Impact of the Inflation Reduction Act on Drug Benefits

Overview

The Inflation Reduction Act of 2022 (IRA) made substantial changes to federal healthcare provisions and will help reduce the cost of insulin and vaccinations for those enrolled in plans such as Medicare Advantage and Part D.

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In this article, we discuss what the IRA is and the implications it has for health plans. We also highlight the challenges the law presents and the solutions available.

Formerly known as the Build Back Better bill, the IRA introduced a hard cap for prescription drug costs for people enrolled in specific government-sponsored programs, including Medicare-related plans. Learn how this law impacts certain drugs covered under Medicare plans, to strategically plan for these changes.

After much revision, this bill was re-introduced as the IRA, and subsequently passed in August 2022, enabling Medicare to negotiate drug prices with pharmaceutical manufacturers for select, sole-source drugs under Medicare Part B and Part D. These new, negotiated drug prices include small-molecule drugs that have been approved by the Food and Drug Administration (FDA) for no less than seven years. The IRA also includes large-molecule biologics that have been approved for at least 11 years.

IRA Prescription Drug Coverage Impact

Here are the IRA's high-visibility impacts on prescription drug coverage:

Cap on Insulin Costs

The IRA caps insulin costs at $35 per month for Medicare Part D enrollees and limits the amount that Part D plans can raise enrollees' premiums. The IRA limits premium growth to no more than 6% each year between 2024 and 2029 and restricts out-of-pocket costs for prescription drugs that cost up to $2,000 in any one year. When beneficiaries' expenses rise higher than $2,000, co-insurance costs will be eliminated, and health plans will become subject to rebates, which they will have to pay to cover the remaining expenses. Medicare Part D will pay 20% of the cost of brand-name drugs and 40% of the generic drug costs. Health plans and drug manufacturers will pay the rest.

Reduction of Out-of-pocket Costs

The IRA gives beneficiaries the option to pay for big out-of-pocket drug costs over time, instead of paying for them immediately when they begin taking the drug.

The IRA also expands eligibility for Part D low-income subsidies to beneficiaries with incomes of up to 150% of the federal poverty level.

According to the Kaiser Family Foundation (KFF), 1.4 million Medicare Part D enrollees without low-income subsidies had annual out-of-pocket drug spending of $2,000 or more in 2020. Based on their income, a larger pool of those beneficiaries may qualify for this new provision.

Cap on vaccine costs

As a result of the IRA, certain FDA-recommended vaccines will no longer require cost-sharing. This means Medicare Part D beneficiaries will receive those vaccines at zero out-of-pocket cost, hopefully increasing utilization in this area of preventive care.

Price negotiation

The IRA enables Medicare to negotiate with manufacturers of select drugs to reach a "Maximum Fair Price" (MFP), which is equal to a percentage of the non-federal average manufacturer price. This equates to 75% for small-molecule drugs as well as vaccines that have been available for 9 to 11 years, or 65% for drugs that are between 12 to 15 years (35% discount offered by the drug maker); or 40% for drugs that have been available for 16 years or longer (60% discount offered by the drug maker).

An Extension of the Part D Senior Savings Model (PDSS)

The IRA effectively memorializes the $35 insulin copayment cap introduced under the Part D Senior Savings Model (PDSS), into law. The PDSS was introduced in 2021 as a five-year pilot program for eligible health plans. It offered a Part D benefit design that included stable, predictable copayments for select insulins (no more than $35 per prescription for the month's supply), which applies to the deductible, initial coverage and coverage gap phases.

How the IRA Impacts Health Plans

Under Part D Redesign, a proportion of the pharmaceutical costs will be shifted to health plans and drug manufacturers. With the IRA requiring health plans to offer select insulin products at such a newly reduced rate, health plans need to work with pharmacies and/or pharmaceutical manufacturers to further negotiate insulin costs.

Health plans that fail to pay the difference when price increases outpace inflation will also be subject to civil money penalties equal to at least 125% of the rebate amount.

Another consequence of the $35 cap is that Part D plans are unlikely to cover insulin products for a copayment of more than $35. Some legal experts predict the IRA changes could also result in health plans narrowing their formularies and covering fewer products. However, the long-term implications this will have on patient health are still yet to be measured.

CMS Model Documents

These new changes meant that the language and the wording contained within model documents needed revision, in order to reflect the change in the benefits and beneficiary expense. The recent cost-sharing changes represented a significant challenge for many health plans that had already prepared their Annual Notice of Changes (ANOC) and Evidence of Coverage (EOC) documents in time for delivery prior to Oct. 1. The process of changing these documents to adhere to recent guidelines and instructions and regulatory distribution deadlines created a significant burden for health plans that may have experienced delays and added costs as a result.

One option available to health plans was to issue the model documents they already had and include a correction letter known as an Errata, which informs enrollees of the new, updated changes.

Additionally, Part D prescription drug plans and Medicare Advantage prescription drug (MA-PD) plans will receive a special Centers for Medicare and Medicaid Services (CMS) subsidy, which is equivalent to the amount of the "aggregate reduction in cost-sharing and deductible." This subsidy may be offered to mitigate the issue impacting the majority of plans who had already submitted their bids to CMS for 2023, prior to the implementation of the IRA's new requirements.

Coverage gap

The IRA eliminates the coverage gap for enrollees, effective January 1, 2025. This means health plans and manufacturers will be subject to mandatory discounts on brand drugs in the initial coverage and catastrophic coverage phases, and a greater proportion of the drug costs will be shifted to health plans and manufacturers.

Impact of the IRA

The long-term impact of the IRA is yet to be realized. What *is* known, is that the IRA will shift a more significant proportion of the drug costs to insurers. As a result, current contracts will have to be renegotiated. The result may be fewer drug choices and some insulins currently used by members may be excluded.

The immediate burden confronting health plan marketing departments at the time the IRA was passed, was the impact on boilerplate language in time-sensitive documents. The required language for insulin benefits and vaccine coverage needed revision which meant important documents already nearing completion, such as the ANOC and EOC had to be updated, leaving little time left on the clock to print and distribute materials.