Brownstein

Summary of Health Care Provisions in the Inflation Reduction Act

BROWNSTEIN CLIENT ALERT, AUG. 16, 2022

Subtitle B — Prescription Drug Pricing Reform

Part 1 – Lowering Prices Through Drug Price Negotiation

Sec. 11001. Providing for Lower Prices for Certain High-Priced Single Source Drugs.

- Establishes the Drug Price Negotiation Program managed by the secretary of Health and Human Services (HHS) that will:
  - Publish a list of selected drugs
  - Enter agreements with drug manufacturers
  - Negotiate and renegotiate prices
  - Enforce compliance and monitoring
- The secretary must negotiate:
  - 10 Part D drugs for the initial 2026 price applicability year, 15 Part D drugs for 2027, 15 Part D or Part B drugs for 2028, and 20 eligible Part D or Part B drugs for 2029 and subsequent years.
- The negotiated price remains in effect until a drug is no longer considered a selected drug.
- Exclusions are made for small biotech drugs and certain orphan drugs designated for only one rare disease or condition.
- Establishes a price ceiling for various categories of drugs:
  - 75% of the non-federal average manufacturer price for drugs on the market between nine and 12 years,
  - 65% of the non-federal average manufacturer price for drugs on the market between 12 and 16 years, and
  - 40% of the non-federal average manufacturer price for drugs that have been on the market for more than 16 years.
- **Impact:** Allows HHS secretary to negotiate prescription drug prices on a small subset of drugs starting in 2026.

Sec. 11002. Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry.

- Allows the HHS secretary to exclude a biosimilar if the secretary determines a biosimilar product will be licensed and marketed within two years following the selected drug publication date.
- Explains the documentation required to be considered for a delay of inclusion in the selected drug list.
- **Impact:** Defines and outlines the process to delay being included in the selected drug list.

Sec. 11003. Excise Tax Imposed on Drug Manufacturers during Noncompliance Periods.

- Imposes a tax on the manufacturer, producer or importer of any selected drug if they do not comply with the negotiation rules.
- The tax amount is equal to the ratio of the tax divided by the sum of the tax and the price for which the drug is sold.

- The tax is:
    - 65% of the sale of the drug in question for the first 90 days following noncompliance;
    - 75% for days 91-180 following noncompliance;
    - 85% for days 181-270 following noncompliance; and
    - 95% for days 271+ following noncompliance.
- **Impact:** Imposes a tax on manufacturers, producers or importers if they do not negotiate with the secretary of HHS. The tax increases the longer there is noncompliance.

Sec. 11004. Funding.

- **Impact:** This provision provides $3 billion to the Centers for Medicare and Medicaid Services (CMS) for fiscal year 2022 to be remain available to carry out the drug price negotiations.

Part 2 – PRESCRIPTION DRUG INFLATION REBATES

Sec. 11101. Medicare Part B Rebate by Manufacturers.

- Beginning in 2023, this bill establishes a mandatory rebate for drug manufacturers for certain Medicare Part B drugs when the price of a drug increases faster than inflation.
- The secretary of HHS calculates a rebate amount based on the total number of units of the Part B drug, including for the Medicare program and the commercial market, and determines the inflation-adjusted payment amount based on the percentage by which the price exceeded the inflation benchmark.
- Should a manufacturer not pay the mandated rebate, the manufacturer shall be subject to a civil monetary penalty equal to or at least 125% of the rebate amount for such calendar quarter.
- **Impact:** If a drug price in Medicare Part B increases faster than inflation, the manufacturer either provides a rebate or pays a monetary penalty.

Sec. 11102. Medicare Part D Rebate by Manufacturers.

- Beginning in 2023, establishes a mandatory rebate for drug manufacturers for certain Medicare Part D drugs with prices increasing faster than inflation.
- The secretary of HHS calculates a rebate amount based on the total number of units with respect to a Part B rebatable drug, including for the Medicare program and the commercial market, and determines the inflation-adjusted payment amount based on the percentage by which the price exceeded the inflation benchmark.
- Should a manufacturer not pay the mandated rebate, the manufacturer shall be subject to a civil monetary penalty equal to or at least 125% of the rebate amount for such calendar quarter.
- **Impact:** If a drug price in Medicare Part D increases faster than inflation, the manufacturer either provides a rebate or pays a monetary penalty.

PART 3—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

Sec. 11201. Medicare Part D Benefit Redesign.

- Beginning in 2025, this bill caps the cost for prescription drugs by setting the annual out-of-pocket limit at $2,000.

- Also beginning in 2025, the bill directs the secretary to establish a manufacturer discount program to enter into agreements with drug manufacturers regarding discounted prices for applicable drugs.
- Provides the secretary with authority to impose a civil monetary penalty for noncompliance.
- Directs the secretary to establish a selected drug subsidy program with respect to covered Part D drugs and appropriates $341 million to CMS for FY24—FY31 to carry out this provision.
- **Impact:** Redesigns Medicare Part D to provide an annual out-of-pocket cap.

Sec. 11202. Maximum Monthly Cap on Cost-Sharing Payments under Prescription Drug Plans and MA-PD Plans.

- Allows eligible beneficiaries who meet the out-of-pocket cap in a single prescription fill to pay for such costs in installments throughout the year.
- Appropriates $10 million to CMS for the purpose of implementing this provision.
- **Impact:** Allows beneficiaries who meet the new out-of-pocket cap in a single prescription to spread the cost throughout the year.

PART 4—CONTINUED DELAY OF IMPLEMENTATION OF PRESCRIPTION DRUG REBATE RULE

SEC. 11301. Extension of Moratorium on Implementation of Rule Relating to Eliminating the Anti-Kickback Statute Safe Harbor Protection for Prescription Drug Rebates.

- Prohibits the implementation before Jan. 1, 2032, of the final rule entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Services Fees" that was published by the Office of the Inspector General of HHS on Nov. 30, 2020.
- **Impact:** Delays the Trump-era Rebate Rule.

PART 5—MISCELLANEOUS

Sec. 11401. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D.

- This provision requires that zero coinsurance apply for vaccines recommended by the Advisory Committee on Immunization Practices under Medicare Part D.
- **Impact:** Requires no coinsurance for recommended vaccines.

Sec. 11402. Payment for Biosimilar Biological Products during Initial Period.

- This provision establishes payments beginning on July 1, 2024, for new biosimilars for the initial period when Average Sales Price is unavailable.
- **Impact:** Revises payments in Medicare Part B for new biosimilars beginning in 2024.

Sec. 11403. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products.

- Updates the add-on payment for biosimilars from 6% to 8% of the reference product average sales price for 2022 to 2027.
- **Impact:** Revises payments to biosimilars for years 2022 to 2027.

Sec. 11404. Expanding Eligibility for Low-Income Subsidies under Part D of the Medicare Program.

- Beginning in 2024, increases the eligibility threshold for low-income subsidies for individuals below 150% of the federal poverty line.
- **Impact:** Expands eligibility for low-income subsidies under Medicare Part D.

Sec. 11405. Improving Access to Adult Vaccines under Medicaid and CHIP.

- Requires coverage of certain adult vaccinations under Medicaid while also eliminating some cost-sharing.
- Increases by 1% the Federal Medical Assistance Percentage (FMAP) for adult vaccines and administration.
- Requires the coverage and eliminates cost-sharing of recommended adult vaccines or individuals ages 19 and older under CHIP.
- **Impact:** Increases vaccine coverage and reduces cost-sharing for vaccines under Medicaid and CHIP.

Sec. 11406. Appropriate Cost-Sharing for Covered Insulin Products under Medicare Part D.

- From 2023 through 2025, cost-sharing for insulin is capped at $35 per month.
- Beginning in 2026, insulin is capped at the lowest of:
    - $35;
    - 25% of the established maximum fair price; or
    - 25% of the negotiated price.
- **Impact**: Caps the cost of insulin in Medicare Part D.

Sec. 11407. Limitation on Monthly Coinsurance and Adjustments to Supplier Payment under Medicare Part B for Insulin Furnished through Durable Medical Equipment.

- Effective Jan. 1, 2023, the bill creates a safe harbor that permits employers with a health savings account qualified high-deductible health plan to cover any insulin dosage of any type before the individual meets the plan's deductible.
- **Impact:** Creates a safe harbor for plans that do not have a deductible for selected insulin products.

Subtitle C — Affordable Care Act Subsidies

Sec. 12001. Improve Affordability and Reduce Premium Costs of Health Insurance for Consumers.

- Extends the ACA enhanced premium tax credits through 2025.
- **Impact**: Extends the ACA enhanced premium tax credits through 2025.