



April 8, 2019

The Honorable Alex Azar, Secretary  
Department of Health and Human Services  
Attention: OIG-0936-P, Room 5527  
Cohen Building,  
330 Independence Ave SW  
Washington, D.C. 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.**

**Submitted electronically via Regulations.gov**

Dear Secretary Azar:

Families USA, a leading national voice for health care consumers, is dedicated to the achievement of high-quality, affordable health care and improved health for all. We seek to make concrete and tangible improvements to the health and health care of the nation – improvements that make a real difference in people's lives. In all of our work, we strive to elevate the interests of children and families in public policy to ensure that their health and well-being is foremost on the minds of policymakers.

We appreciate the opportunity to comment on the proposed safe harbor rule changes.

We ask that these comments, and all supporting citations referenced herein, be incorporated into the administrative record in their entirety.

Under the proposed rule, discounts awarded by prescription drug manufacturers to plan sponsors under Medicare Part D and Medicaid managed care organizations or their contracted Pharmacy benefits managers (PBMs) would no longer be eligible for safe harbor under the Federal anti-kickback provisions of the Social Security Act. The proposed rule would also create a new safe harbor to protect discounts awarded by manufacturers to those same entities at the point-of-sale (referred to as chargebacks), as well as PBM service fees.

We support the goals of this proposed rule: to rein in abusive tactics by pharmacy benefit managers that can inflate the price of drugs and to ensure that beneficiaries see lower out of pocket costs by passing rebates to the point-of-sale. However, we have concerns about the extent to which any savings for beneficiaries are contingent upon the behavior of manufacturers. Because CMS is statutorily prevented from "interfering" in price negotiations in Part D, actuaries are not in agreement regarding the effects the rule will have on the overall system and beneficiary costs.

We also oppose the inclusion of Medicaid managed care organizations in the safe harbor change, as this will increase costs to Medicaid without decreasing enrollees' out of pocket costs. Therefore, we strongly

urge the Department to maintain the current safe harbor for rebates for Medicaid managed care organizations.

Although this rulemaking is a step in the right direction, the Department should work with Congress on long-term statutory changes that lower prescription drug prices directly.

**CMS should maintain the current safe harbor protections for Medicaid Managed Care Organizations.**

The proposed rebate rule would eliminate an existing safe harbor in federal anti-kickback laws, rendering rebates negotiated by Pharmacy Benefit Managers (PBMs) on behalf of Medicare Part D or Medicaid managed care organizations unlawful, unless the rebate becomes a “point-of-sale” discount.

While the rule does not affect federally-mandated rebates like the Medicaid Drug Rebate Program or supplemental rebates negotiated directly by states, it would lead to higher costs for states and put Medicaid programs at risk by affecting supplemental rebates negotiated by Medicaid managed care organizations (MCOs).<sup>i</sup> The proposed rule protects supplemental rebates arranged by states directly, stating that the Department is “also aware that many states have negotiated supplemental rebate agreements with drug manufacturers, which the Department does not presently believe should be affected by this proposal.”<sup>ii</sup>

For a majority of states, removing the existing safe harbor for Medicaid MCOs would increase costs for Medicaid programs. Most states rely on MCOs to negotiate voluntary supplemental rebates. Removing the existing safe harbor for MCOs would drive up costs that would be passed along to states, leading to potential cuts in state Medicaid programs. According to the CMS Office of the Actuary, removing this safe harbor would increase Medicaid spending by nearly \$2 billion over 10 years, with an estimated \$200 million more spent by states.<sup>iii</sup> Additionally, if manufacturers do not lower list prices, Medicaid costs could grow even more.

The proposed rule is designed so that the point of sale rebates allowed under the new safe harbor would fully flow through to consumers at the pharmacy counter and reduce out-of-pocket costs for beneficiaries. As Medicaid beneficiaries already have low out-of-pocket costs for prescription drugs, the consumer savings would not apply here to offset increases in spending.

We strongly urge the department to maintain the current safe harbor for supplemental rebates negotiated by Medicaid MCOs in order to avoid increasing Medicaid costs.

**Rebates negotiated by PBMs contribute to higher list prices.**

PBMs act as a middleman between prescription drug purchasers and prescription drug manufacturers. They also serve a role in benefit design and administering pharmacy networks. In theory, PBMs negotiate lower prices paid to manufacturers by leveraging formulary placement, coverage within the plans of their clients, and other market forces. These deals made by PBMs are often based on giving preferential formulary placement to pharmaceutical manufacturers who offer the largest rebates to the PBM itself or agree to terms that result in larger rebates for PBMs. These deals are currently legal under safe harbor rules as interpreted today, contributing to overall brand name utilization in Medicare Part D and Medicaid plans.

PBMs push list prices higher by negotiating larger rebates from new prescription medications in a given clinical class. When a new medicine enters the market, it competes with whichever medicines have been

approved first for its clinical class. With competition, one might expect the price of a second product to be lower than that of the market leader. However, the second product has to compete for the largest rebate to be covered in plans. This, in turn, can cause list prices to increase for medicines launching in a given class. The current system has created competition among manufacturers for the size of the rebate they grant, rather than the list price of the medicine brought to market.<sup>iv</sup>

The proposed rule, as written, would allow point-of-sale discounts on medicines, helping to rein in out of pocket costs for consumers who take expensive medicines and pay list price, particularly those enrolled in Medicare Part D plans with significant cost sharing. The new safe harbor would incentivize more transparency at the point-of-sale, giving further insight into negotiated chargebacks.

As the actuarial estimates prepared by the CMS Office of the Actuary (OACT) and on behalf of the Assistant Secretary for Planning and Evaluation of Health and Human Services (ASPE) show, this may simultaneously raise premiums.<sup>v</sup> Although some beneficiaries may not see the immediate effects of lower priced medicines, 40 percent of the Medicare enrolled population take five or more different prescription drugs in a 30-day period and the average costs for those taking four to five medicines reached \$30,000 in 2017.<sup>vi</sup> OACT and ASPE both predict lower out of pocket costs for beneficiaries following the rule change, balanced with increased member premiums in all cases. The magnitude of these expenses for beneficiaries is dependent on the behavior of payers and manufacturers in the system under the new rules. In 2020 alone, OACT estimates \$2.5 billion less in household spending on drugs for beneficiaries. Although average beneficiary costs would decrease, the majority of beneficiaries would see an increase in total premium costs.<sup>vii</sup>

PBMs negotiate rebates by leveraging formulary position and preferences for brands that provide larger rebates. In one scenario highlighted by ASPE's commissioned report, changes in formularies under the new rule would result in lower costs for beneficiaries by removing the incentive to give higher-priced medicines preferred placement in the formulary design.<sup>viii</sup> If this indeed happens in practice, beneficiaries could see savings by being guided towards lower cost medicines in some cases.

In assessing the net effects of formulary design and the balance between out of pocket and premium costs, we support the rule change. But in the absence of statutory authority for CMS to ensure that rebates are translated into POS discounts or list price reductions, the effects of the rule change are hard to predict and could be negative for many consumers. We therefore urge the Department to closely, frequently, and publicly monitor the impacts of this rule change including: the impact on beneficiaries' cost-sharing and premium costs, the utilization of brand versus generic medicines, and how manufacturers, PBMs, and Part D plans may be responding to this change with additional tactics that could drive up beneficiary or overall system costs.

**Monitoring is Needed: There is no guarantee that list prices will decrease with this rule or that manufacturers will convert rebates to point-of-sale chargebacks.**

The Department has proposed a new safe harbor (Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products) that would protect point-of-sale price reductions offered by manufacturers on prescriptions paid under Medicare Part D or by Medicaid MCOs. In its rulemaking, the department has sought comments on whether this safe harbor would incentivize manufacturers to provide chargeback discounts. Indeed, if manufacturers maintain practices in terms of the total amount of rebates granted,

but shift them from post-sale to point-of-sale, savings for beneficiaries would be notable. However, there remains a great deal of uncertainty regarding whether manufacturers will do so.

OACT assumes that a vast majority of the rebates currently negotiated from manufacturers would remain intact. Specifically, OACT assumes that 85 percent of current discounts would remain, with 75 percent of those applied as chargebacks and 25 percent reflected in lower list prices.<sup>ix</sup> Further, OACT assumes that pharmaceutical manufacturers will retain 15 percent of their current discounts because many current rebates are “contingent on measures such as market share, that would not be possible in the chargeback system,” and that manufacturers have increased rebates to “compete for certain drugs that vary across payers.”<sup>x</sup> OACT also finds that this proposal would allow manufacturers to cover revenues lost by the recent change in the Medicare Coverage Gap Discount Program as included in the Bipartisan Budget Act of 2018.<sup>xi</sup>

If OACT’s assumptions are correct, it makes sense to assume that some of the rebates would be retained by manufacturers.<sup>xii</sup> However, because of the non-interference clause of the Medicare statute, the rule has no requirement or safeguards to guarantee manufacturers pass on a majority of the current rebate amounts under the new safe harbor. The ASPE impact assessment mapped out a scenario wherein manufacturers retain 20 percent of current rebates and all other behaviors in the market remain the same. In the ASPE scenario, increased beneficiary premium costs outpace out of pocket savings, while the federal government also sees increased costs.<sup>xiii</sup> And ASPE is not even a worst case scenario. Indeed, if pharmaceutical manufacturers retain more than OACT or ASPE predict, costs will increase proportionally throughout the system.

Another key assumption in OACT’s calculation is that within the 85 percent of the remaining discount (after industry retains 15 percent), some 25 percent is due to lower list prices. List prices, however, are not guaranteed to lower with the rule as written.<sup>xiv</sup> Any list price reductions could have spillover effects by lowering the list price of medicines outside of Medicare, since the Wholesale Acquisition Cost is “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States” and thus not limited to Medicare Part D or Medicaid.<sup>xv</sup> Given that the size and scale of the market outside of Medicare Part D and Medicaid is still quite large, there will still be incentives to keep higher list prices for other payers.<sup>xvi</sup>

As the rule is written (and in the absence of statutory change), pharmaceutical manufacturer market power and incentives in a new environment will have tremendous impacts on the overall effects of the rule. The rule has potential to bring vast savings for beneficiaries, but without a statutory mechanism that the new safe harbor will be used to convert PBM rebates into savings of nearly the same magnitude for beneficiaries, there is concern about how much of those potential savings will become reality.

If the Department moves forward with this rulemaking, it should implement comprehensive and frequent monitoring programs. The Department should conduct an annual review and publish a report on the effects on list prices, the extent to which rebates converted to chargebacks, and overall costs to the beneficiaries in the form of both out of pocket and premium costs.

More fundamentally, both the failure of PBMs to control price and the risks associated with this rule change stem from the same statutory limit on federal price negotiation. Working with Congress, the Department should look for statutory changes in the future which will seek to address the list price with

a more direct mechanism allowing government negotiation on list prices in Medicare Part D or a similar national mechanism for regulating manufacturer pricing.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Justin Mendoza at [jmendoza@familiesusa.org](mailto:jmendoza@familiesusa.org) or 202-628-3030, or Eliot Fishman at [efishman@familiesusa.org](mailto:efishman@familiesusa.org).

Respectfully submitted,

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<sup>i</sup> J. Klaisner, et. al, op. cit

<sup>ii</sup> 42 CFR 1001, RIN 0936-AA08

<sup>iii</sup> P. Spitalnic and B. Pelzer. Op. cit.

<sup>iv</sup> Adam Fein, *Don't Blame Drug Prices on 'Big Pharma'*, Wall Street Journal, February 3, 2019.

<sup>v</sup> J. Klaisner, K. Holcomb, and T. Filipek. (January 31 2019). Impact of Potential Changes to the Treatment of Manufacturer Rebates. Prepared for the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Retrieved April 1, 2019, from:

<https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf>; P. Spitalnic and B. Pelzer. (August 30, 2018). Proposed Safe Harbor Regulation. Center for Medicare and Medicaid Services: Office of the Actuary. Retrieved April 1, 2019, from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/RxSafeHarbor.html>

<sup>vi</sup> National Center for Health Statistics. (n.d.). *Health, United States, 2017–Data Finder, "Prescription drug use in the past 30 days, by sex, race, and Hispanic origin, and age: United States, selected years 1988–1994 through 2011–2014*. Retrieved March 25, 2019, from <https://www.cdc.gov/nchs/data/hus/2017/079.pdf>; S. Schondelmeyer and L. Purvis. (September 2018). Trends in Retail Prices of Brand Names Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update. Retrieved February 22, 2019, from

<https://www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf>.

<sup>vii</sup> P. Spitalnic and B. Pelzer. Op. cit.

<sup>viii</sup> J. Klaisner, et. al, op. cit.

<sup>ix</sup> P. Spitalnic and B. Pelzer. Op. cit.

<sup>x</sup> *Ibid.*

<sup>xi</sup> *Ibid.*

<sup>xii</sup> *Ibid.*

<sup>xiii</sup> J. Klaisner, et. al, op. cit.

<sup>xiv</sup> 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, 84 FR 2340 (proposed February 6, 2019) (to be codified at 42 CFR 1001).

<sup>xv</sup> 42 USC § 1395w-3a(c)(6)(B)

<sup>xvi</sup> Health Insurance Coverage of the Total Population. (January 02, 2019). The Henry J. Kaiser Family Foundation. Retrieved April 3, 2019: <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22collId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D>