COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

April 26, 2019

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Prescription Drug Coverage in the Medicare Program"

On **Tuesday, April 30, 2019, at 10:30 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing entitled, "Prescription Drug Coverage in the Medicare Program."

I. THE MEDICARE PART B PRESCRIPTION DRUG PROGRAM

Medicare Part B provides coverage for physician services and hospital outpatient services, including coverage for a limited number of prescription drugs. Part B generally covers drugs administered by infusion or injection in physician offices or hospital outpatient departments (HOPDs).

Part B drug spending is concentrated in a small number of expensive drugs used to treat conditions such as cancer, macular degeneration, and rheumatoid arthritis. However, the program also covers many inexpensive drugs such as flu shots, saline, and corticosteroids. Beneficiaries generally are responsible for a 20 percent coinsurance for Part B drugs, leaving beneficiaries exposed to significant out of pocket costs. Many of the most expensive drugs in the program have annual per beneficiary costs ranging from about $10,000 to $30,000 per year, with some drugs having higher annual costs.[1]

Currently, Medicare Part B reimburses health care providers for drugs through a "buy and bill" system, where the provider is responsible for purchasing and storing the drug and may bill Medicare after the drug is administered. The Part B program pays providers 106 percent of the average sales price of a drug (ASP +6 percent). Currently, Part B covered drugs are subject to a two percent sequester cut, reducing payment to ASP +4.3 percent.[2]

---

[1] *Id.*

[2] Cole Werble, *Medicare Part B*, Health Affairs (Aug. 10, 2017) (www.healthaffairs.org/do/10.1377/hpb20171008.000171/full/).

Some argue that the ASP +6 percent formula creates an incentive for providers to purchase drugs with a higher ASP to receive higher reimbursement. In addition to ASP +6 percent, Medicare makes a separate payment to the physician or hospital for the act of administering the drug. The ASP is calculated by the Centers for Medicare and Medicaid Services (CMS) based on a weighted average of sales to all purchasers of a drug nationwide according to quarterly data submitted by the manufacturers. Current law requires only manufacturers with Medicaid drug rebate agreements in place to report ASP data to CMS.[3]

In October 2018 CMS released an advance notice of proposed rulemaking (ANPRM), that would institute a mandatory, nationwide demonstration called the International Pricing Index (IPI) Model.[4] The model would impact about half of Medicare Part B providers. The model would: (1) allow private-sector pharmaceutical vendors to buy and bill Medicare for drugs and supply those drugs to providers rather than the providers doing so directly; (2) change the Part B ASP +6 percent reimbursement system to a flat fee paid to providers for administering the drug; and (3) tie reimbursement to an international reference price (calculated based on prices in 16 other countries).[5]

II. THE MEDICARE PART D PRESCRIPTION DRUG PROGRAM

Medicare Part D is a voluntary outpatient prescription drug benefit offered as a standalone prescription drug plan (PDP) to augment traditional Medicare or bundled as a Medicare Advantage prescription drug plan (MA-PD). This program became effective in 2006 following the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[6] In 2018, nearly 44 million Medicare beneficiaries had prescription drug coverage under Medicare Part D, either in standalone PDPs or in MA-PDs. Additionally, Medicare Part D provides drug coverage for individuals that are dually eligible for Medicare and Medicaid.[7] [8]

---

[3] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System, Chapter 2* (June 2017)(www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0).

[4] Department of Health and Human Services (HHS), *HHS Advances Payment Model to Lower Drug Costs for Patients* (Oct. 25, 2018)(www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html).

[5] Rachel Sachs, *Administration Outlines Plan To Lower Pharmaceutical Prices In Medicare Part B* (Oct. 26, 2018)(www.healthaffairs.org/do/10.1377/hblog20181026.360332/full/).

[6] Suzanne Kirchoff, *Medicare Part D Prescription Drug Benefit*, Congressional Research Service (Aug. 13, 2018)(www.crs.gov/Reports/R40611?source=search&guid=7 e4ff5e72c624014b24700ddd5bb9145&index=0#_Ref348084928).

[7] MedPAC, *Part D Payment System* (Oct. 2018)(http://medpac.gov/docs/default-source/paymentbasics/medpac_payment_basics_18_ partd_final_sec.pdf?sfvrsn=0).

[8] MedPAC, *The Medicare prescription drug program (Part D): Status Report* (Mar. 2019) (http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0).

PDPs compete to cover beneficiaries based on a variety of factors, including premiums, drug coverage, pharmacy networks, and how the PDP designs their benefit.[9] The Medicare program pays PDPs through a competitive bidding process which is used to calculate a plan's premiums.[10] In 2019, the Part D base beneficiary premium for PDPs is $33.19.[11] Beneficiaries in each state choose from multiple plans that must offer a defined benefit or actuarially equivalent alternative. Beneficiary cost-sharing for standard benefit plans includes a $415 deductible and 25 percent coinsurance up to the initial coverage limit of $3,820.[12] After a beneficiary reaches the initial coverage limit, a beneficiary will enter the coverage gap or "doughnut hole," when he or she pays 25 or 37 percent for brand-name and generic drugs respectively.[13] Once a beneficiary reaches the catastrophic coverage threshold, Medicare pays 80 percent, plans pay 15 percent, and beneficiaries pay either 5 percent or a fixed fee. [14]

With the exception of certain low-income beneficiaries, Part D beneficiaries are not protected by an out-of-pocket maximum. As a result, beneficiaries face significant financial responsibility for high costs drugs, including for high cost specialty drugs – or those that cost more than $670 per month.[15] Estimated annual out-of-pocket costs in 2019 average $8,109 per enrollee across the 28 specialty tier drugs covered by Part D plans.[16] The Congressional Budget Office (CBO) recently 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. Part D beneficiary costs are projected to increase at a faster rate over the next decade.[17]

---

[9] 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).

[10] *Id.*

[11] Centers for Medicare and Medicaid Services, *Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information* (July 31, 2018)(www.cms.gov/Medicare/HealthPlans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2019.pdf).

[12] 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).

[13] *Id.*

[14] *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/).

[15] Juliette Cubanski, et al., *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019,* Kaiser Family Foundation (Feb. 1, 2019)(www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/).

[16] *Id.*

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

The Department of Health and Human Services (HHS) has proposed a series of rules that impact the Part D program, including a proposed rule issued on November 30, 2018 entitled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses".[18] This rule would permit PDPs to more broadly use prior authorization and step therapy for certain classes of drugs and exclude certain protected classes drugs from formularies if the drug is a new formulation or if the price increased beyond a certain threshold.[19] Additionally, this rule would shift pharmacy price concessions to the point of sale and permit greater use of prior authorization and step therapy for Medicare Part B drugs covered through a Medicare Advantage plan.

In addition to the proposed rule described above, HHS and the HHS Office of Inspector General (HHS OIG) issued a proposed rule on January 31, 2019 that would exclude from safe harbor regulations certain prescription drug discounts currently protected from liability under the federal anti-kickback statute for Part D and Medicaid managed care programs.[20] The CMS Office of the Actuary (OACT) estimated that as a result of this rule, federal spending would increase by $196 billion and Part D enrollee premiums would increase by $50 billion.[21] Both proposed rules are currently pending.

MedPAC has proposed a number of recommendations to improve Part D and drive down costs for beneficiaries and the federal government. In 2016, the Commission recommended transitioning the reinsurance subsidy the federal government provides to PDPs from 80 percent to 20 percent over time to incentivize plans to better manage risk.[22] Currently Medicare subsidizes nearly 75 percent of Part D costs through direct capitated subsidy payments and through reinsurance above the Part D out-of-pocket threshold. Under the current structure, MedPAC has analyzed that plans are less likely to sufficiently manage risk given that Medicare pays the largest proportion for reinsurance. MedPAC's proposal would shift a greater percentage

---

[18] HHS, Centers for Medicare & Medicaid Services, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, 83 Fed. Reg. 231 (Nov. 30, 2018)(www.govinfo.gov/content/pkg/FR-2018-11-30/pdf/2018-25945.pdf).

[19] *Id.*

[20] HHS, Office of Inspector General, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 25 (Feb. 6, 2019) (www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf).

[21] Centers for Medicare & Medicaid Services, Office of the Actuary, *Proposed Safe Harbor Regulation* (Aug. 30, 2018)(https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf).

[22] MedPAC, *Improving Medicare Part D* (June 2016)(http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf).

of the government's subsidy to the capitated payment and a smaller portion to reinsurance, meaning that plan sponsors would face greater risk above the out-of-pocket threshold and may be more incentivized to move high-cost enrollees to lower cost drugs, for example.[23] In addition, MedPAC has recommended capping enrollee's out-of-pocket spending by eliminating cost sharing above the out-of-pocket threshold.[24]

III. MEDICARE DRUG SPENDING NUMBERS

Over 60 million seniors and people with disabilities get their prescription drugs covered by Medicare. In 2016, prescription drugs covered under Medicare Part B and Part D accounted for nearly 20 percent ($129 billion) of total Medicare spending, with the majority of that spending occurring in Part D (13 percent).[25]

Total Part B drug expenditures were $32.0 billion in 2017, an increase of about 10 percent from 2016.[26] Since 2009, Part B drug spending has grown at an average rate of about 9.6 percent per year. The Medicare Payment Advisory Commission (MedPAC) estimated that more than half of the growth in Part B drug spending between 2009 and 2015 was accounted for by price growth, reflecting increases in the prices of existing drugs and new drugs becoming available.[27]

Total Part D drug expenditures were $93.9 billion in 2017, an increase of about 2.5 percent from 2016.[28] Part D program spending increased from about $46 billion to about $80

---

[23] *Id.*

[24] *Id.*

[25] 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/).

[26] MedPAC, *Two Medicare payment strategies to improve price competition and value for Part B drugs: reference pricing and binding arbitration* (Mar. 7, 2019)(http://www.medpac.gov/docs/default-source/default-document-library/part-b-drugs-march-19-public.pdf?sfvrsn=0).

[27] MedPAC, *Payment Basics: Part B Drugs Payment Systems* (October 2018)(www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_partb_final_sec.pdf?sfvrsn=0).

[28] MedPAC, *The Medicare prescription drug program (Part D): Status Report* (Mar. 2019)(http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0).

billion between 2007 and 2017, for an average annual growth of 5.6 percent.[29] MedPAC has noted that among high-cost enrollees, nearly all growth in spending was a result of increases in the average price per prescription filled.[30] In 2010, 33,000 Part D enrollees filled a prescription for which a single claim would have been sufficient to meet the Part D out-of-pocket threshold. However, by 2016 that number jumped to 360,000.[31]

IV. WITNESS

James E. Mathews, Ph.D.
Executive Director
Medicare Payment Advisory Commission

[29] MedPAC, *The Medicare prescription drug program (Part D): Status Report* (Mar. 2019)(http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0).

[30] *Id.*

[31] *Id.*