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April 8, 2019

Honorable Daniel R. Levinson
Inspector General
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via regulations.gov

RE: 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 (RIN 0396-AA08)

Dear Inspector General Levinson:

AARP, on behalf of our nearly 38 million members and older Americans nationwide, is pleased to submit the following comments on the proposed rule removing safe harbor protection for prescription drug rebates and creating new safe harbor protections for certain point-of-sale discounts and pharmacy benefit manager service fees.

Prescription drugs are critical to curing or managing disease, maintaining health, and improving quality of life. Older Americans use prescription drugs more than any other segment of the U.S. population but many – including Medicare beneficiaries – struggle to afford them. Ensuring that older adults have access to and can afford their prescriptions is essential. We strongly support policies to lower drug prices and reduce consumers' drug costs – with the ultimate goal of increasing access to necessary medications at affordable prices.

Unfortunately, AARP is concerned that the rule as proposed will not achieve these goals and may in fact lead to even higher prescription drug prices. While the intent behind the proposed rule is laudable, we are troubled by estimates that the proposal will increase Medicare and taxpayer spending, raise premiums for all Medicare Part D beneficiaries, and increase revenue for drug manufacturers. As we look at solutions to lower prescription drug prices and costs to consumers, we need to find solutions that will

actually lower prescription drug prices and not simply shift costs around within the system.

Shifting Costs Instead of Addressing Manufacturers' Prices

Currently, pharmaceutical manufacturers pay rebates to secure favorable positions on health plans' drug formularies. Because the rebates are paid after a beneficiary has already purchased the drug, they typically are not reflected in beneficiaries' out-of-pocket costs and are instead used to slow premium growth.

Under the proposed rule, drug manufacturers would be required to provide any price reductions at the pharmacy counter. This would be accomplished by changing an exception to the Anti-Kickback Statute. Rebates offered to pharmacy benefit managers (PBMs), Medicare Part D plan sponsors, and Medicaid managed care organizations would now be considered illegal kickbacks, but discounts provided at the pharmacy counter would be protected.

- a. Manufacturers not required to provide discounts or lower prices to replace rebates

HHS hopes that manufacturers would respond by replacing rebates with price discounts at the pharmacy counter or by lowering list prices overall. However, manufacturers would not be compelled to do so, and major drug company executives testifying before the Senate Finance Committee would not commit to lowering their prices in response to the proposed rule, particularly since the rule would not apply to the commercial market.¹

Under the best-case scenario, in which manufacturers convert all or most of existing rebates to discounts at the pharmacy counter, a minority of Medicare beneficiaries would see a meaningful reduction in their out-of-pocket costs. More specifically, only those beneficiaries taking a drug with a substantial rebate² that was replaced with an equivalent discount and who are also in a plan where the given drug is covered using coinsurance (not a fixed co-payment) could see lower costs. Only one in four Part D brand name drugs are estimated to offer substantial rebates, and unfortunately the exact number of beneficiaries who may benefit – and by how much – remains unclear.

- b. Part D premiums will increase for all enrollees

Meanwhile, under the proposal, premiums would increase for all Part D enrollees because rebates would no longer be available to offset premium costs. In fact, HHS estimated that the proposed rule could increase beneficiary premiums by 25 percent

¹ <https://www.aarp.org/politics-society/advocacy/info-2019/senate-hearing-drug-prices.html>

² Defined as the 25th percentile of rebates, or 12 percent of gross drug cost. Twenty-seven percent of Part D brand name drugs are estimated to offer such rebates. N. Johnson, C. Mills, M. Kridgen, Prescription Drug Rebates and Part D Drug Costs; Analysis of historical Medicare Part D drug prices and manufacturer rebates Milliman, July 2018, <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf>.

over the next 10 years. Since premiums costs are shared by Medicare beneficiaries and the federal government, taxpayer spending would increase as well: HHS estimated that the proposed rule could increase Medicare costs by as much as \$196 billion over the next 10 years.³

c. Drug manufacturers will see increased revenues

The best-case scenario also anticipates a major revenue boost for drug manufacturers. HHS estimates that manufacturer revenue could increase by approximately \$171 billion over ten years under the proposal.⁴ This increased revenue is driven by a reduction in rebates and discounts offered under the program, as well as a reduction in manufacturer contributions for beneficiaries who are in the Medicare Part D coverage gap.

AARP is concerned that even this best-case scenario simply shifts costs from one part of the system to another. Moreover, should manufacturers decline to replace rebates with equivalent discounts and/or make only modest changes to their list prices, this proposal could be disastrous for Medicare, Medicaid, and their beneficiaries. It would also be extremely difficult to explain to the vast majority of Medicare beneficiaries – who will see higher premiums and no offsetting benefit – why policies touted as helpful simply lead to higher premiums, particularly if drug prices remain the same or even continue to increase.

Insufficient Understanding of Impact

The proposed rule provided impact estimates from multiple consultants in addition to HHS' own actuaries. Altogether, the consultants and actuaries analyzed a total of 8 different scenarios, highlighting the high level of uncertainty around the impact of the proposal on prescription drug prices, beneficiary out-of-pocket costs and premiums, and federal and taxpayer spending. More importantly, none of the impact assessments included critical analytic information that we believe is necessary to properly evaluate the impact of the proposed rule.

a. Impact on drug prices

Throughout the proposed rule, HHS makes it clear that it does not know whether prescription drug prices will increase, decrease, or stay at the same levels if rebates are eliminated. Similarly, the alternative scenarios present a broad range of possible impacts on drug prices. In some scenarios, manufacturers replace rebates with discounts. In others, manufacturers partially replace rebates with discounts. In at least one scenario, manufacturers respond by raising drug prices.

³ <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>

⁴ <https://www.pewtrusts.org/-/media/assets/2019/03/pew-charitable-trusts---letter-to-senate-aging---proposals-to-modify-medicare-part-d.pdf>

Given that prescription drug price trends are already widely viewed as unsustainable, we find this high degree of uncertainty to be extremely concerning. Moreover, it is a strong indication that this proposal is not directed at the root cause of the problem that it is trying to address—the pricing behavior of drug manufacturers.

b. Impact on individuals

HHS does not provide a clear estimate of the number of Medicare beneficiaries who would experience meaningfully lower out-of-pocket costs if rebates were eliminated (i.e., those beneficiaries taking a drug with a substantial rebate who are also in a plan where the given drug is covered using coinsurance). Simply providing a broad percentage of beneficiaries with high enough drug costs that they *could* experience enough of a reduction in out-of-pocket costs to make up for the average increase in premium is not as informative as knowing who *would* benefit and by how much. The lack of data on such a major change is alarming, and we believe a detailed impact analysis is essential to any proper evaluation of the proposed rule.

c. Impact on formulary generosity

Under existing practice, plans, PBMs, and manufacturers use rebates as a tool to negotiate preferred placement of a drug on a plan's formulary. Without this tool, it is extremely unclear how formulary negotiations and formularies would evolve over time. It is entirely possible that plans and PBMs will respond by reducing the generosity of their formularies, a fact that the Administration has alluded to in the proposed rule and subsequent communication as “tougher negotiation.”⁵ Nevertheless, HHS does not include a comprehensive analysis of this possibility in the proposed rule, including how it may impact beneficiary access to needed prescription drugs. AARP believes the possibility of major formulary changes should be an essential aspect of any impact analysis and should be considered before the rule is finalized.

AARP is also concerned by the possibility that Part D plans could further reduce or even eliminate their use of fixed copayments. Under the proposed rule, any reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale. Although the proposed rule notes that patients with fixed copayments may not see changes in their cost-sharing at the point-of-sale, plans that do not wish to run afoul of the new rule may decide to simply convert all of their cost-sharing to coinsurance, making it considerably easier to pass through rebates at the point-of-sale and ensure compliance. This shift would expose all beneficiaries to drug manufacturers' pricing behavior directly and would be particularly problematic for those taking non-

⁵ <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>; <https://www.hhs.gov/blog/2019/03/11/patients-need-transparency-and-relief-from-high-drug-costs.html>

rebated brand name drugs, who could end up having to pay as much as 50 percent of the cost of their drugs⁶ without the benefit of a point-of-sale rebate.⁷

d. Uncertainty about discounts

In issuing this proposed rule, the Administration is encouraging the replacement of retrospective rebates with upfront discounts. However, there is concern within the legal community that the replacement of rebates with differential discounts from drug manufacturers may not be a lawful alternative under the applicable federal antitrust laws.⁸ Some legal advisors have observed that a legislative change to the antitrust laws would be necessary to clearly permit upfront differential pricing by manufacturers to the purchasers of its drugs.

Given that Medicare itself is prohibited from negotiating with drug manufacturers directly, HHS has acknowledged that PBMs and Part D plans are skilled at negotiating with drug manufacturers to obtain rebates for the drugs on their formularies. These findings have been confirmed by the Medicare Trustees, which projected significantly slower growth in Part D spending in their most recent report in part due to higher manufacturer rebates negotiated by PBMs.⁹

Without a clear alternative to rebates or a resolution of potential legal barriers to offering differential discounts — as well as the aforementioned no commitment from manufacturers that they will lower their prices in response to the proposed rule¹⁰— AARP believes that the likelihood of manufacturers fully replacing rebates with upfront discounts is low.

Another discount-related concern identified by HHS in the proposed rule is the possibility that moving to discounts could allow interested parties to “reverse engineer” drug prices. This high level of price transparency could dampen manufacturer incentives to offer lower prices and even encourage manufacturers to set higher prices to match their competitors. HHS did not offer a resolution to these concerns.

⁶ Medicare Part D plans are allowed to charge a maximum of 50 percent coinsurance for non-preferred drugs in 2020. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>

⁷ Only 13% of protected class brand name drugs and 36% of brand name drugs overall receive manufacturer rebates. N. Johnson, C. Mills, M. Kridgen, Prescription Drug Rebates and Part D Drug Costs; Analysis of historical Medicare Part D drug prices and manufacturer rebates Milliman, July 2018, <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf>.

⁸ T. Barker, R. Margulies, and E. Schulwolf, “Antitrust Implications of HHS’ Proposed Rule to Limit Manufacturer Rebates”, *FoleyHoag*, March 2019, <https://foleyhoag.com/publications/ebooks-and-white-papers/2019/march/antitrust-implications-of-a-proposed-hhs-rule-to-limit-manufacturer-rebates>.

⁹ The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds. “[2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds](#),” 2018.

¹⁰ <https://www.aarp.org/politics-society/advocacy/info-2019/senate-hearing-drug-prices.html>

Proposed Rule Should Be Delayed until Implications are Better Understood

AARP appreciates HHS' ongoing efforts to address prescription drug costs. However, given the high degree of uncertainty associated with this proposed rule, we are encouraged that CMS will conduct a comprehensive demonstration program to better understand the impact it would have Medicare Part D and its enrollees. AARP strongly believes that any efforts to improve Medicare Part D should make such coverage more – not less – affordable for Part D enrollees. While the intent behind this proposed rule is commendable, HHS could explore other policies that more directly address manufacturers' pricing behavior.

AARP remains pleased that high drug costs remains a top priority for the Administration. We look forward to continuing to work with HHS to implement workable solutions that will lead to lower prices and reduced costs for older Americans. If you have any additional questions, feel free to contact me or have your staff contact Amy Kelbick on our Government Affairs staff at akelbick@aarp.org or 202-434-2648.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a long horizontal flourish extending to the right.

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs