

# **INSULIN Act**

## **Section-by-Section**

### **Title I: Patient Protections with Respect to the Cost of Insulin Covered under Private Health Insurance**

#### *Section 101 – Certification of Insulin Products*

Beginning January 1, 2024, manufacturers of insulin products can seek designation of insulin as a certified insulin. To do so, a manufacturer must attest that the list price of an insulin product for a plan year will not be greater than the weighted average of the Medicare Part D negotiated prices for such insulin, net of all manufacturer rebates, received by plans in 2021.

Manufacturers can subsequently certify beginning on January 1, 2025 and each plan year thereafter that the certified product has not increased the list price higher than the consumer price index for all urban consumers (CPI-U), and that it will not grow in excess of inflation in the subsequent year.

*Special Rule for Certain Insulin* – For products not licensed and marketed as of December 31, 2021, manufacturers may certify new insulin products attesting that the average list price of such insulin is not greater than the weighted average negotiated price under Medicare Part D net of all manufacturer rebates for that category of insulin. Insulin categories include rapid-acting, short-acting, intermediate-acting, long-acting and pre-mixed.

*Decertification* – Products may be decertified during a plan year if the list price for such insulin is increased above the certified price. If a product is decertified, plans must maintain out-of-pocket requirements through the plan year for enrollees already receiving such insulin.

*Public Posting* – No later than April 15, 2023 and January 15 of each subsequent year, the Secretary shall post a list of certified insulin products for the applicable plan year and the weighted average negotiated price for the purposes of the special rule for certain insulin.

*Audits and Penalties* – The Inspector General for the Department of Health and Human Services (HHS) may audit the financial records of any manufacturer certifying insulin products. If a manufacturer is found to have increased the list price of a certified insulin product above the certified price, the Inspector General shall assess a civil monetary penalty equal to the difference between the certified price and the actual wholesale acquisition cost, multiplied by the number of units sold at the increased price.

#### *Sec. 102 – Patient Protections for People with Diabetes*

For certified insulin products, group health plans, health insurance issuers offering group or individual plans and pharmacy benefit managers contracted on behalf of such plans (plans) shall not:

- Receive price concessions for certified insulin products or for any other product tied to the coverage of such insulin;

- Apply any deductible or impose any cost-sharing requirements in excess of the lesser of \$35 or 25% of list price for a 30-day supply; and,
- Impose any utilization management tools, such as prior authorization or step therapy, for certified insulins except as clinically justified for safety to ensure reasonable quantity limits.

*Sec. 103 – Requirements with Respect to Cost-Sharing for Certain Insulin Products*

Beginning January 1, 2023, plans must select at least one insulin product (selected insulin) of each dosage form and type. For selected insulin products, plans shall not apply any deductible or impose any cost-sharing requirements in excess of the lesser of \$35 or 25% of the list price for a month's supply.

**Title II: Patient Protections with Respect to the Cost of Insulin Covered under Medicare**

*Sec. 201 – Appropriate Cost-Sharing for Insulin Products Covered under Medicare Part D*

For plan year 2023, Medicare Part D and Medicare Advantage plans must select at least one insulin product (selected insulin) of each dosage form and type. For selected insulin products, plans shall not apply any deductible or impose any cost-sharing requirements in excess of the lesser of \$35 or 25% of the list price for a month's supply. Plans must also include all selected insulin products on the plan's formulary.

*Sec. 202 – Additional Protections under Medicare Part D*

For certified insulin products beginning plan year 2024, Medicare Part D and Medicare Advantage plans:

- Shall not receive price concessions for certified insulin products or for any other product tied to the coverage of such insulin;
- Shall not apply any deductible or impose any cost-sharing requirements in excess of the lesser of \$35 or 25% of the list price for a month supply;
- Must include the certified insulin product on the plan's formulary; and,
- Shall not impose any utilization management tools, such as prior authorization or step therapy, for certified insulins except as clinically justified for safety to ensure reasonable quantity limits.