August 3, 2020

Filed via email at Alex.Azar@HHS.GOV

The Honorable Alex M. Azar, II
Secretary of Health and Human Services
U. S. Department of Health and Human Services
Attention: OIG–0936– P Room 5527, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: Supplemental Comment Filing on Health and Human Services Office of the Inspector General's (HHS-OIG's) Proposed Rule ("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") (RIN: 0936-AA08)

Dear Secretary Azar:

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the exchanges established by the Affordable Care Act (ACA).

We contend that the withdrawal of the Proposed Rule referenced above on July 10, 2019 was a final agency action requiring a new notice-and-comment period in advance of promulgating any final rule. We otherwise reserve all other rights regarding action the agency has taken or will take regarding said Proposed Rule.

The comments below supplement PCMA's detailed comments filed in April 2019[1] in response to the Proposed Rule published by the Department of Health and Human Services ("HHS" or the "Department") entitled: "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals."[2] Should HHS choose to re-propose the same rule, or propose a new rule intending to achieve a similar result, PCMA will file additional comments at that time during the statutorily-required 60-day comment period. In addition to the wide range of legal and regulatory failings of the Proposed Rule, in those comments we also demonstrated, through reliance on actuarial estimates available at the time, that the Proposed Rule would fail to achieve the Department's stated objectives of lowering prescription drug prices and out-of-pocket costs for America's seniors.[3] The rule was withdrawn from consideration in July 2019 by the White

[1] PCMA. April 8, 2019. https://www.pcmanet.org/wp-content/uploads/2019/04/PCMA-Comments-on-Safe-Harbor-Proposed-Regulations.pdf.
[2] 84 Fed. Reg. 2340 (February 6, 2019).
[3] "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients," HHS Press Release (January 31, 2019).

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House, “[b]ased on careful analysis and thorough consideration.”[4] Secretary Azar himself summarized the withdrawal this way: “The President is deeply committed to protecting America’s seniors. He does not want any risk that any action could cause seniors’ premiums to increase.”[5] If the 2019 Proposed Rule is finalized as proposed, the prior analyses from CMS Office of the Actuary(OACT) must stand, as supported by Congressional Budget Offices’ (CBOs’) later published analysis. Federal spending will increase, as will beneficiary Part D premiums. There is no conceivable way the Secretary could confirm a different budgetary effect under the Proposed Rule.

I. Comments Regarding the Administrative Record

On July 24, 2020, President Donald J. Trump signed an Executive Order (“EO”) directing HHS to “complete the rulemaking process” with respect to the Proposed Rule if the Secretary could verify three specified economic impact targets (lower premiums, lower out-of-pocket costs, and lower costs to the Federal government).[6] We are submitting these comments, supplementing our previous submission, in light of this intervening event (the issuance of the EO) and the resulting need for HHS to consider critical developments following the closing of the public comment period on April 8, 2019 nearly 16 months ago.

Notwithstanding PCMA’s understanding that the administrative record in this rulemaking is currently closed on the basis that the July 2019 withdraw constituted a final agency action,[7] if HHS wishes to take any additional action to amend or otherwise change the rule, it must re-initiate the rulemaking process as the public no longer has notice of the potential agency action.[8] Failure to re-open the administrative record, provide adequate notice, and allow for due consideration of these and other public comments would constitute an abuse of agency discretion.[9]

Finally, beyond the need for HHS to address developments since the prior comment period closed, we also are frankly confused about several of the statements in the EO and how the rebate rulemaking it describes appears to be different than the rebate rule as proposed in 2019. For example, the title of the EO is "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen." As there are no references in the Proposed Rule to “middlemen,” we are confused as to what rule the White House thinks the EO is addressing. Indeed, the EO itself contains several different references to who are the middlemen. The first section notes that middlemen are those entities "hired by the insurance companies" but then goes on to say they are "health

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[4] Susan Morse. Trump administration withdraws drug rebate rule. July 11, 2019. https://www.healthcarefinancenews.com/news/trump-administration-withdraws-drug-rebate-rule.

[5] The Hill, White House Withdraws Controversial Rule to Eliminate Drug Rebates, 7/11/19. https://thehill.com/policy/healthcare/452561-white-house-withdraws-controversial-rule-to-eliminate-drug-rebates.

[6] “Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen,” July 24, 2020.

[7] 5 U.S.C. § 551 (“agency action” is defined as: “includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof*, or failure to act*”).

[8] *See Anne Arundel County v. EPA*, 963 F.2d 412, 417-18 (D.C. Cir. 1992) (holding that the EPA did not provide adequate notice because the County “had no reason to anticipate, on the basis of the proposed rule alone, that the [EPA would finalize its determination]).”

[9] 5 U.S.C. § 706(2)(A).

plan sponsors and PBMs." However, Section 3(a) then seems to indicate that the middlemen are "health plan sponsors, pharmacies or PBMs." Because the intent of the EO appears to be focused on a term that is not defined in the Proposed Rule, any future rulemaking would very clearly need to define the term and allow for public comment on its scope.

II. Evidence Published Following the Closure of the Proposed Rule Comment Period Further Highlights the Excessive Costs of the Rebate Rule

In PCMA's previous comments we noted that the three actuarial analyses, commissioned by HHS and included in the Proposed Rule, were some of the strongest arguments against it. For example, the analysis prepared by the CMS OACT concluded that 70% of non-low-income beneficiaries would pay more in premiums than they would save in cost-sharing under the proposal, and that Federal spending on Part D would increase by $196.1 billion.[10]

Since the closing of the original comment period in April 2019, additional analyses and reports have further diminished any arguments in favor of the rebate rule. In addition, ongoing innovations in the Part D program that have occurred in the intervening time period, introducing greater price transparency for beneficiaries, would be significantly hampered should a future rebate policy be adopted. Below we reiterate our previous comments which highlight the main economic arguments against the original rule. We then describe more recent independent analyses published following the closing of the comment period that further argue against these potential changes.

a. As a starting point, HHS's own regulatory impact analysis argues against moving forward with this rule

Given that the July 2020 EO is conditioned upon a rebate policy that does not increase costs to Medicare beneficiaries or to the Federal government, HHS cannot issue a rule limiting rebates. As previously established and acknowledged by the Secretary, the 2019 Proposed Rule would have clearly violated the plain language of this critical condition precedent contained in the EO. The regulatory impact analysis in the Proposed Rule paints an accurate picture of the likely outcome of the rule were it to be finalized. As published in 2019, the rule would increase premiums and federal spending, while only reducing aggregate out-of-pocket costs (total out-of-pocket costs for many seniors would, in fact, increase). As we stated in our public comments filed at the time, "[t]he OACT analyses accompanying the rule are indeed the strongest arguments against it." The regulatory impact analysis concludes that any out-of-pocket savings on the aggregate are overcome by premium increases. If HHS does not undertake a new analysis, it cannot reasonably meet the requirements of the EO that the rule does not increase premiums, out-of-pocket costs, or federal spending.

b. A subsequent CBO analysis concludes that limiting rebates would dramatically increase federal spending

As noted above, Section 4 of the EO requires that any limit on rebates not "increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." As part of its annual budget outlook process in 2019 and following the closure of the 2019 Proposed Rule

[10] Pelzer B, Spitalnic P. "Proposed Safe Harbor Regulation," CMS Office of the Actuary (August 30, 2018).

public comment period but before the Proposed Rule's official withdrawal, the CBO undertook an analysis of the then-pending Proposed Rule. In May 2019, CBO published an 8-page supplement to its annual budget outlook that concluded that the rule would increase Medicare spending by $170 billion over the 10-year budget window (and overall federal spending by $177 billion).[11] While CBO did not estimate the size of the premium increase (because it is not their purview to do so), they state:

> "Under current rules, plans may use manufacturers' rebates to reduce premiums for all beneficiaries. If those rebates were no longer paid directly to plans, Part D premiums would rise."

Put simply, under all assumptions, limiting rebates or requiring them to be reflected at the point-of-sale will increase premiums. CMS pays Part D plans a direct subsidy in direct proportion to beneficiary premiums, so there is similarly no feasible set of assumptions that would not lead to higher federal spending.

c. CBO's analysis included dynamic effects of the rule beyond OACT's analysis

In addition to the static analysis yielding an increase in federal spending, CBO also considered two dynamic effects. First, CBO estimated the administrative costs of a new "chargeback" system. In the Proposed Rule, HHS described a possible system where a third party would administer the discounts, rather than PBM-administered discounts.[12] CBO concluded that the costs of this new system would contribute an additional one percentage point increase in Part D premiums.

Second, CBO also considered whether the rule would increase the overall utilization of prescription drugs and found it would do so, accounting for an increase in Part D costs by $10 billion, which would lead to $20 billion in lower medical spending under Parts A and B. This dynamic scoring assumption is favorable to the drug industry.[13] These $10 billion in net Medicare savings explains much of the difference between CBO's Medicare federal spending estimate ($170 billion in new costs) and OACT's ($196 billion in new costs). Yet even with the favorable assumption, federal costs still increase if the withdrawn rule were to be implemented.

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[11] Congressional Budget Office, Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029. May 2019. Available at https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf. In Congressional budget terms, half of the costs or savings generated by a proposed rule needs to be accounted for in the baseline budget. CBO does not typically "score" proposed rules like these unless they would have significant effects on the budget baseline.

[12] In brief, pharmacies would bill the administrator for the difference between their acquisition cost and the beneficiary- and plan-paid amounts. The administrator would bill manufacturers for these amounts and provide payments to pharmacies to make them "whole." This system would be similar to but not the same as the 340B hospital chargeback model.

[13] This offset methodology was first incorporated into CBO's models in 2012. See CBO, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf.

d. CBO remains the gold standard for economic projections

Some have argued that CBO's analysis should be dismissed.[14] The argument appears to be that, because CBO has overstated drug costs, the estimates should be discounted. They point to the 2004 CBO projections of $60 premiums by 2013 in the Part D program, compared to the actual average premium of $31, which grew only to $33 for 2019. However, according to MedPAC, Part D premiums have stayed low in part due to rebates negotiated by PBMs, not because drug prices moderated at all. Without these rebates, premiums will rise.[15]

A second complaint lodged against CBO's methodology is that it should not have assumed that drug manufacturers would retain any existing rebates as increased revenue (which OACT also assumed). However, leading academic economists have been crystal clear on this question: tacit collusion is real, and the transparency of final net cost information leads to *higher* prices, not lower prices, overall.[16] In addition, manufacturers will not discount as deeply when they cannot know for certain that their volume goals that would justify a deeper discount will be reached. That is possible only with the reconciliation that accompanies after-the-fact rebates, the system currently in effect that the withdrawn rule would upend.[17]

Rather than be criticized, CBO instead should be lauded for continually updating its methodology to account for new information. It remains the gold standard for budget impacts and is relied upon by both elected officials and nonpartisan policymakers to "call balls and strikes" on legislative proposals. It is less than fair to assail this important report based on projections for a program *that hadn't even enrolled its first beneficiary*. While OACT operates independently of CBO, any analysis relied upon by HHS to move forward with this rule should be consistent with CBO's time-tested methodology and not wishful behavioral assumptions.

e. Other government reports following the close of the public comment period further validate the role of rebates in helping PBMs safeguard the Part D program

Since the comment period closed on the rebate rule in April 2019, two independent government reports have focused on how rebates lower Part D program costs.

First, HHS-OIG published a report in September 2019 using the most recently available information on Part D rebates. HHS-OIG – the same Agency that issued the withdrawn rebate rule – concluded that "increases in rebates substantially reduced the percentage increase in reimbursement for brand-name drugs in Part D from 2011 to 2015" and "unit reimbursement increased for nearly all brand-name drugs in Part D, regardless of whether these drugs' unit

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[14] T. Wilbur, "What you need to know about the CBO rebate rule score," PhRMA (May 23, 2019).

[15] MedPAC. March 2020 Report to Congress, Chapter 14. http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.

[16] Testimonies of Drs. Fiona Scott-Morton and Craig Garthwaite to the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets." March 7, 2019. https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1976.

[17] Barker T, Margulies R, et al. "Antitrust Implications of HHS' Proposed Rule to Limit Manufacturer Rebates." Foley Hoag LLP (August 2018) (available at https://foleyhoag.com/publications/ebooks-and-white-papers/2018/august/antitrust-implications-of-hhs-proposal-to-limit-manufacturer-rebates).

rebates increased or decreased across the 5 years reviewed."[18] Put another way, rebates save money in the Part D program, and drug prices increase regardless of the presence of rebates. A rule that limits rebates will lead to out-of-control Part D spending and will have no effect on the prices and price increases of brand name drugs.

Second, the U.S. Government Accountability Office (GAO) issued a report in July 2019 (after the final rule had been withdrawn from Office of Management and Budget (OMB) considerations) on the role of PBMs in the Part D program.[19] GAO found that competition within therapeutic classes drives down net costs. It also concluded that rebates were not a major source of PBM revenue: 99.6% of rebates were passed through to plan sponsors.

f. Future analyses should conform to established professional standards

A rule cannot be finalized that meets the terms of the EO without a new actuarial analysis. Such an analysis needs to follow professional standards as set forth by the Society of Actuaries, through its Actuarial Standards of Practice (ASOP). Of specific relevance:

- ASOP 1 (Introductory Actuarial Standard of Practice) comments on reasonability and reliance.[20]
    - Reasonability: "Because actuarial practice commonly involves the estimation of uncertain events, there will often be a range of reasonable methods and assumptions, and two actuaries could follow a particular ASOP, both using reasonable methods and assumptions, and reach different but reasonable results."
    - Reliance: "Actuaries frequently rely upon others for information and professional judgments that are pertinent to an assignment. Similarly, actuaries often rely upon others to perform some component of an actuarial analysis. Accordingly, some ASOPs permit the actuary to rely in good faith upon such individuals, subject to appropriate disclosure of such reliance, if required by applicable ASOPs."
- ASOP 23 (Data Quality) comments on the reliance on other information relevant to the use of data.[21] Specifically, the ASOP states: "The validity and completeness of such information are the responsibility of those who supply such information. The actuary may rely on such information supplied by others, unless it is or becomes apparent to the actuary in the course of the assignment that the information is unsuitable for use in the actuary's analysis. … If the actuary believes the information is unsuitable, or inconsistencies between the information and the data suggest that the information may

[18] HHS Office of the Inspector General, Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015. OEI-03-19-00010. September 2019. Available at https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf.

[19] US Government Accountability Office, MEDICARE PART D Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization. GAO 19-48. July 2019. Available at https://www.gao.gov/assets/710/700259.pdf.

[20] See http://www.actuarialstandardsboard.org/asops/introductoryactuarialstandardpractice/.

[21] See http://www.actuarialstandardsboard.org/asops/data-quality/.

be unsuitable, the actuary should make a professional judgment about whether to use the information."

- ASOP 41 (Actuarial Communications) remarks upon an explanation of material differences: "If a later actuarial communication produced by the same actuary, which opines on the same issue, includes materially different results or expresses a different opinion from the former communication, then the later communication should make it clear that the earlier results or opinion are no longer valid and explain why they have changed."[22]
- ASOP 56 (Modeling) discusses considerations when setting assumptions and when relying on modeling conducted by others.[23]
    - Considerations When Setting Assumptions:
        - "Actual experience properly modified to reflect the circumstances being modeled, to the extent actual experience is available, relevant, and sufficiently reliable; Other relevant and sufficiently reliable experience, such as industry experience that is properly modified to reflect the circumstances being modeled […]; Future expectations or estimates […] when available and appropriate; and other relevant sources of data or information."
        - "The actuary may consider using a range of assumptions and, if so, whether the number of model runs analyzed reflects a set of conditions consistent with the intended purpose."
        - "The actuary should use, or confirm use of, assumptions that are appropriate given the model's intended purpose."
    - When relying on models developed by others, actuaries should make reasonable attempts to have a basic understanding of the model, including:
        - Original intent, general operations, major sensitivities and dependencies within model, and key strengths and limitations.
        - When relying on experts consider, "The extent to which the model has been reviewed or validated by experts in the applicable field, including known material differences of opinion among experts concerning aspects of the model that could be material to the actuary's use of the model; whether there are industry or regulatory standards that apply to the model or to the testing or validation of the model, and whether the model has been certified as having met such standards […]"
        - "Where practical and appropriate, the actuary reusing an existing model should evaluate whether input unchanged from a prior model run is still appropriate for use in the current model run."

In summary, ASOPs exist to identify what actuaries in the United States should consider, document, and disclose when performing an actuarial assignment. ASOP #56, Modeling, is about to become effective in October 2020. There are standards in place for data quality and

[22] See http://www.actuarialstandardsboard.org/asops/actuarial-communications/.

[23] See http://www.actuarialstandardsboard.org/asops/modeling-3/, expected to be effective October 2020.

the selection of data and assumptions. Actuarial analyses performed by OACT and CBO follow these standards. A new analysis should consider these standards and may use prior projections to inform future analyses. Actuarial standards also require explanation should a modeled result differ materially from an actuary's prior analysis on the same topic. Should HHS's model project a reduction in member premium when shifting rebates to the point of sale, its methodology should be subject to rigorous peer review.

g. Any analysis should also comply with existing federal guidance to agencies regarding standards for regulatory impact analysis

Finally, in addition to conforming to the norms of the professions of actuarial science and economics, any analysis published by HHS to support finalizing a rule limiting rebates would need to meet existing federal standards. For example, HHS published in 2016 Guidelines for Regulatory Impact Analysis,[24] and OMB has established standards for agencies conducting regulatory analyses.[25] This Administration has also offered additional guidance, including with regard to any regulations issued during the current public health emergency.[26] An analysis that ignores the rules of regulatory impact analysis cannot be confirmed as meeting the terms of the EO.

In summary, since April 2019, three significant independent government reports have been added to the knowledge base on Part D, PBMs, and rebates. Accounting for these reports, and wholly aligned with OACT's findings in the original rule, any change to limit rebates or require them to be reflected at point of sale in the Part D program will lead to significant increases in premiums for all beneficiaries, while only a select few would pay significantly less in cost-sharing compared to the premium increase. Under no set of reasonable assumptions would federal spending decrease, either. HHS is obliged to significantly alter the rule and conduct a new actuarial analysis before proceeding in order to meet the terms of Section 4 of the EO. These significant changes would, under basic principles of administrative law, also have to be subject to notice-and-comment rulemaking so the public can comment upon the methods used in the analysis.

III. Finalizing a Rule Limiting Rebates is Incongruent with the Part D Regulatory System and Ongoing Innovations

In our April 2019 public comments, we provided HHS-OIG with seven pages of questions related to existing regulations and guidance in the Part D program that would need to be addressed before rebates could be limited as proposed.[27] (We also shared these questions with our partners at CMS.) Since the Proposed Rule was withdrawn, none of these important

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[24] HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE). Guidelines for Regulatory Impact Analysis. 2016. https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

[25] US Office of Management and Budget. Regulatory Analysis. September 2003. https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

[26] See for example the White House, Executive Order on Regulatory Relief to Support Economic Recovery. May 2020. https://www.whitehouse.gov/presidential-actions/executive-order-regulatory-relief-support-economic-recovery/

[27] PCMA. April 8, 2019. https://www.pcmanet.org/wp-content/uploads/2019/04/PCMA-Comments-on-Safe-Harbor-Proposed-Regulations.pdf. See pages 65-71.

conflicts have been resolved, and they remain critical operational barriers to implementing such changes.

Since the HHS-OIG proposed rule comment period closed, and after it was withdrawn from consideration, CMS has continued to offer innovative policy solutions for high-cost drugs. In the May 2019 final rule for the Part D program, CMS required that Part D plans offer real-time benefit checks (RTBT) for prescribers and made changes to the Explanation of Benefits document for 2021.[28] The May 2020 final rule did not finalize patient-level RTBT for 2022 as proposed, but CMS states it plans to finalize rulemaking to further improve these tools.[29] These changes bring needed transparency to beneficiaries about drug costs and lower-cost therapeutic alternatives. Incorporating point-of-sale rebates or chargebacks into these tools would be a monumental undertaking and likely delay the implementation and availability of these tools.

As PCMA noted in our April 2019 comment letter on the Proposed Rule, these CMMI models cannot properly function if rebates are limited in the way HHS-OIG proposed. It is counterproductive for HHS to subvert CMS's delegated authority over the Part D program. CMMI continues to announce new models that would help beneficiaries who are taking high-cost drugs, in ways that leverage private and public partnerships rather than demonizing an important stakeholder in the supply chain. For example, in March 2020, CMMI announced the Senior Savings demo, which Administrator Seema Verma described as:

> "[a] market-based solution, in which insulin manufacturers and Part D sponsors compete to provide lower costs and higher quality for patients, will allow seniors to choose a Part D plan that covers their insulin at an average 66 percent lower out-of-pocket cost throughout the year."[30]

Under the demo, Part D plans will offer insulin at no more than $35 copayments for a 30-day supply, by specifically applying manufacturer rebates to drug costs throughout the benefit.[31] This model is the pinnacle of CMS's efforts to combat the price of insulin. It is unclear how the model and point-of-sale rebates would interact, threatening the viability of this model. Beyond this insulin-specific demo, CMMI also continues to test changes to reinsurance benefit designs, "smoothing" beneficiary cost-sharing throughout the Part D benefit year to address high out-of-pocket costs, and allowing for other innovative benefits such as "split fills" for high-cost drugs in its Payment Modernization demo.[32] We are concerned that these smaller-scale tests would also be at risk.

[28] 84 Fed. Reg. 23832, May 23, 2019.

[29] 85 Fed. Reg. 33796, June 2, 2020.

[30] CMS. President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors. May 26, 2020. https://www.cms.gov/newsroom/press-releases/president-trump-announces-lower-out-pocket-insulin-costs-medicares-seniors.

[31] See https://innovation.cms.gov/innovation-models/part-d-savings-model for more information.

[32] See https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model for more information.

Finally, just last week CMS announced with great fanfare only a modest increase in average monthly premiums for 2021, continuing its recent trend of maintaining affordability.[33] As stated by the Administrator:

> "At every turn, the Trump Administration has prioritized policies that introduce choice and competition in Part D … Part D premiums continue to stay at their lowest levels in years even as beneficiaries enjoy a more robust set of options from which to choose a plan that meets their needs."[34]

Why would the Department put at risk the successes that the existing Part D regulatory framework has generated in keeping premiums affordable for America's seniors? HHS should let CMS continue to successfully operate the Part D program, working with Part D plan sponsors to provide a wide set of plan choices and keeping premiums affordable.

IV. Conclusion

PCMA appreciates the Department's attention to this supplementary regulatory filing. In this letter we have highlighted new analyses and inconsistencies with the EO, any potential rule limiting rebates, and ongoing Part D program operations. If you have any questions, please contact me (wkrasner@pcmanet.org or Tim Dube (tdube@pcmanet.org).

Sincerely,

Wendy Krasner

Wendy Krasner
Senior Vice President, Regulatory Affairs

cc: John Brooks, Counselor to the Secretary and Senior Advisor for Drug Pricing, HHS
Christi Grimm, Principal Deputy Inspector General
Greg Demske, Chief Counsel to the Inspector General
Robert Charrow, HHS/OGC
Seema Verma, Administrator, CMS
Russ Vought, Director, Office of Management and Budget
Theo Merkel, NEC
Brooke Rollins, Acting Director, Domestic Policy Council

[33] CMS. Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information. July 29, 2020. https://www.cms.gov/files/document/july-29-2020-parts-c-d-announcement.pdf. The average base beneficiary premium will rise just 1% from $32.74 in 2020 to $33.06 in 2021.

[34] CMS. Trump Administration Continues to Keep Out-of-Pocket Drug Costs Low for Seniors. July 29, 2020. https://www.cms.gov/newsroom/press-releases/trump-administration-continues-keep-out-pocket-drug-costs-low-seniors.