begin in 2023 when the government announces the first group of drugs eligible for a maximum fair price. The first negotiated prices are expected to be concluded in 2026 for 10 drugs. This figure rises to 15 drugs for each of the years 2027 and 2028 and to 20 drugs for 2029 and each following year. The negotiated price will be in effect until there is a generic or biosimilar on the market. Drugs for rare diseases, or plasma-derived products, are exempt from this process. There is also a temporary price floor for drugs from small biotechnology companies.

According to the healthcare lawyer Rachel Sachs, the

focus of this part of the legislation are drugs that command high prices and have been on the market without generic or biosimilar competition for some time.[5] An example is Humira (adalimumab) which was first approved by the US Food and Drug Administration for rheumatoid arthritis in 2002 and is only expected to face biosimilar competition in 2023. Humira has been the world's top selling drug since 2012, only slipping to the number two position in 2021 after the launch of the Pfizer-BioNTech Covid-19 vaccine. In 2021 Humira achieved revenue of $20.7 billion.

In addition to direct negotiation, the legislation leans heavily on generic and biosimilar competition to manage prices. For example, the health secretary could delay negotiating a price for certain biologics for up to two years if a biosimilar is expected to come onto the market during that period. On the other hand, originator companies could face penalties if there is evidence that they have prevented a biosimilar from coming to the market.

The inflation rebate, the second major provision, requires manufacturers to make annual payments to Medicare if they increase the prices of their drugs above an inflation threshold established every 12 months. This policy takes effect in 2023, using 2021 as the base year. As noted earlier, the Office of Health Policy has reported that the prices of 1,216 drugs increased faster than the rate of inflation in the year to July 2022. The rate of inflation for this period was 8.5%, while the average price increase for these drugs was 31.6%. This data is based on list prices for the drugs, which are the wholesale prices set by the manufacturers. The net prices for the same drugs take into account rebates paid by the manufacturers to pharmacy benefit managers. Pharmacy benefit managers are the middlemen who handle prescription drug benefits for private health insurers and for Medicare.

Out-of-pocket payments

The third provision of the legislation limits the amount of money Medicare beneficiaries have to pay out-of-pocket for their drugs. To start with, the cost of the Part D Medicare benefit is shared between the beneficiary and the government. Going forward, the beneficiary's out-of-pocket share of this cost will be capped at a threshold ("the catastrophic threshold") which is $7,050 for 2022. From 2025, the out-of pocket spending required to meet this threshold will be capped at $2,000. Importantly, the new legislation also puts a cap of $35 per month for insulin payments, starting in 2023.

"Currently, there is no out-of-pocket cap for Medicare beneficiaries in Part D; once patients reach the 'catastrophic phase' of the benefit, they can be asked to pay five percent of the cost of their drugs, without limit, which can total many thousands of dollars per year," Ms Sachs writes. "For the first time, the IRA not only eliminates this five percent cost-sharing in the catastrophic phase, but also caps patients' out-of-pocket costs in Part D at $2,000."

Separately, researchers at the Kaiser Family Foundation say this provision will be especially helpful for people who take expensive drugs for conditions such as cancer or multiple sclerosis. For example, in 2020 the average out-of-pocket spend by Medicare enrolees taking Revlimid (lenalidomide), a drug for multiple myeloma, was $6,200. This drug is used by 33,000 beneficiaries. The average out-of-pocket spend for Imbruvica (ibrutinib), a drug for lymphoma which is used by 21,000 beneficiaries, was $5,700. And the out-of-pocket spend for Avonex (interferon beta 1a) for multiple sclerosis was $4,100. This drug is used by 2,000 beneficiaries.

Reaction to the legislation

The Congressional Budget Office has estimated that the *Inflation Reduction Act* will result in fewer new drugs coming to the US market over the next 30 years. But it puts this loss at 1%.

The pharmaceutical industry association PhRMA has harsher words for the new legislation, declaring in a letter to Congress that it could discourage development of up to 100 new treatments for multiple chronic conditions over the next two decades.

The investment group Jefferies estimates that the actual incremental impact on pharma revenues coming directly from the law might be $40 billion. This translates into a loss of $100 billion in market capitalisation for public companies involved in price negotiations, or 3% of their current market value. However the real impact is expected over the longer term because the price negotiations are perpetual.

Writing for *STAT News*, Steve Pearson, head of ICER, an independent health technology assessment body, said the short-term benefits of lower drug prices from the new law are undeniable. Over a longer term however, this could lead to lower profits on some drugs, causing pharmaceutical companies to shift their investments to more profitable treatments, or even reduce investment in new drug development.

"Managing tradeoffs of this nature is an inescapable part of any health system, and I argue that the *Inflation Reduction Act* is indeed a major victory in that it marks progress in managing the potential tradeoffs between affordability and future innovation more openly and honestly," he writes.

References:

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