Prescription Drug Pricing

Below is an overview of the agreement on prescription drugs. The policy is structured around three main provisions:

1. Providing the authority, the mandate, and the tools for Medicare to negotiate drug prices outside their initial exclusivity period.
2. Redesigning the Part D benefit to protect seniors from high out-of-pocket spending.
3. Instituting rebates for drug prices that grow faster than inflation.

Negotiation: Under this policy, Medicare will negotiate prices for a subset of drugs. The process begins with the Secretary of HHS selecting from a list of the highest gross spending drugs in each of the Part B and Part D programs that are single source drugs outside of their initial exclusivity periods – 9 years for small molecule drugs and 12 years for biologics – as well as insulin products.

The proposal specifies that the Secretary will negotiate up to 10 drugs for 2025. In each following year, that number will increase until reaching up to 20 drugs for 2028 and beyond. CMS indicated that those numbers are feasible.

After selecting the drugs for negotiation, manufacturers will submit information about the selected drug, such as their research & development costs, prior federal financial support, extent to which the drug addresses an unmet need, whether the drug represents a therapeutic advance beyond existing treatments, and more. The Secretary then uses this information to engage in a back and forth with the manufacturer to arrive at an agreed to fair price. During this process, the Secretary is explicitly directed to consider the innovation that the selected drug represents.

The negotiated price cannot exceed the following:

- 75% of its 2021 non-federal average manufacturer price for a small molecule drug fewer than 12 years but more than 9 years passed initial exclusivity.
- 65% of its 2021 non-federal average manufacturer price for a drug 12 – 16 years passed initial exclusivity.
- 40% of its 2021 non-federal average manufacturer price for a drug more than 16 years passed initial exclusivity.

For manufacturers that refuse to negotiate, they will be subject to an excise tax; however, CBO assumes this tax is never actually levied.

When the Secretary and manufacturer arrive at an agreed to negotiated price, the Secretary will then require that the negotiated drug be carried on the formulary by all Part D plans so that all patients have access to it.

Inflation Rebates: The base year for the inflation rebate is 2021. The rebate is calculated based on total drug units sold.

Part D Redesign: The policy creates an annual out-of-pocket patient spending cap of $2,000, and allows those costs to be smoothed over the calendar year. Insulin co-pays are capped at $35 per month. In addition, the beneficiary share of costs in the initial coverage phase will be decreased from the current 25%; lawmakers will include a placeholder reduction and work expeditiously to finalize a design to

reduce beneficiary costs that does not increase premiums and that manages federal costs. Drugs that have been negotiated are exempt from manufacturer liability. The framework is:

Benefit Phase	Current Law	Proposed Law
Deductible ($445)	**Beneficiary**: 100% of costs	**Beneficiary**: 100% of costs
Initial Coverage Phase	**Beneficiary**: 25% of costs **Plan**: 75% of costs **Manufacturer**: 0% of costs	**Beneficiary**: <25% of costs **Plan**: 65% of costs for brands, biologics and biosimilars; 75% of costs for generic drugs **Manufacturer**: 10% of costs for brands, biologics and biosimilars; 0% of costs for generic drugs
Coverage Gap	**Beneficiary**: 25% of costs **Plan**: 5% of costs for brands, biologics and biosimilars; 75% of costs for generic drugs **Manufacturer**: 70% of costs for brands, biologics and biosimilars	**Eliminated**
Catastrophic Phase	**Beneficiary**: 5% of costs **Plan**: 15% of costs **Manufacturer**: 0% of costs **Medicare**: 80% of costs	**Beneficiary:** 0% of costs **Plan:** 60% of costs **Manufacturer**: 20% of costs for brands, biologics and biosimilars; 0% of costs for generics **Medicare:** 20% of costs for brands, biologics and biosimilars; 40% of costs for generics

Special Rules for Small Biotech: The policy contains a number of special rules for the small biotech market:

- Exempts from negotiation all drugs that contribute less than $200 million in Medicare spending.
- Excludes companies that meet a definition of small biotech from negotiation for the first 3 years, i.e. no negotiated price applies until 2028 at the earliest.
- Phases-in any reductions from negotiations for the first two years negotiated price applies for companies that meet a definition of small biotech.
- Phases in manufacturer liability in the Part D redesign over 6 years for companies that meet a definition of small biotech.

A small biotech is defined as a company where one drug makes up 80% of the manufacturer's Medicare revenue, but that drug constitutes less than 1% of Medicare drug spend.

Transparency: The policy will require PBMs to report their rebates to employers and plans sponsors.