



MEMORANDUM

September 18, 2019

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans”

On Wednesday, September 25, 2019, at 10:30 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Health will hold a legislative hearing entitled, “Making Prescription Drugs More Affordable: Legislation to Negotiate A Better Deal for Americans.”

I. BACKGROUND

American consumers bear a significant burden for the rising costs of prescription drugs as prices continue to increase and total drug spending continues to grow. The number of adults who report that they or a family member have not filled a prescription, rationed medication below their prescribed dose, or skipped doses altogether because they could not afford the full cost of their medicines has risen to nearly 30 percent in 2019.¹ Additionally, one in ten adults report that their health has declined because they were unable to afford to take their prescription as recommended.²

As drug prices rise, so do the out-of-pocket costs that consumers face. Nearly half of the most expensive brand-name prescription drugs—those exceeding \$500 million in U.S. sales—have more than doubled in price in less than a decade.³ In 2017, total U.S. retail prescription

¹ Kaiser Family Foundation, *Health Tracking Poll – Prescription Drugs* (Mar. 1, 2019) (www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/).

² *Id.*

³ The Journal of the American Medical Association, *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States* (May 31, 2019) (jamanetwork.com/journals/jamanetworkopen/fullarticle/2734804).

drug spending was \$333 billion, of which American consumers paid \$47 billion out-of-pocket, representing 14 percent of total drug spending.⁴

For Americans enrolled in Medicare Part D, under current law, beneficiaries have no out-of-pocket maximum and lack the financial certainty to know what their total out-of-pocket spending could be annually. Under the current Part D standard benefit design, enrollees have cost-sharing including a \$415 deductible and 25 percent coinsurance up to the initial coverage limit of \$3,820.⁵ After an enrollee reaches the initial coverage limit, a beneficiary will enter the coverage gap or “donut hole” when he or she pays 25 or 37 percent for brand-name and generic drugs respectively.⁶ Once a beneficiary reaches the catastrophic coverage threshold, currently set at \$5,100, Medicare pays 80 percent, Part D plans (PDP) pay 15 percent, and beneficiaries pay either 5 percent or a fixed fee.⁷

Prescription drug prices are growing at levels that are increasing health insurance premiums⁸, driving unsustainable cost growth in Medicare and Medicaid,⁹ and putting Americans’ health at risk.¹⁰

A large portion of these growing costs stem from the utilization of single-source brand drugs that lack generic competition. In 2017, brand drugs accounted for 77 percent of total Part D spending (\$117.1 billion) and specifically single-source brand drugs accounted for almost three-quarters (72 percent) of total Part D spending (\$109.3 billion).¹¹

⁴ Kaiser Family Foundation, *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?* (May 20, 2019) (www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/).

⁵ MedPAC, *Part D Payment System* (Oct. 2018) (http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_partd_final_sec.pdf?sfvrsn=0).

⁶ *Id.*

⁷ *An Overview of the Medicare Part D Prescription Drug Benefit*, Kaiser Family Foundation (Oct. 12, 2018) (www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/).

⁸ Health Affairs, *Prescription Medications Account For One In Four Dollars Spent By A Commercial Health Plan* (Aug. 24, 2018) (www.healthaffairs.org/doi/10.1377/hblog20180821.820628/full/).

⁹ Kaiser Family Foundation, *10 Essential Facts About Medicare and Prescription Drug Spending* (Jan. 29, 2019) (www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/).

¹⁰ *Annals of Pharmacotherapy, Cost of Prescription Drug-Related Morbidity and Mortality* (Mar. 26, 2018) (www.ncbi.nlm.nih.gov/pubmed/29577766).

¹¹ *Avalere Analysis Examines Drug Spending in Medicare Part D*, Kelly Brantley et. al (June 21, 2019) (<https://avalere.com/insights/avalere-analysis-examines-drug-spending-in-medicare-part-d>).

Most other high-income countries spend significantly less on prescription drugs than the United States, despite similar drug utilization levels.¹² In fact, it has been estimated that citizens across 10 other high-income countries have spending on average that is 56 percent of what Americans spend on the exact same drug.¹³ Researchers have also found that the United States spends the most per capita on prescription drugs as compared with other high-income countries¹⁴ and that drug prices in the United States are the single largest category of health care overspending as compared with Europe.¹⁵

Some researchers have argued that granting the Secretary of Health and Human Services (HHS) the authority to negotiate with drug manufacturers for the price of prescription drugs on behalf of the Medicare population could reduce prescription drug costs and bring prices closer to those in other high-income countries.¹⁶

Under current law, the Secretary is prohibited from interfering with “the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors...”¹⁷ This clause, often referred to as the “noninterference clause” of the Medicare Part D statute, was enacted in the Medicare Modernization Act of 2003, which established the Medicare Part D program. Since the implementation of the Medicare Part D program, Medicare spending for Part D has increased from about \$46 billion in 2007 to about \$80 billion in 2017, for an average annual growth of 5.6 percent.¹⁸ Additionally, the Congressional Budget Office (CBO) has determined that for Part D beneficiaries who took brand-name specialty drugs, the average annual net spending on such drugs tripled between 2010 and 2015.¹⁹

¹² The Commonwealth Fund, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?* (October 5, 2017) (www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier).

¹³ The Journal of the American Medical Association, *Health Care Spending in the United States and Other High-Income Countries* (Mar. 13, 2018) (jamanetwork.com/journals/jama/article-abstract/2674671)

¹⁴ The Commonwealth Fund, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?* (October 5, 2017) (www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier).

¹⁵ *Supra* note 9.

¹⁶ The Journal of the American Medical Association, *The High Cost of Prescription Drugs in the United States* (August 23, 2016) (www.ncbi.nlm.nih.gov/pubmed/27552619).

¹⁷ Sec.1860D-11(i)

¹⁸ MedPAC, *The Medicare prescription drug program (Part D): Status Report* (Mar. 2019) (www.medpac.gov/docs/defaultsource/reports/mar19_medpac_ch14_sec.pdf).

¹⁹ Congressional Budget Office, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid* (Mar. 2019) (www.cbo.gov/system/files/2019-03/54964-Specialty_Drugs.pdf).

II. LEGISLATION

A. H.R. 3, Lower Prescription Drug Costs Now Act

i. Title I: Negotiation

H.R. 3, introduced by Chairman Frank Pallone, Jr., and Reps. Richard Neal (D-MA) and Bobby Scott (D-VA), establishes a fair price negotiation program and empowers the Secretary of HHS to negotiate directly with drug manufacturers for the prices of certain drugs that lack competition. Under Title I, the Secretary is required to identify and publish a list of 250 negotiation-eligible brand drugs with the greatest total cost to Medicare and the U.S. health system, based on data to determine aggregate costs. From these 250 negotiation-eligible drugs, the Secretary shall select no fewer than 25 drugs to be subject to negotiation. For each of these selected drugs, the Secretary shall enter into an agreement with the manufacturer in order to begin a voluntary negotiation process. Insulin products would also be subject to negotiation, in addition to the other selected drugs.

In prioritizing the selection of drugs for negotiation each year, the Secretary shall select for inclusion the drugs that will result in the greatest savings to the Federal Government or consumers. Additionally, once a drug is selected for negotiation it will remain a selected drug until competition enters the market.

After entering into agreements with each manufacturer of a selected drug, the Secretary will directly negotiate with each manufacturer to establish a maximum fair price (MFP) that will be applied to the Medicare program, as well as available to group health plans or health insurance issuers offering health insurance coverage in the individual or group market. H.R. 3 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 price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the average international market (AIM) price.

While negotiating the MFP, the Secretary shall take into consideration a number of factors, including research and development costs of the drug, as well as the cost of production, information on alternative treatments and the extent to which the drug represents a therapeutic advance over existing alternatives, 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 MFP is agreed to, then the manufacturer will be assessed an escalating excise tax levied on the manufacturer's sales during the period of noncompliance.

ii. Title II: Rebates by Manufacturers for Medicare Part B and Part D Drugs with Prices Increasing Faster than Inflation

H.R. 3 establishes a mandatory rebate for drug manufacturers of all covered Part B and Part D drugs that increase in price faster than inflation. A Part B rebatable drug is defined as a

drug or biological paid for under Medicare Part B, excluding certain vaccines and drugs that have average total allowed charges for a year per individual of less than \$100. For manufacturers of a Part B rebatable drug, the rebate shall be based on the percentage increase the Average Sales Price (ASP) above the consumer price index for all urban consumers (CPI-U) from the payment amount benchmark period beginning January 1, 2016.

For Medicare Part D, a Part D rebatable drug is defined as a covered part D drug except if a drug or biological has an average total cost under a PDP per individual who uses such drug that is less than \$100. For manufacturers of a Part D rebatable drug, the rebate shall be based on the percentage increase of the average manufacturer price (AMP) for the rebatable drug above CPI-U from the payment amount benchmark year which begins January 1, 2016.

iii. Title III: Part D Modernization and Redesign

H.R. 3 would make changes to the structure of the standard benefit design for Medicare Part D and create an out-of-pocket maximum for Part D enrollees. Starting for plan year 2022, Part D enrollees' out-of-pocket costs would be capped at \$2,000 and a new manufacturer discount program would be created to ensure manufacturers are responsible for a portion of the Part D spending in the initial coverage phase, as well as the catastrophic phase of coverage. Additionally, this provision would phase out the current coverage gap discount program to streamline the standard benefit design to include a deductible phase, an initial coverage phase, and a catastrophic coverage phase.

In the initial phase of coverage, following an enrollee's deductible phase, PDPs would be responsible for 65 percent of spending, while enrollees would be responsible for 25 percent and manufacturers would be responsible for 10 percent. Following the initial coverage phase, an enrollee's out-of-pocket drug costs will be capped at \$2,000 and in the catastrophic coverage phase the federal government will be responsible for 20 percent reinsurance payments, while PDPs will be responsible for 50 percent, and manufacturers will be responsible for 30 percent.

B. H.R. 1046, Medicare Negotiation and Competitive Licensing Act of 2019

H.R. 1046, introduced by Rep. Lloyd Doggett (D-TX), requires the Secretary of HHS to negotiate prices for all drugs covered under Medicare Part D and take into account certain factors when negotiating, including: comparative clinical effectiveness and cost effectiveness; the budgetary impact of providing coverage of such drug; the financial burden on patients; unmet patient need for a drug; and total revenues and associated investment in research and development. Should the Secretary be unable to successfully negotiate an appropriate price for a covered part D drug, the Secretary shall authorize the use of any patent, clinical trial data, or other exclusivity granted by the federal government for the purposes of manufacturing such drug for sale by a PDP. The manufacturer may seek recovery for reasonable compensation in the United States Court of Federal Claims. In the interim period wherein a third party seeks approval for a drug subject to a compulsory license from the Food and Drug Administration (FDA), the bill would require that PDPs pay no more than the average price of the drug in ten Organization for Economic Cooperation and Development (OECD) countries.

C. H.R. 448, Medicare Drug Price Negotiation Act

H.R. 448, introduced by Rep. Elijah Cummings (D-MD), instructs the Secretary of HHS to negotiate with drug manufacturers the prices to be charged to PDPs for covered Part D drugs furnished to Part D enrollees during the applicable period. If the Secretary is not successful in obtaining an appropriate price for an applicable covered Part D drug during negotiations with the drug manufacturer, the price charged to PDPs during the applicable period shall be the lowest of three options: (1) the contract price for drugs for certain federal agencies; (2) the average of the prices available in the most recent 12-month period in Canada, the United Kingdom, Germany, France, and Japan; or (3) the Medicaid best price. The bill also instructs the Secretary to prioritize certain covered Part D drugs for the purposes of negotiation.

H.R. 448 also establishes and applies a formulary for required use by PDPs or requires PDPs to take into account negotiations carried out by the Secretary and make changes as necessary. H.R. 448 would also require drug manufacturers to provide mandatory rebates for drugs purchased by Part D low-income subsidy enrollees who have incomes up to 150 percent of the federal poverty level and meet certain asset tests.

D. H.R. 275, Medicare Prescription Drug Price Negotiation Act of 2019

H.R. 275, introduced by Reps. Peter Welch (D-VT) and Francis Rooney (R-FL), gives the Secretary of HHS authority to negotiate the prices, including discounts, rebates, and other price concessions, that may be charged to PDPs for covered Part D drugs. H.R. 275 would not authorize the Secretary to establish or require a particular formulary or affect the Secretary's authority to ensure plan compliance with existing Part D formulary requirements.