The Inflation Reduction Act Impact on Prescriptions

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IN OUR LAST COLUMN, WE MENTIONED HOW the Inflation Reduction Act (IRA) signed into law on Aug. 16, 2022, may lead to increased healthcare costs for many patients in 2023 and beyond. We want to share more specifics about the myriad components of the IRA that impact prescription drugs and what pharmacists need to know to help their patients.

We all know that Medicare is a health benefits program offered for people aged 65 and older or those with certain disabilities. Medicare is made up of several parts, and the segments focused on prescriptions include Part D, Part B, and Medicare Advantage. Part D provides prescription benefits when accessed through pharmacies; Part B covers drugs provided by physicians or outpatient facilities; and Medicare Advantage combines all aspects of Medicare into comprehensive coverage offered by a sponsor, and is subject to the rules and oversight from Medicare. The following six aspects of Medicare Part D, Medicare Part B, and Medicare Advantage are changing based upon the Inflation Reduction Act:

- Negotiated prices.
- Price increase greater than inflation.
- Benefit design and premium maximum increase.
- Vaccine coverage.
- Biosimilar reimbursement.
- Insulin payment cap.

MEDICARE NEGOTIATED PRICES

The Centers for Medicare & Medicaid Services (CMS) will have three years to implement price negotiations for up to 10 drugs by 2026. The negotiation process will occur in the upcoming years, but the prices will not be utilized until 2026. The process excludes new-to-market drugs and those with generic or biosimilar competition. CMS will increase the selected products to 15 drugs in 2027 and 20 drugs in 2029.

Drugs will be selected from a list of the top 50 drugs (by total drug expenditures) in Part B and Part D. Eligible products must be single source for at least seven years post new drug application (NDA) or at least 11 years post biologics license application (BLA) licensure, unless the only indication is for a rare disease. Any drug or biologic with less than $200 million in annual spend beginning June 1, 2022, and ending May 31, 2023, will be excluded, and this exclusion limit will increase annually based upon the inflation rate.

The manufacturers of the selected drugs will negotiate with CMS a "maximum fair price" (MFP). The law defines the ceiling of the MFP to place a known cap or upper bound for the MFP. The ceiling for the MFP is the lower of amounts paid by Part D and/or Part B or the average nonfederal average manufacturer price (non-FAMP) for 2021 or the first full year following market entry, indexed to consumer price index (CPI) changes. The MFP can be negotiated lower than the ceiling values. The MFP will be a published value once it is established for the selected drugs. If a drug continues to be a selected drug in subsequent years, the MFP could increase by the CPI or be renegotiated. The drugs selected will be required to be covered by Part D plans (and are likely covered by many plans already, due to the high spend).

The MFP can set a new lower ceiling price for 340B and is included as a "best price" for Medicaid. The MFP will be excluded from average manufacturer price (AMP) calculations. Starting in 2026, long-standing brand-only medications that cost Medicare millions to billions of dollars every year will be subject to negotiations to lower both Medicare and beneficiary costs. The likely impact of this legislation will be higher launch prices for potential blockbuster drugs used in the senior population to account for the expected future costs of the MFP process.

PRICES INCREASE GREATER THAN INFLATION

Beginning Jan. 1, 2023, Part B and Part D brands and biologics will be subject to inflation rebate adjustments. If a Part B drug's average sales price (ASP) experiences a price increase above the CPI, then the manufacturer will be required to pay a rebate to Medicare for the amount of the price increase above the CPI rate. Similarly, Part D drugs with an AMP increasing above the CPI will be required to pay an inflation rebate. This rebate and resulting lower price are excluded from best price and AMP requirements. If a drug is experiencing a shortage or severe supply chain disruption, the rebate may be reduced or waived. Pharmaceutical manufacturers will take into account the CPI rates when raising prices for their products.

BENEFIT DESIGN AND PREMIUM MAXIMUM INCREASE

In 2025, the Part D benefit design will change to eliminate the donut hole, reduce the beneficiary out-of-pocket cost to $2,000 across all phases, and change the catastrophic phase to zero patient responsibility. Part of that $2,000 out-of-pocket maximum can be a deductible, but after the $2,000 spend, the beneficiary will be able to use prescriptions without additional out-of-pocket outlays. Also, the government is reducing the beneficiary's financial responsibility in all aspects of the new benefit design, making the plan sponsor responsible for a greater percentage of the overall drug spend.

Between 2024 and 2029, Medicare drug premiums will have a maximum 6% annual increase. This establishes a known maximum change for beneficiaries and prevents plans from implementing drastic changes to offset benefit design changes. Bids for 2023 were already set by the time the act was signed; 2025 is the year when more of the financial burden will apply to the Part D sponsor. We expect prescription drug plans (PDPs) and Medicare Advantage plans to use the 6% maximum increase in their pricing to reflect the risk associated with the launch of new drugs that could potentially jeopardize their financial viability, for example required coverage of new obesity medications.

VACCINE COVERAGE

Starting Jan. 1, 2023, all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) will be covered by Medicare plans without deductibles, coinsurance, or patient cost-sharing. This changes the patient cost to zero for all beneficiaries, without regard to their plan choice, benefit design, or household income. This brings Medicare in line with the Affordable Care Act provisions that apply to commercial health coverage.

BIOSIMILAR REIMBURSEMENT

Payments for biosimilars are getting a boost in Part B. Previously, biosimilars were reimbursed at a rate of the biosimilar ASP plus 6% of the reference biologic ASP. This offered the same price markup as the reference biologic, but with the presumed lower biosimilar cost. The new payment uses the same formula, but the 6% markup is changed to an 8% markup. This change became effective Oct. 1, 2022, and will be in place for five years. This also requires the biosimilar ASP to be less than the reference biologic ASP. Now, physicians will have an increased incentive to prescribe and administer a biosimilar to Medicare Part B beneficiaries.

INSULIN CAP

Patient payments for insulin will now have a maximum cap. Starting Jan.1, 2023, insulin will not be subject to any deductible, and the maximum patient copay will be $35 in the first three months of 2023; any amounts greater than $35 paid by the member must be refunded to the beneficiary within 30 days. This implementation approach provides plans with additional time for system updates. Starting in 2026, the member copay will be the lesser of $35 or 25% of the MFP or negotiated price if applicable. This will allow for an insulin product to become one of the selected drugs subject to price negotiation and offer the opportunity for patients to share in the savings.

Pharmacies and Medicare beneficiaries will experience many changes to copays, pricing, reimbursement, benefit design, and premiums over the upcoming seven years. Pharmacists must understand these changes and ensure their patients understand the benefits they are receiving from each change as it gets implemented. **CT**

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