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March 6, 2019

The Honorable Susan Collins  
Chairman, Special Committee on Aging  
413 Dirksen Senate Office Building  
Washington, D.C., 20510

The Honorable Bob Casey  
Ranking Member, Special Committee on Aging  
393 Russell Senate Office Building  
Washington D.C., 20510

Re: Proposals to Modify Medicare Part D Rebate Structure

Dear Chairman Collins and Ranking Member Casey:

As you continue to consider ways to address increased government and beneficiary spending in the Medicare program, the Pew Charitable Trusts (Pew) offers this letter discussing a current proposal to modify the Medicare Part D rebate structure. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Pew commends the Senate Special Committee on Aging for its long-standing attention to drug costs. This letter addresses drug costs in the Medicare Part D program, focusing on a recent proposal to modify the program's structure to shift existing drug discounts from a rebate model to a point-of-sale price reduction.<sup>1</sup> While this proposal would reduce costs at the pharmacy counter for some seniors, Medicare's own estimates (discussed in more detail below) project that it will increase seniors' Medicare Part D premiums by 25 percent, increase Medicare spending by \$196 billion, and increase drug manufacturer revenues by \$171 billion. The net effect will be higher taxpayer spending on prescription drugs. The Committee may wish to explore alternate proposals to reduce senior's pharmacy payments without increasing manufacturer revenues.

This letter outlines the impact of the proposal on drug prices, on Medicare and Medicaid spending, on manufacturer revenues, and on beneficiary spending. We also compare the fiscal impact of this proposal to other recent Congressional proposals addressing drug spending, and we outline alternative strategies to reduce seniors' pharmacy payments. Throughout this letter, we refer to financial modeling performed

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<sup>1</sup> 84 Federal Register 2340-2363. Department of Health and Human Services, Office of Inspector General. OIG-0936-P; Fraud and Abuse; Remove 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 (RIN 0936-AA08). February 6, 2019.

by the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT).<sup>2</sup> As part of the proposal, the Department of Health & Human Services (HHS) commissioned three separate financial models. The first two models (including the CMS OACT model), dated August 30, 2018, showed significant increases in Medicare spending under the proposal.<sup>3</sup> The third analysis, dated January 31, 2019, included a range of estimates that generated both increased Medicare spending and Medicare savings.<sup>4</sup> However, the estimates of Medicare savings presume that either Medicare Part D plans will increase drug access restrictions or that drug manufacturers will offer greater discounts, two scenarios that may be less plausible. Therefore, this letter relies on the initial CMS OACT estimate.

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## Overview of the Proposal

Currently, Medicare Part D plans negotiate discounts with pharmaceutical manufacturers for favorable treatment of a manufacturer's drugs. These negotiations are typically administered by a Pharmacy Benefits Manager (PBM), and these discounts take the form of a periodic rebate payment from the manufacturer to the PBM based on the quantity of drugs used by each plan's beneficiaries.<sup>5</sup> Because these rebates are paid after a beneficiary has already purchased and used a particular drug, these payments generally do not affect a beneficiary's pharmacy payments; instead, PBMs and plans use these payments to offset total spending, reducing premium costs for all beneficiaries.<sup>6</sup> Under the proposal, drug manufacturers would be required to offer the discount when the beneficiary purchases the drug. If the beneficiary's pharmacy payment is calculated as a percentage of the drug's cost (called "co-insurance"), this discounted pharmacy price would result in a lower pharmacy payment by the beneficiary compared with the current system.<sup>7</sup> To achieve this policy change, the proposal changes an exception to the Anti-Kickback Statute that allows manufacturers to offer discounts via rebate payments. Under the proposal, rebates would now be considered illegal kickbacks, but pharmacy discounts would be protected.<sup>8</sup>

## Impact on Drug Prices

The proposal is unlikely to reduce drug prices; indeed, it is more likely to increase drug prices. The CMS OACT model estimates that manufacturers will reduce their total discounts by 15 percent when

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<sup>2</sup> Centers for Medicare & Medicaid Services, Office of the Actuary (CMS OACT). "Proposed Safe Harbor Regulation." August 30, 2018.

<sup>3</sup> Wakely Consulting Group. "Estimate of the Impact of Eliminating Rebates for Reduced List Prices at Point-of Sale on Beneficiaries." August 30, 2018.

<sup>4</sup> Milliman. "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates." January 31, 2019. Note that the proposal dates the Milliman analysis to September 2018 in its citations, but the version released with the proposal is dated January 31, 2019.

<sup>5</sup> Pharmaceutical Care Management Association. "Our Industry: What is a PBM?" <https://www.pcmanet.org/our-industry>.

<sup>6</sup> 84 Fed. Reg. 2341.

<sup>7</sup> 84 Fed. Reg. 2353.

<sup>8</sup> 84 Fed. Reg. 2348-2350.

switching from a rebate to a pharmacy discount;<sup>9</sup> based on CMS OACT's estimated current 24 percent rebate,<sup>10</sup> this correlates to a 5 percent increase in net drug prices for the Medicare Part D program.<sup>11</sup>

In addition, the proposal could lead to a circumstance that the Federal Trade Commission (FTC) has identified as a risk for anticompetitive behavior by manufacturers that would increase prices. Currently, manufacturer rebates to PBMs are secret, and two competing manufacturers do not know the rebate offered by their competitor. However, the proposal acknowledges that entities could "reverse engineer" the discounts provided.<sup>12</sup> The FTC warns that this type of price transparency may "allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price or increases the likelihood that they can coordinate on higher prices."<sup>13</sup> Empirical evidence from outside the drug industry lends support for this theory: In the early 1990's, the Danish Competition Council required the publication of privately negotiated discounts for ready-mixed concrete; following this publication, prices rose 15-20% within a year, which experts attribute to increased collusion among the oligopoly of producers.<sup>14</sup> In the brand drug market, where a limited number of manufacturers offer similar products within a therapeutic class, net price transparency may cause these manufacturers to collectively raise prices.

### **Impact on Medicare Spending**

The CMS OACT estimates the proposal will increase Medicare spending by \$196.1 billion over ten years.<sup>15</sup> This increased spending has two drivers: 1) the higher net cost of drugs under the proposal, and 2) the structure of the Medicare Part D program. The higher net cost of drugs, discussed in the previous section, accounts for a significant portion of the increased Medicare spend, but the structure of the Medicare Part D program drives a \$39.8 billion increase.

Medicare Part D is financed by three parties: beneficiaries, the Medicare program (through taxpayers), and manufacturers. Beneficiaries and the Medicare program make premium payments that plans use to pay for a portion of pharmaceutical costs, with the remainder paid by beneficiary cost-sharing payments at the pharmacy counter. However, once the plan and the beneficiary together have paid at least \$3,820 to the pharmacy, the "coverage gap" phase of the Medicare program begins, and manufacturers are required to offer a discount to offset costs.<sup>16</sup> This manufacturer discount, called the coverage gap

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<sup>9</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.3. August 30, 2018.

<sup>10</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.4. August 30, 2018.

<sup>11</sup> Under the proposal, the net price on a \$100 drug would be  $\$100 - .85 * \$24$ , or \$79.60, a 4.7 percent increase over the current estimated price of \$76 ( $\$100 - \$24$ ).

<sup>12</sup> 84 Fed. Reg. 2349.

<sup>13</sup> Koslov, TI, Jex, E. "Price transparency or TMI?," Federal Trade Commission, July 2, 2015, <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>.

<sup>14</sup> Albæk, Svend, Peter Møllgaard, and Per B. Overgaard. "Government-assisted oligopoly coordination? A concrete case." *The Journal of Industrial Economics* 45.4 (1997): 429-443.

<sup>15</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

<sup>16</sup> Pew Charitable Trusts. Medicare Part D Coverage Gap Proposal Would Not Reduce Drug Spending. Dec. 4, 2018. Available at: <https://www.pewtrusts.org/en/research-and-analysis/articles/2018/12/04/medicare-part-d-coverage-gap-proposal-would-not-reduce-drug-spending>.

discount, increased from 50 percent to 70 percent of drug costs in 2019 following changes Congress made in 2018.<sup>17</sup> Currently, manufacturer rebates do not affect the calculation of the \$3,820 threshold.

Under the proposal, discounts applied at the pharmacy counter would slow the accumulation of \$3,820 in pharmacy payments, reducing the number of beneficiaries that reach the coverage gap phase. That means fewer beneficiaries will be eligible for manufacturer coverage gap discounts, reducing manufacturers' contributions to the Medicare Part D program. CMS OACT estimates that this change will reduce manufacturers' coverage gap payments by \$39.8 billion over ten years<sup>18</sup> – payments that will now be covered through increased Medicare and beneficiary premiums.

### **Impact on Manufacturer Revenue**

Based on CMS OACT estimates, manufacturer revenue would increase by approximately \$171 billion over ten years under the proposal. This increased revenue is driven by both the reduction in total discounts offered under the program as well as the reduction in manufacturer contributions in the coverage gap, discussed above. While total Medicare spending will increase by \$196.1 billion, net beneficiary spending will decrease by \$25.2 billion (discussed below), resulting in a net increase in drug payments of \$170.9 billion.<sup>19</sup> While it is possible that some of these increased payments will be retained by pharmacies, Medicare plans, or PBMs, because these increased payments are driven by higher prices and lower coverage gap contributions, manufacturers will receive nearly all of this increased spending as revenue.

Manufacturers would also see greater revenue from reduced rebates under the Medicaid Drug Rebate Program<sup>20</sup> and reduced discounts under the 340B Drug Discount Program, which allows federally-designated providers to purchase discounted drugs.<sup>21</sup> Medicaid rebates and 340B discounts have two components: a base rebate/discount of 23.1 percent (for brand drugs) and an additional rebate/discount to offset price increases above inflation. These two rebates/discounts are calculated based on a drug's Average Manufacturer Price (AMP), which is an average of the prices of retail community pharmacy sales of the drug.<sup>22</sup> The CMS OACT estimates that AMP will fall by 3.2 percent under the proposal, reducing Medicaid rebates by \$18.5 billion over ten years (no estimate is provided for reduced 340B discounts).<sup>23</sup> CMS OACT estimates that lower drug prices under the proposal will offset most of this reduction, though this offsetting estimate assumes that manufacturers will voluntarily offer discounts to pharmacies for drugs dispensed to Medicaid patients.

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<sup>17</sup> Public Law No. 115-123: Bipartisan Budget Act of 2018. February 9, 2018.

<sup>18</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

<sup>19</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

<sup>20</sup> Centers for Medicare & Medicaid Services. "Medicaid Drug Rebate Program." November 13, 2018. Available at: <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

<sup>21</sup> U.S. Health Resources & Services Administration Office of Pharmacy Affairs. "340B Drug Pricing Program | Official web site of the U.S. Health Resources & Services Administration." <https://www.hrsa.gov/opa/>. Accessed February 25, 2019.

<sup>22</sup> 42 U.S.C. § 1396r-8(k).

<sup>23</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.6. August 30, 2018.

## Impact on Beneficiary Spending

Under the proposal, CMS OACT estimates that all Medicare Part D beneficiaries would see higher monthly premiums; premiums would increase by 19 percent in 2020, with a 25 percent total increase over the next ten years.<sup>24</sup> Over ten years, beneficiaries would spend an additional \$58.0 billion in premiums.<sup>25</sup>

While all beneficiaries would see higher premiums under the proposal, only some beneficiaries would see lower pharmacy payments. Beneficiaries who take only generic drugs or very few drugs would be unlikely to see lower pharmacy costs, as these drugs generally do not have discounts that would move from rebates to lower pharmacy prices. However, beneficiaries taking expensive brand name drugs that currently have significant rebates would see much lower cost-sharing under the proposal.<sup>26</sup> Overall, the proposal would reduce beneficiary cost-sharing by \$83.2 billion over ten years,<sup>27</sup> an 18 percent reduction in pharmacy payments.<sup>28</sup>

Some of the reduction in beneficiary cost-sharing may actually accrue to manufacturers, rather than beneficiaries. Medicare beneficiaries may be eligible to receive help paying their cost-sharing under Patient Assistance Programs (PAPs), which are charitable organizations that provide cost-sharing assistance.<sup>29</sup> Manufacturers generally fund PAPs, which are subject to a variety of requirements to avoid triggering liability under the AKS.<sup>30</sup> However, if beneficiary cost-sharing for high-priced drugs is reduced, any portion of that cost-sharing paid by the PAP will also fall, reducing the need for manufacturer contributions to the PAP. We are unaware of any reliable estimates of the amount of Medicare Part D cost-sharing currently covered by PAPs, but any estimated reduction in beneficiary cost-sharing that is currently paid by PAPs would accrue to PAPs and manufacturers, not beneficiaries.

## Comparison to Other Drug Spending Proposals

Compared to other proposals to reduce drug spending, the current proposal significantly increases Medicare spending and manufacturer revenue while offering limited and uneven reduction in beneficiary costs. In 2018, Congress passed legislation increasing manufacturers' contributions to Medicare in the coverage gap from 50 percent to 70 percent.<sup>31</sup> Absent the proposal, this change would

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<sup>24</sup> 84 Fed. Reg. 2358.

<sup>25</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

<sup>26</sup> 84 Fed. Reg. 2357.

<sup>27</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

<sup>28</sup> 84 Fed Reg. 2358

<sup>29</sup> Centers for Medicare & Medicaid Services. "Pharmaceutical Manufacturer Patient Assistance Program Information." July 23, 2018. Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html>.

<sup>30</sup> Howard, David H. "Drug companies' patient-assistance programs—helping patients or profits?." *New England Journal of Medicine* 371.2 July 10, 2014. 371:97-99.

<sup>31</sup> Public Law No. 115-123: Bipartisan Budget Act of 2018. February 9, 2018.

save Medicare \$11.8 billion over ten years.<sup>32</sup> The proposal, however, effectively nullifies Congress' change in only one year, with Medicare estimated to spend an additional \$13.4 billion in 2020 under the proposal.<sup>33</sup> Over the course of ten years, manufacturer coverage gap discounts would be \$39.8 billion lower<sup>34</sup> – even after Congress increased the manufacturer coverage gap discount from 50 to 70 percent.

Recent legislation to increase generic competition, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), is estimated to reduce government expenditures by \$3.3 billion over ten years and increase government revenues by \$0.6 billion through increased fees.<sup>35</sup>

Similar to the proposal, a recent CMS proposed rule, CMS–4180-P Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,<sup>36</sup> would increase manufacturer revenues and increase Medicare spending.<sup>37</sup> This proposed rule would reduce beneficiary cost-sharing by applying a portion of pharmacy payments called Direct and Indirect Remuneration at the point of sale, similar to the proposal's application of current rebates at the pharmacy counter. This proposed rule would increase manufacturer revenues by \$5.8 billion over ten years through reduced coverage gap discount payments; it would increase Medicare premium spending by \$16.6 billion and beneficiary premium spending by \$5.6 billion, offset by a \$14.8 billion reduction in cost-sharing for some beneficiaries.<sup>38</sup>

### **Alternatives to Reduce Cost-Sharing**

Other policies could reduce beneficiary cost-sharing without increasing manufacturer revenues. Under the Medicare Part D program, beneficiaries are generally required to cover 25% of total program costs through premiums and cost-sharing; the remainder is paid by taxpayers.<sup>39</sup> Congress could change this allocation, which would require plans to reduce beneficiary cost-sharing (though Medicare would make up the difference).

To maintain competition through rebates and to maintain manufacturer contributions in the coverage gap, CMS could require plans to calculate beneficiary cost-sharing as a percentage of the net cost of a drug after rebates but accumulate beneficiary progression to the coverage gap based on the drug's up-

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<sup>32</sup> Congressional Budget Office. "CBO's Estimates of the Effects of Changes in the Manufacturers' Discount in the Part D Coverage Gap." July 20, 2018. Available at: <https://www.cbo.gov/publication/54192>.

<sup>33</sup> 84 Fed. Reg. 2360.

<sup>34</sup> CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

<sup>35</sup> Congressional Budget Office. "S. 974, Creating and Restoring Equal Access to Equivalent Samples Act of 2018." September 18, 2018. Available at: <https://www.cbo.gov/publication/54479>.

<sup>36</sup> 83 Federal Register 62152-62201, 62184. CMS–4180-P; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (RIN 0938-AT92). Nov. 30, 2018.

<sup>37</sup> Pew Charitable Trusts. "Pew Comments on Proposals to Modernize Medicare Drug Payments." January 25, 2019. Available at: <https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/01/25/pew-comments-on-proposals-to-modernize-medicare-drug-payments>.

<sup>38</sup> 83 Fed. Reg. 62192.

<sup>39</sup> Centers for Medicare & Medicaid Services. "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information." July 31, 2018. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2019.pdf>.

front cost. This would shift some of the drug's cost from beneficiary pharmacy payments to premiums, but it would maintain manufacturers' contributions in the coverage gap. Shifting some costs to premiums may be desirable, however, as it reduces the cost burden on the sickest beneficiaries by spreading it evenly across all beneficiaries.

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We commend the Committee for its attention to drug spending. Should you have any further questions, please contact us by phone at 202-540-6392 or via email at [acoukell@pewtrusts.org](mailto:acoukell@pewtrusts.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Allan Coukell". The signature is fluid and cursive, with a large initial "A" and "C".

Allan Coukell, BscPharm  
Senior Director, Health Programs

A handwritten signature in blue ink, appearing to read "Sean Dickson". The signature is cursive and written in a light blue color.

Sean Dickson, JD MPH  
Officer, Drug Spending Research Initiative  
The Pew Charitable Trusts