

April 5, 2019

The Honorable David R. Levinson
Inspector General
Department of Health and Human Services
Cohen Building Room 5527
330 Independence Avenue SW
Washington, DC 20201

Submitted electronically via regulations.gov

RE: [OIG-0936-P] 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 PBM Service Fees

Dear Inspector General Levinson:

On behalf of the more than 54 million Americans and 300,000 children in the United States with doctor-diagnosed arthritis, the Arthritis Foundation appreciates the opportunity to comment on the proposed rule that would remove safe harbor protection for rebates involving prescription pharmaceuticals and create a new safe harbor for certain point-of-sale reductions in price on prescription medications. We agree on the need to find solutions that lower list prices, as drug costs and affordability are top concerns for people with arthritis. Policies should be developed in a way that balance these concerns while avoiding either unintended consequences for patient access or adverse impacts on research and development of innovative medicines.

About 30 percent of Medicare beneficiaries live with arthritis. Beneficiaries with arthritis are also more likely to have at least one chronic condition such as heart disease or diabetes.^{1,2} In addition, spending in Medicare Part D for biologics that treat inflammatory forms of arthritis such as rheumatoid arthritis have increased significantly from 2013-2017. The latest CMS dashboard on Medicare Part D drugs indicates that the annual growth rate in average spending per dosage unit for these self-injectable medications was about 18 percent during that timeframe. Further, the average spending per beneficiary by Medicare Part D exceeded \$35,000 for 2017.³

Out-of-pocket-costs for beneficiaries in Part D can also have serious consequences. A recent Kaiser Family Foundation study showed that rheumatoid arthritis is one of the disease areas for which beneficiaries are most likely to reach the catastrophic phase, and the median out-of-pocket costs for some common

¹ CMS. (2012). Chronic Conditions Among Medicare Beneficiaries. <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>

² CMS. (2015). Medicare Chronic Conditions Dashboard. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/chronic-conditions-state/cc_state_dashboard.html

³ CMS. (2019). Medicare Part D Drug Spending Dashboard and Data. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>

arthritis drugs surpasses \$5,000.⁴ Further, out-of-pocket costs have risen substantially in the last three years. Perhaps more alarming is the number of people with rheumatoid arthritis who cannot remain on their medication when they transition into Medicare because the Part D cost-sharing structure is prohibitive for them. The Arthritis Foundation often hears stories from patients who have had to switch to a physician-administered drug because they could only afford the cost-sharing under Medicare Part B. In many cases, these drugs are less efficacious for them or cause serious harm. It is critically important for arthritis disease management that people who are stable on a drug can remain on that drug.

The Arthritis Foundation supports the broader goals of the proposed rule to address list price increases and improve health care transparency. We believe that amending current statute to exclude discounts to Medicare Part D plan sponsors from the existing discount safe harbor is one element of achieving those aims. However, there is significant uncertainty regarding how market participants will respond if the manufacturer rebate system is disrupted in the way contemplated by the proposed rule. Below please find our specific comments on the rule.

We are willing to accept a trade-off of slight premium increases in Medicare Part D if average cost-sharing across all beneficiaries is reduced significantly. As we noted previously, people with inflammatory forms of arthritis often have some of the highest out-of-pocket expenses with respect to the cost of needed medications. As part of its work to understand the impact of the proposed rule, HHS obtained analyses from the CMS Office of the Actuary and two independent actuarial firms to model a variety of market participant behaviors. HHS notes up front in the proposed rule that “it is difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response.” In any case, these analyses generally agree that “beneficiary cost-sharing would decrease, and premiums would increase, and that the decrease in total beneficiary cost-sharing would offset the total increase in premiums across all beneficiaries.”⁵ Beneficiaries with high out-of-pocket costs are especially likely to benefit from the proposed rule at the expense of slight increases in premiums for non-low-income beneficiaries (estimated between \$2.70 to \$5.64).⁶ Importantly, it is possible premiums would increase much more than anticipated in the proposed rule as we note below. We urge HHS to work closely with patient advocacy organizations and other market participants to assure any changes in premiums are appropriate and reasonable.

We also support more predictable out-of-pocket spending for beneficiaries at the point-of-sale, provided that premiums remain within the range of actuarial estimates. Point-of-sale rebates were first contemplated by the administration in 2017. If implemented appropriately, this policy would allow Medicare beneficiaries to directly benefit from upfront discounts. The proposal would also drive greater transparency regarding coverage and out-of-pocket costs. A core component of this policy should ensure beneficiaries have access to easily understandable information to determine what plan best meets their needs. For instance, coinsurance should be presented to enrollees as a dollar amount; a recent analysis

⁴ Cubanski, J. C., Koma, W., & Neuman, T. (2019, February 01). The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019. Retrieved from <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/>

⁵ Solicitation of New Safe Harbors and Special Fraud Alerts. (2017, December 27). Retrieved from <https://www.federalregister.gov/documents/2017/12/27/2017-27117/solicitation-of-new-safe-harbors-and-special-fraud-alerts>

⁶ Ibid.

by Avalere found an average 41 percent increase over three years (2015-2018) in the number of drugs on coinsurance tiers in Medicare Part D.

Given significant uncertainty around how relevant stakeholders will react if the rule is finalized as proposed, HHS should obtain commitments from manufacturers and other players affirming that they will actually work to lower list prices. In February, executives from seven leading manufacturers appeared before the Senate Finance Committee to discuss recent federal proposals on drug pricing. During the hearing, members of both political parties expressed concern about high list prices. In addition, all executives testified that they were generally supportive of the rule but hedged on whether the regulatory change would result in lower list prices. Some witnesses indicated they would lower list prices if the rebate rule was effectuated in both Medicare and the commercial markets, while others noted patients would benefit from the upfront discounts at the point-of-sale.⁷ The Arthritis Foundation believes manufacturers should follow through on their commitments to lower list prices if this rule goes into effect, and the administration should work with relevant stakeholders to ensure manufacturers are held accountable.

Further, the unpredictability of how relevant stakeholders will react if the rule is finalized as proposed leaves a significant grey area in the drug channel. For instance, it is possible that elimination of rebates would lead to smaller discounts and higher net prices negating any benefit to beneficiaries over the long-term. Ultimately, payers and actuaries are responsible for managing risk; without the certainty of lower list prices under the proposal, premiums could rise much more than projected. Conversely, to minimize premium impacts, plan sponsors could choose to design more restrictive formularies by imposing further utilization management practices or covering fewer drugs. For these reasons, we encourage the administration to ensure that the proposed rule does not eliminate the ability of manufacturers and payers to continue engaging in appropriate negotiation.

It is unclear how the rule will interact with other recent proposals from the administration affecting prescription drugs and beneficiary access to medications. Over the last several months, the administration has put forward a number of ambitious proposals that would fundamentally alter incentives and payment structures for public programs. As an example, the international pricing index model for Medicare Part B drugs,⁸ Medicare Part D and Medicare Advantage changes,⁹ and pending new direct to consumer (DTC) advertising requirements,¹⁰ among other proposals, put forward in quick succession, make it difficult to predict how relevant stakeholders will respond if and when such regulations are finalized and promulgated. Specific to the rebate safe harbor proposal, the uncertainty is further compounded when private insurance markets are considered. While we have heard that it is feasible for some stakeholders to implement changes contemplated in the proposed rule by January 1, 2020, it may

⁷ Herman, B., & Baker, S. (2019, February 26). Drug companies hedge on lowering prices. *Axios*. Retrieved from <https://www.axios.com/drug-companies-prices-senate-hearing-b86112ce-2b7c-4dd9-9712-6ab7ad758168.html>

⁸ Medicare Program; International Pricing Index Model for Medicare Part B Drugs. (2018, October 30). Retrieved from <https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs>

⁹ Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses. (2018). <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf>

¹⁰ Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency. (2018, October 18). Retrieved from <https://www.federalregister.gov/documents/2018/10/18/2018-22698/medicare-and-medicare-programs-regulation-to-require-drug-pricing-transparency>

be prudent for the administration to take time to further study the issue given the multiple concurrent changes that will take effect over the next 12 months. A change in the effective date could provide the administration an opportunity to engage in further discussions with patient advocacy organizations, plan sponsors, pharmacy benefit managers, manufacturers, pharmacists, employers, and other stakeholders to clarify how the proposed rule would be fully operationalized.

As a general matter, we appreciate that the administration has engaged Congress on a number of these proposals and hope this outreach continues in order to minimize disruption to multiple sectors of the health care system at once. In each case, the Arthritis Foundation is squarely focused on how policies will affect patient access to affordable health care and needed medications.

Medicaid should be carved out of the proposal. We urge HHS to leave in place the current safe harbor for rebates under Medicaid managed care organizations (MCOs). States rely on Medicaid MCOs to negotiate supplemental prescription drug rebates in addition to rebates that are required under the Medicaid Drug Rebate Program. The Medicaid and CHIP Payment and Access Commission (MACPAC) estimated that manufacturers paid over \$31 billion in rebates to states and the federal government in fiscal year 2016, which lowered prescription drug costs in Medicaid by over 50 percent.¹¹ MACPAC recently discussed the proposed rule at their March meeting where consensus among the commissioners seemed to be that Medicaid should not be considered within the scope of the proposed rule, principally because capitation rates would increase as MCOs see an increase in net drug costs.¹²

HHS should analyze the potential impact on drug formularies before moving forward with the proposed rule. While the use of generic medications is close to 90 percent under the Part D program, utilization of branded drugs for which there are no generic equivalents has been slowly increasing. Formulary design is the principal tool employed by prescription drug plans (PDPs) under Medicare Part D to manage drug benefits, and how a formulary is structured depends on the contracting incentives between health plans, manufacturers, and pharmacy benefit managers. The Arthritis Foundation is concerned about how incentives will change for key stakeholders, particularly whether there will be an increase in narrowed benefit and formulary design practices. It is imperative that HHS take time to fully understand how formularies may change under the proposal, including how the use of utilization management tools may be more aggressive by plan sponsors and pharmacy benefit managers.

HHS should ensure value-based contracts are not affected by the proposed rule. HHS states that although the agency is exploring value-based arrangements and their use in the sale of prescription drugs, the proposal is not intended to impact existing protections for value-based contracts between plan sponsors and manufacturers. We agree with the administration's view that value-based arrangements are an important component of ensuring high quality under Medicare Part D. However, since the proposed rule does not elaborate on how value-based arrangements would be protected, we urge HHS to clarify the impact to avoid any unintended consequences.

¹¹ MACPAC. (2018). Exhibit 28: Medicaid gross spending and rebates for drugs by delivery system. https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28_-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2017.pdf

¹² MACPAC. (2019). Proposed rule affecting safe harbors for prescription drug rebates. <https://www.macpac.gov/wp-content/uploads/2019/03/Proposed-Rule-Affecting-Safe-Harbors-for-Prescription-Drug-Rebates.pdf>

Proposals to bring down list prices should be accompanied by an out-of-pocket cap under Medicare Part D. The President’s fiscal year 2020 budget again calls for providing beneficiaries with more predictable spending on prescription drugs by creating an out-of-pocket cap in Medicare Part D. The Arthritis Foundation continues to be strongly supportive of this proposal and believes it complements the safe harbor proposed rule to alleviate burdensome costs on beneficiaries. A Health Affairs study showed that almost 60 percent of patients taking specialty drugs for rheumatoid arthritis reached the catastrophic coverage threshold by the month of May.¹³ In other words, most rheumatoid arthritis patients in the Medicare Part D program spent nearly half the plan year in the catastrophic coverage phase – meaning that the reduced co-insurance rate in this phase of coverage (today about 5%) translates into significant out-of-pocket costs. We urge HHS to work with Congress to pass legislation that makes an out-of-pocket cap in the Part D program a reality.

In conjunction with the proposed rule, we also encourage the administration to pursue other policies that could result in lower patient out-of-pocket costs such as biosimilars. Biologics have revolutionized the treatment of inflammatory forms of arthritis by preventing joint damage and preserving function and mobility. The Arthritis Foundation believes that biosimilars hold promise to reduce costs and add to the overall treatment options available to patients. There are two key factors that could prevent wide-spread adoption of biosimilars: patient and provider trust in their safety and efficacy; and market policies that make it difficult for biosimilars to be offered to patients. Biosimilars educational resources and interchangeability are critical to overcoming these obstacles. We look forward to continuing to engage with the administration on these issues.

The Arthritis Foundation appreciates the opportunity to comment on the proposed rule and looks forward to continued discussions with the administration on solutions that balance issues of drug pricing and affordability with access to life-changing treatments. Please contact Vincent Pacileo, Director of Federal Affairs, at vpacileo@arthritis.org or 202-843-0114, with questions or for more information.

Sincerely,



Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation

¹³ Trish, E., Xu, J., & Joyce, G. (2016). Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase. Health Affairs (Project Hope), 35(9), 1564–1571. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5573178/>.