Medicare Drug Price Negotiation Act
Section-by-Section Summary

Section 1: Title – Medicare Drug Price Negotiation Act

Section 2: Negotiation of Lower Covered Part D Drug Prices on Behalf of Medicare Beneficiaries and Establishment and Application of Formulary by the Secretary of Health and Human Services Under Medicare Part D

Negotiation Framework

This Section strikes the provision of current law (the noninterference clause) that prohibits the Secretary of Health and Human Services (HHS) from negotiating drug prices on behalf of Medicare Part D beneficiaries and directs the Secretary to negotiate directly with drug manufacturers for lower prices on covered Part D drugs.

The Secretary is directed to prioritize the following categories of drugs for negotiation: high-cost drugs, drugs that have had significant price increases, drugs that drive up Medicare Part D spending, and drugs without competition (single source drugs and biologics) that also meet one of the other criteria for prioritization.

The Secretary is directed to issue public guidance before negotiations begin which identifies criteria to be considered during negotiations, including the particular drug's comparative clinical and cost-effectiveness, budgetary impact on Medicare, and the number of similarly effective drugs available. The Secretary is also directed to issue a public report following each negotiation period to document how these criteria were assessed in a given negotiation.

Negotiations will be conducted in groupings identified in advance by the Secretary. Negotiations will be conducted over the course of one plan year. The first negotiation year will begin on January 1, 2019. Once a price is reached, that price will remain in effect for three years.

Use of Formulary and Fallback Prices

This Section directs the Secretary to either establish one national drug formulary for use by all prescription drug plan sponsors or direct plan sponsors to make certain changes to their own formularies for drugs that are under price negotiation. Plan sponsors are able to use benefit design and other formulary tools to secure steeper discounts or rebates below the prices negotiated by the Secretary.

This Section also establishes fallback prices that are adopted automatically if negotiations between the Secretary and a drug manufacturer are not successful after one plan year. The fallback prices are the lowest of the Federal Ceiling Price (the highest price that can be charged to direct federal purchasers of drugs), the lowest price charged by ten Organization for Economic Cooperation and Development (OECD) countries with similar GDPs per capita as the United States, and the lowest, or "Best Price" obtained by the Medicaid program.

Patient Protections

This Section preserves critical protections for patient access by including in any formulary certain categories and classes of drugs that are protected under current law and by strengthening the patient appeals process for accessing drugs that are not covered by the formulary.

This Section directs the Medicare Payment Advisory Commission to study whether price negotiations are effective in securing lower prices for Part D beneficiaries, generating savings for the federal government, and affecting drug prices in the commercial market.

Section 3: Requiring Manufacturers to Provide Drug Rebates for Drugs Dispensed to Low-Income Individuals

This Section restores minimum rebates for low-income Medicare beneficiaries that were lost when Medicare Part D was established in 2006. Prior to Medicare Part D, individuals who were dually eligible for Medicare and Medicaid received their prescription drug benefits through the Medicaid program. After Part D was created, these people began receiving their drug benefits through Medicare. Drug manufacturers that participate in Medicaid are required to provide back to Medicaid statutory discounts in the form of rebates, but there are no similar rebates for Medicare. This Section applies to both brand-name and generic drugs and extends rebates to all Medicare beneficiaries who are covered by the Low-Income Subsidy, in addition to those who are dually eligible for Medicare and Medicaid. The Congressional Budget Office has projected that restoring these rebates would save $145 billion over ten years.