



April 8, 2019

VIA ELECTRONIC SUBMISSION

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: OIG-0936-P. 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

Dear Secretary Azar:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the on the proposed changes to the Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and other proposals in OIG-0936-P.

Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to three million people with Medicare, family caregivers, and professionals each year.

While we are encouraged by the Department of Health and Human Services' (HHS) efforts to improve transparency within the Part D drug pricing system, we are disappointed that this proposed rule has few guarantees when it comes to lowering high drug prices or beneficiary out-of-pocket costs and leaves open significant questions about its efficacy and impacts.

General comments

Every year, prescription drug affordability is among the most common reasons for calls to our National Consumer Helpline.¹ Increasingly, it is not just lower-income beneficiaries who are struggling to cover their drug costs. In 2017, over 40% of Helpline callers screened for Part D assistance programs, such as

¹ Medicare Rights Center, "Medicare Trends and Recommendations: An Analysis of 2017 Call Data from the Medicare Rights Center's National Helpline" (April 4, 2019), <https://www.medicarerights.org/pdf/2017-helpline-trends-report.pdf>.

Extra Help, did not qualify due to having income and assets that exceeded the program’s eligibility thresholds.²

The consequences of prescription drug unaffordability are significant, both for the Medicare program and those who rely on it. Beneficiaries who cannot purchase their medications may be forced to go without care—leading to worse health outcomes and quality of life, hospitalizations, or even death. And the cost to the Medicare program is also extreme, as beneficiaries who forgo needed medications and experience declining health as a result are likely to need more costly interventions later, like emergency department or inpatient care.

Access and affordability challenges are especially prevalent among people living with disabilities and chronic conditions, due to their reliance on often multiple medications to control or manage those conditions and the conditions’ impact on work and income. The proliferation of coinsurance rather than copayments in Part D has increased beneficiary out-of-pocket cost exposure.³ This is exacerbated by basing beneficiary coinsurance amounts on the drug’s negotiated price,⁴ rather than the net price actually paid by the plan or Pharmacy Benefit Manager (PBM) when rebates and other discounts are taken into account.

In recognition of these complexities, we support efforts to reduce out-of-pocket costs, improve transparency, and better align incentives throughout the drug pricing system—including by eliminating distortions that drive up drug prices at the expense of beneficiaries and taxpayers. In our response to the Administration’s drug pricing blueprint, we expressed general support for reforming the opaque system of manufacturer-to-PBM rebates in order to improve transparency.⁵ However, we also urged caution in this approach, given its potentially negative impacts on beneficiary and federal health program spending, and noted that focusing on these arrangements—which may have some effect on drug costs—does not address the underlying issue of high list prices.⁶

Here, we continue to recommend that rebates and other discounts that encourage manufacturers to inflate list prices not be incentivized. We also continue to urge that extensive modelling and careful testing be done before introducing any such changes into the system, and again note that while more transparency and accountability may help control costs, rebates are a symptom and not a driver of the fundamental problem of high drug prices and a complex, opaque, and fractured pricing system.

Though we applaud the Administration’s intent to improve upon the current system, we are concerned that the proposed rule does not do enough to ensure that beneficiaries would benefit from the recommended corrections. The proposal does not require the conversion of PBM rebates into point-of-sale rebates for beneficiaries, nor does it directly address already-high list prices. Perhaps most

² *Id.*

³ Kaiser Family Foundation, “An Overview of the Medicare Part D Prescription Drug Benefit” (October 12, 2018), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

⁴ 42 CFR § 423.104, <https://www.law.cornell.edu/cfr/text/42/423.104>. This is distinct from “list price,” or price without insurance, because it varies from Part D plan to Part D plan, as reflected in the Medicare Plan Finder tool. For example, a recent Medicare Plan Finder search for the brand name drug Nexium showed a negotiated rate (and price in the deductible) of approximately \$270 under one plan and \$240 under another. The list price is difficult to ascertain but some websites place it between \$270 and \$300, <https://www.wellrx.com/prescriptions/esomeprazole%20magnesium/04103#>.

⁵ Department of Health and Human Services, “American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

⁶ Medicare Rights Center, “Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs [RIN 0991-ZA49]” (July 16, 2018), <https://www.medicarerights.org/pdf/071618-drug-pricing-blueprint-RIN-0991-ZA49.pdf>.

importantly, the proposed rule does not increase federal oversight of Part D plans, PBMs, or pharmaceutical manufacturers in any concrete way. This would leave manufacturers free to continue to increase prices, and beneficiaries at risk of ever-rising premiums, cost sharing amounts, and out-of-pocket costs.

We are also troubled by the wide-ranging estimates as to how the proposed rule would impact beneficiary premiums, and its substantial cost to the Medicare program. Accordingly, we urge HHS to better understand the market before finalizing this rule and to work in the interim both administratively and with Congress to remedy the misaligned incentives in Part D that allow plans to largely escape repercussions for flawed price negotiation, and allow drug manufacturers to raise prices without consequence.

We also strongly urge HHS to carve out the current Medicaid rebate structure from any final rule. The Medicaid rebates do not burden beneficiaries with unfair out-of-pocket cost escalations. Removing the current rebate system would simply and disastrously shift costs from pharmaceutical manufacturers to the states and the federal government. Indeed, we have repeatedly encouraged the Centers for Medicare & Medicaid Services (CMS) and Congress to extend the Medicaid rebate program to include Part D enrollees in the Low-Income Subsidy (LIS) program.

Part D Incentive Misalignment

The current rebate system privileges large rebates over low list prices for PBMs and plans. This perverse incentive structure leads to higher costs being imposed on certain beneficiaries while artificially driving down premiums for others at their expense.

While beneficiary choice drives some rebate payments based on scale, unlike others in the supply chain, they receive no financial benefits from the current rebate system. Instead, the rebates offset premium rates for all Part D beneficiaries. This means beneficiaries who take rebated drugs are subsidizing those who take other, or no medications, which is counter to the purpose of health coverage.⁷ As outgoing Food and Drug Administration Commissioner Scott Gottlieb has candidly stated, “sick people aren’t supposed to be subsidizing the healthy.”⁸

Eliminating rebates, encouraging discounts that are appropriately captured in the negotiated rate reported to CMS and included in the Medicare Plan Finder tool, and decreasing beneficiary costs at the point-of-sale could benefit some people with Medicare. It could also reduce the opacity of the current system and mitigate its counter-intuitive source of upward pressure on drug prices. That said, this proposed rule does not establish such a system. It does not guarantee that any savings would be passed along to beneficiaries, let alone at amounts equal to current rebates.

Secretary Azar has stated “there is no reason why those rebates should not convert equally from rebates to discounts for the patients.”⁹ But there is a reason: If pre-bid reductions in negotiated rates or passed-through rebates at the point-of-sale do not carry with them the competitive advantages the market

⁷ Peter Sullivan, “Gottlieb: Drug rebates not benefiting sicker patients,” The Hill (March 6, 2019), <https://thehill.com/policy/healthcare/432857-gottlieb-drug-rebates-not-benefiting-sicker-patients>.

⁸ Meg Tirrell, “FDA commissioner to health insurers: You’re doing it wrong,” CNBC (March 7, 2018), <https://www.cnbc.com/2018/03/07/fda-commissioner-to-health-insurers-youre-doing-it-wrong.html>.

⁹ Shannon Firth, “HHS Proposes Scrapping Rebates to PBMs, Giving Discounts to Patients,” MedPage Today (February 1, 2019), <https://www.medpagetoday.com/publichealthpolicy/healthpolicy/77775>.

actors see in the current rebate system, those reductions would either not occur or would be at a greatly reduced rate. While it is possible that markets could respond by passing any savings along to beneficiaries, it is also possible that markets could not. This proposal does not include requirements or incentives to encourage manufacturers to lower list prices or to pass rebates on to the consumer at the point-of-sale. Given the high stakes, HHS must not assume that its proposal would result in beneficiary savings. Further study and careful consideration are needed.

We support the proposal to make PBM compensation flat, transparent, and connected to the value-added services they provide. Formulary decisions must be based on a drug's efficacy and value, not its ability to provide increased profits.

Increasing Meaningful Oversight

HHS must improve its oversight of the current drug pricing system in order to better understand how its proposed rule would impact people with Medicare and the program as a whole. We urge the Administration not to move forward before obtaining this baseline data and outlining clear standards for meaningful oversight that it would employ to ensure beneficiaries not only benefit from any changes to the current rebate system but also do not experience unintended negative consequences, such as narrower formularies; increased deductibles, coinsurance rates, and copayments; more stringent utilization management; or other limitations on access.

To be successful, any changes to the rebate system must actually result in lower out-of-pocket costs for Medicare beneficiaries. Accordingly, HHS must increase its monitoring and oversight of trends in deductibles, coinsurance, and copayments to ensure that any changes lower beneficiary costs at the point-of-sale and overall. Before finalizing any changes, the agency must also put in place a fallback if the rule were to fail to lower costs or otherwise harm beneficiaries, or cause unforeseen damage to the market.

Regardless of the disposition of this rule, we strongly urge HHS to increase its oversight of Part D and Medicare Advantage plan drug benefit designs, including formulary design and utilization management practices. This should include strong oversight of:

- Plan operations, including timeliness and resolution of appeals;
- Formulary design, including discriminatory benefit design;
- Pharmacy and Therapeutic Committee membership, including consumer representation, and process and procedural requirements;
- Utilization management tools, including but not limited to step therapy, prior authorization, medication substitution, quantity limits, and other efforts; and
- Mid-year price increases, formulary changes, or health changes that create unforeseen conflicts with the beneficiaries' chosen plans.

We also encourage the Administration to take additional action to protect beneficiaries from high cost sharing and ensure that they have access to physician-directed and person-centered courses of treatment. These actions include supporting efforts to cap beneficiary out-of-pocket costs in Part D, and in Medicare more broadly; and increasing CMS and other HHS agency oversight of Part D plans, including formularies, utilization management practices, plan operations, and overall out-of-pocket

spending. Further, we continue to urge the administration to ensure that beneficiaries have the information and tools they need to make informed choices about their coverage options.

Thank you again for this opportunity to comment. We look forward to working together to bring down out-of-pocket costs for Medicare Part D beneficiaries while preserving access to needed prescription medications and protecting the financial stability of the Medicare program. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Baker". The signature is fluid and cursive, with the first name "Joe" being more prominent than the last name "Baker".

Joe Baker
President
Medicare Rights Center