

H.R. 3 – Title Summary

TITLE I – Drug Price Negotiation

Drug Selection Process

Every year, the Secretary would identify the 250 brand-name drugs that lack price competition with the greatest cost to Medicare and the whole U.S. health system. The Secretary would use data provided by Medicare, Medicaid, and commercial insurance to make the determination about aggregate cost, which is a measure of price and volume of sales.

An eligible drug that lacks price competition will be defined as a brand-name drug that does not have a generic or biosimilar competitor on the market. Insulin would also be included for negotiation. The overwhelming volume of costs in Medicare is disproportionately concentrated in the segment of drugs that would be eligible for negotiation the first year:

Part D Negotiable Drug Spending Rank	Percent of Total Part D Spending	Part B Negotiable Drug Spending Rank	Percent of Total Part B Spending
1-25	23%	1-25	66%
26-50	9%	26-50	16%
51-75	6%	51-75	7%
76-100	4%	76-100	5%
101-125	3%	101-125	2%

In prioritizing drugs for negotiation each year, the HHS Secretary would take into account the drugs for which the greatest savings to taxpayers, patients, and all payers may be achieved. The Secretary will negotiate as many drugs as possible each year, with a bare minimum of 25 annually, recognizing the practical capacity and bandwidth constraints on HHS.

A drug selected for negotiation would continue to be included in the program until competition enters the market.

Negotiation of Maximum Fair Price

The HHS Secretary would directly negotiate with drug manufacturers to establish a maximum fair price. The legislation establishes an upper limit for the price reached in any negotiation as no more than 1.2 times (or 120 percent) of the volume-weighted average of the price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the Average International Market (AIM) price.

While negotiating the price, the HHS Secretary would take into consideration:

- research and development costs of the drug as well as cost of production;
- information on alternative treatments and the value of the drug; and,
- domestic and international sales information.

If a manufacturer refuses to enter into negotiations after being selected by the Secretary or if the manufacturer leaves the negotiation before a maximum fair price is agreed to, then the manufacturer will be assessed an escalating excise tax levied on the manufacturer's annual gross sales – starting at 65 percent and increasing by 10 percent every quarter the manufacturer is out of compliance, to a maximum of 95 percent.

This steep, escalating penalty creates a powerful financial incentive for drug manufacturers to negotiate and abide by the final price, while ensuring that patients maintain uninterrupted access to the medicines they

need. The penalty gives the HHS Secretary leverage without resorting to a restrictive formulary and without the interruptions of contracting, building and approving a whole new production line. Given drug prices in the United States are so much higher than in other industrialized countries, a penalty of this magnitude is needed to ensure manufacturers come to the table to negotiate, instead of opting to pay the penalty and still profiting off of American consumers.

The goal is for the HHS Secretary and the manufacturer to negotiate a mutually agreed maximum fair price that is below the Average International Market (AIM) price through a voluntary, bi-lateral negotiation process. Once a price is negotiated, the manufacturer may not increase the price faster than inflation in the subsequent years until sufficient price competition enters the market. The Secretary or the manufacturer may request a re-negotiation if new information becomes available after the maximum fair price is agreed to.

Application of Maximum Fair Price to Medicare and Other Payers

The maximum fair price would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. A manufacturer would also be required to offer the negotiated price to the commercial market, to group and individual health insurance plans. It is at the discretion of these payers whether to accept the negotiated price.

If a manufacturer has agreed to a maximum fair price, and then overcharges Medicare or fails to offer the maximum fair price to other payers, the manufacturer would be subject to a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price for the drug.

Protecting Innovation

The best way to support future pharmaceutical innovation is to build a sustainable market-based system for pricing prescription drugs. At the same time, this proposal addresses a clear market failure that exists in our system, for extremely high-priced prescription drugs that have no competition. Innovation does not benefit Americans if they cannot afford it.

TITLE II – Medicare Part B & D Inflation Rebates

Year after year, Americans have watched drug companies hike the costs of drugs well above the rate of inflation, subjecting patients to soaring prices even for long-ago discovered drugs that have been on the market for years or decades.

To reverse these unjustified price hikes, all of the more than 8,000 drugs in Medicare Part B and D would face a new inflation rebate. If a drug company has raised the price of a drug in Part B or D above the rate of inflation since 2016, they can either lower the price or be required to pay the entire price above inflation in a rebate back to the Treasury.

TITLE III – Capping Out-of-Pocket Spending for Seniors and Individuals with Disabilities & Modernizing Part D

Title III creates an out-of-pocket spending maximum for the 46 million Medicare beneficiaries who are enrolled in the Medicare Part D prescription drug program. Currently, the Medicare program does not have an out-of-pocket cap, meaning that Medicare beneficiaries lack the financial certainty to know how much their total annual drug spending could be. Medicare beneficiaries pay \$5,100 before the catastrophic coverage begins, but even then, under current law beneficiaries still can face significant cost-sharing. Among Medicare

beneficiaries, 21 percent of out-of-pocket spending in 2016 went to prescription drugs.¹ According to MedPAC, 370,000 Medicare beneficiaries reached the catastrophic phase (spent nearly \$5,000 out of pocket) after filling *only one prescription* in 2017.²

This bill creates a cap on the costs for prescription drugs for Medicare Part D beneficiaries by setting the annual out-of-pocket limit at \$2,000. This means that beneficiaries who have more than \$2,000 in prescription drug spending will face no additional cost-sharing over that amount.

Title III also realigns incentives to require health plans to pay more in the catastrophic coverage phase, and reduces government reinsurance subsidies. Reinsurance for the catastrophic spending grew by over 500 percent from \$8.0 billion in 2007³ to nearly \$40.9 billion in 2018 – and is now the single-largest component of total Part D spending.⁴ This bill would decrease the government reinsurance from 80 percent to 20 percent, and increase plan responsibility from 20 percent to 50 percent, thereby increasing incentives for plans to better manage drug spending.

Additionally, Title III converts the current coverage gap discount program into a benefit-wide responsibility, and requires prescription drug manufacturers to pay for drug coverage in both the initial and catastrophic phases of the benefit. Under current law, manufacturers pay 70 percent of the costs for beneficiaries in the coverage gap. This bill requires drug manufacturers to be responsible for 30 percent of costs in the catastrophic coverage phase, to ensure that drug companies help pay more of the costs for expensive drugs in catastrophic coverage. Additionally, manufacturers would be required to pay 10 percent costs in the initial coverage phase.

These program enhancements would be implemented beginning in plan year 2022.

TITLE IV – Historic Improvements to Medicare & Additional Investments

With the significant savings achieved by getting American consumers a fair deal on their drug prices, H.R. 3 will strengthen and improve Medicare for seniors and people with disabilities for generations to come. H.R. 3 will reinvest billions of dollars where they belong: in the search for new treatments and cures and transformational improvements to Medicare for America’s seniors and people with disabilities. If the savings are great enough, these improvements could include Medicare coverage for vision, hearing and dental as well as improvements to benefits for low-income Medicare beneficiaries.

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¹ Kaiser Family Foundation, “10 Essential Facts About Medicare and Prescription Drug Spending” Jan 2019.

² http://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf?sfvrsn=0

³ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>

⁴ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf>