

April 8, 2019

Department of Health and Human Services
Office of Inspector General
Attention: OIG-0936-P, Room 5527
Cohen Building
330 Independence Ave SW
Washington, D.C. 20201

Comments of Consumer Action, Consumer Federation of America, Consumer Reports, NETWORK Lobby for Catholic Social Justice, and U.S. PIRG

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 Services Fees, (RIN 0936-AA08, OIG-0936-P)

To whom it may concern:

The undersigned stakeholders, representing consumer groups, who are concerned about the high cost of prescription medications, submit these comments in the above-referenced proceeding.¹ We support the Department of Health and Human Services Office of Inspector General’s (“HHS”) proposed new rules to eliminate the safe harbor for rebates in Medicare Part D plans and to create new safe harbor protections for discounts to patients at the point of sale and certain flat fees that pharmaceutical manufacturers pay to pharmacy benefit managers (“PBMs”) for services.

I. Summary

¹ 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 Services Fees. Department of Health and Human Services, published on February 6th, 2019. Available at <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>. This proposal would update the discount safe harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to PBMs, Part D, and Medicaid managed care plans from the safe harbor’s definition of a “discount.”

In our July 2018 comments on the President’s Blueprint to lower drug costs, we recommended the elimination of rebates.² The Administration’s proposal to eliminate rebates is critical to lowering the cost of prescription drugs for seniors. The contracting and negotiating practices of PBMs have resulted in the escalation of list prices and out-of-pocket costs for consumers.³ Because the PBM market is not competitive, regulated or transparent, the three largest PBMs are able to wield their market power and extract massive rebates from pharmaceutical manufacturers, which are not shared with payors or patients to the extent that they should be. Indeed, rebates have more than doubled in the last five years and in 2018, pharmaceutical manufacturers paid \$166 billion in rebates and price concessions to PBMs, insurers, and the supply chain.⁴

As rebates have increased, so have the list prices of drugs.⁵ Perversely, rebates create an incentive for PBMs and payors to seek higher list prices and sales of higher-priced brand drugs over lower-cost brand and generic alternatives, which often results in higher out-of-pocket expenses for millions of Medicare beneficiaries.⁶ Inexplicably, the current rebate system results in sicker patients in effect subsidizing healthier patients’ insurance premiums.⁷ Food and Drug Administration Commissioner Scott Gottlieb has candidly stated, “sick people aren’t supposed to be subsidizing the healthy.”⁸

Accordingly, we support HHS’ proposed rule changes to eliminate rebates, thereby encouraging prices that more closely reflect actual costs, with competitive incentives to offer any discounts directly to patients at the pharmacy counter. This should eliminate a significant conflict of interest, and would be expected to result in lower costs to payors and patients overall.

I. Lack of Competition in the PBM Market Increases Drug Prices and Costs for Consumers

² Comments of Consumers Union, U.S. PIRG, Consumer Action and Coalition to Protect Patient Choice to Department of Health and Human Services on HHS Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs RIN: 0991-ZA49. Available at <https://uspirg.org/sites/pirg/files/resources/Consumer%20group%20comments%20on%20HHS%20Blueprint%20--%207-16-18%20--%20FINAL.pdf>.

³ Adam Fein, *Don’t Blame Drug Prices on ‘Big Pharma’*, Wall Street Journal, February 3, 2019.

⁴ *Id.*; Adam J. Fein, *The Gross Net Bubble Topped \$150 billion in 2017*, Drug Channels, April 24, 2018.

⁵ Fein, *supra* note 3. Johnson & Johnson, Merck, and Novartis disclosed that their drug prices declined in 2018.

⁶ *Id.*

⁷ Peter Sullivan, *Gottlieb: Drug rebates not benefiting sicker patients*, The Hill, March 6, 2019.

⁸ Meg Tirrell, *FDA Commissioner to Health Insurers: You’re Doing it Wrong*, CNBC, March 7, 2018.

Although PBMs offer the potential to control prescription drug prices, consumers are paying higher prices for drugs than they should be because PBMs are not adequately fulfilling their function in controlling costs. The PBM market is broken. It lacks the essential elements for a competitive market, namely: (1) choice, (2) transparency and (3) a lack of conflicts of interest.⁹

A tight oligopoly. According to the White House Council of Economic Advisers (“CEA”), three PBM firms - OptumRx, Express Scripts, and CVS Caremark - control more than 85% of the PBM market, “which allows them to exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves.”¹⁰ Indeed, the three largest PBMs have a higher gross margin than any other players involved in the drug supply chain (distributors, insurers, or pharmacies).¹¹ PBM profits exceed \$11 billion annually.¹² Rebates create a perverse disincentive to reducing drug prices because PBM profits increase as drug list prices increase, in large part because PBMs use their market power to secure higher rebates based off a percentage of the list prices.¹³

Further evidence of PBMs’ market power was their ability in the past to implement “gag” clauses in pharmacy contracts that prohibited pharmacists from informing consumers of lower-priced alternatives. These gag clauses served no procompetitive purpose. In fact, their only purpose was to conceal the costs of prescription drugs from consumers at the pharmacy, causing consumers to pay more, with the only clear benefit going to the PBM’s bottom line. Fortunately, Congress stepped in and outlawed the practice in the fall of 2018.¹⁴ Nonetheless, the fact that PBMs had been able to force pharmacies not to disclose this information demonstrates their market power and is a clear market failure.

Lack of Transparency. Moreover, the PBM market lacks transparency. As CEA observed, “[t]he size of manufacturer rebates and the percentage of the rebate

⁹ “*Protecting Consumers and Promoting Health Insurance Competition*,” Testimony of David Balto, Before House Judiciary Committee, Subcommittee on Courts and Competition Policy, October 8, 2009 at <http://www.dcantitrustlaw.com/assets/content/documents/CAP/protecting%20consumers.pdf>.

¹⁰ Reforming Biopharmaceutical Pricing at Home and Abroad, The Council of Economic Advisors, White Paper, February 2018. (hereinafter referred to as CEA White Paper).

¹¹ Charley Grant, *Hidden Profits in the Prescription Drug Supply Chain*, Charlie Grant, February 24, 2018, Wall Street Journal.

¹² Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*, Altarum, April 2018.

¹³ Peter J. Pills, *PBMs Are Hogging Our Discounts*, Fortune, August 28, 2018; Charles Roehrig, *Rebates, Coupons, PBMs, And the Cost of the Prescription Drug Benefit*, Health Affairs, April 26, 2018.

¹⁴ On October 10, 2018, President Donald Trump signed into law the “Know the Lowest Price Act of 2018” and the “Patients’ Right to Know Drug Prices Act of 2018”.

passed on to health plans and patients are secret.”¹⁵ PBMs fight transparency at every turn, opposing federal and state legislation that would require disclosure of PBM rebates and fees.¹⁶ While PBMs claim they are lowering drug prices, they provide limited rebate data to their own payors, even large ones, which naturally tends to lead to excessive retention of rebates by PBMs. Moreover, in addition to the base rebate, many PBM contracts with manufacturers also require that, if a drug’s list price increases by more than a certain percentage, the manufacturer must provide a “price protection” rebate, reimbursing the PBM for increases above the amount stated in the contract.¹⁷ In certain drug categories, the price protection rebate can exceed the value of the base rebate.¹⁸

As an indication of the magnitudes involved, for example, in 2016, Anthem, the nation’s second largest health insurer, sued Express Scripts for \$15 billion in damages, alleging that the PBM violated its contract by not passing along \$3 billion a year in additional rebate pass-through amounts.¹⁹

Conflicts of interest. Given the lack of choice and transparency, preventing conflicts of interests is crucial to keeping prescription drug prices low. Here, conflicts of interest abound, and the most significant involve how rebates are shared by PBMs and payors. PBMs were formed to lower drug costs, but when PBMs share in rebates, it creates an incentive for them to want higher not lower drug list prices. The CEA found that “the system encourages manufacturers to set artificially high list prices, which are reduced via manufacturers’ rebates but leave uninsured individuals facing high drug prices.”²⁰

Further, the three major PBMs each have additional conflicts of interest, because they are vertically integrated with health insurers, mail-order operations, and specialty pharmacies. Health plans and employers contract with PBMs, the middlemen, to secure prescription drugs from pharmaceutical manufacturers and services from pharmacies. When health plans and employers make contracts with PBMs, they want the services of “honest brokers” who will secure the lowest prices and best services from both drug manufacturers and payors. But, when

¹⁵ CEA White Paper.

¹⁶ California SB 17 enacted in 2018, requires disclosure.

¹⁷ Midwestern Business Group on Health. Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies. September 2017.

¹⁸ *Id.*

¹⁹ Bob Herman, *Anthem Sues Express Scripts for \$15 Billion Over Drug Pricing*, Modern Healthcare (March 21, 2016 01:00 AM), <https://www.modernhealthcare.com/article/20160321/NEWS/160329992/anthem-sues-express-scripts-for-15-billion-over-drug-pricing>. The case was filed in the Southern District of New York and is ongoing.

²⁰ CEA White Paper.

PBMs are commonly owned with some of the entities they are supposed to bargain with in equivalent fashion, there is an inherent conflict of interest, which can lead to deception, anticompetitive conduct, and higher prices.

In sum, the lack of choice and transparency, coupled with numerous conflicts of interest, are leading to rapidly escalating list prices for prescription drugs and higher out-of-pocket costs for consumers. For good reason, the role of PBMs and their rebate practices have been under scrutiny by the Administration²¹ because PBMs wield so much power and perversely benefit from rising list prices.²² For these reasons we strongly support the Administration's proposal.

II. Responses To HHS' Inquiries

HHS asks whether the proposed rule will better align incentives. We strongly agree. The perverse incentives of rebates lead to higher costs for chronically ill Medicare beneficiaries. Moreover, it encourages the usage of more expensive brand drugs, discourages the use of lower cost generics and biosimilars, and increases the out-of-pocket costs of consumers, including seniors, living on fixed incomes. Unfortunately, a lack of meaningful regulatory oversight means there is little incentive for PBMs to behave in a competitive manner. We agree with HHS's view that the implementation of the proposed rules will result in "an improved alignment of incentives ... that may curb list price increases, reduce financial burdens on beneficiaries, lower ... Federal expenditures, improve transparency, and reduce the likelihood that rebates" would encourage more Medicare Part D and Medicaid MCO spending.²³

A. How would implementation of the proposed rules affect beneficiary out-of-pocket costs?

Under the current rebate system, the PBMs' and payors' incentives are not aligned with those of patients.²⁴ While patients taking prescription drugs for chronic illnesses generate the majority of manufacturer rebate payments, they

²¹ Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Request for Information, U.S. Department of Health & Human Services ("HHS"), May 14, 2018. "American patients," HHS points out, "have the right to know what their prescription drugs will really cost before they get to the pharmacy."

²² Secretary Alex Azar Interview on CNBC's Squawk Box, May 11, 2018 at <https://www.cnbc.com/2018/05/11/azar-says-everybody-is-wetting-their-beak-on-high-drug-list-prices.html>. In some instances, PBMs and payors' incentives are aligned especially when it comes to obtaining rebates, but in other fundamental respects, they are at odds with each other.

²³ Notice, *supra* note 1.

²⁴ Sullivan, *supra* note 7.

currently receive little or no financial benefits from the rebates.²⁵ In fact, these rebate payments are used to offset total plan costs for the Medicare Part D plan, not to offset the out-of-pocket costs incurred by the patients whose prescriptions are generating those rebates.²⁶ Patients with prescription drug deductibles and coinsurance face higher out-of-pocket costs because their coinsurance amounts and payments within the deductible phase are based on a drug's list price not the net price paid by the payor.²⁷ According to HHS, the average difference between a drug's list price, and its net price after a rebate is 26 to 30%.²⁸ Thus, patients are paying a greater share of the true cost to the payor than the listed coinsurance percentage.

Eliminating rebates and encouraging discounts at the point of sale will benefit patients by lowering their out-of-pocket costs and realizing substantial savings at the pharmacy. Drug manufacturers will now be under more direct scrutiny so they will be incentivized to lower list prices to reflect the actual transaction price of drugs, with perhaps additional discounts provided openly, at the point of sale. As Secretary Azar has stated, "there is no reason why those rebates should not convert equally from rebates to discounts for the patients."²⁹ Patients' out-of-pocket costs would also subsequently decrease because their coinsurance and deductibles would now be based on a lower list price.

B. How would implementation of the proposed rules affect pharmaceutical manufacturers' setting of list prices for newly launched drugs?

The current rebate system harms consumers as reflected by the fact that list prices have risen more rapidly than actual prices paid for prescription drugs.³⁰ This occurs as manufacturers are encouraged to increase list prices and pay higher rebates to PBMs in order to obtain and maintain preferred positions on their drug formularies. Today, manufacturers of newly launched drugs have to match the list price and rebate of the market-leading product to be considered by the PBM. Manufacturers' incentives to increase list prices for newly launched drugs will disappear once rebates are eliminated. A manufacturer of a newly launched drug would no longer need to increase the list price or match the market leader's rebate.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ HHS Fact Sheet, available at <https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf>.

²⁹ Shannon Firth, *HHS Proposes Scrapping Rebates to PBMs, Giving Discounts to Patients*, MedPage Today, February 1, 2019.

³⁰ Fein, *supra* note 3.

They would instead launch with lower list prices than the market leader. Accordingly, we would expect that list prices would be significantly lower than they are today.

C. How would implementation of the proposed rules affect the federal government?

Payors, pharmaceutical manufacturers and the federal government share responsibility in covering portions of Medicare Part D spending. As a patient's out-of-pocket spending and total drug spending reach certain stages, the cost sharing changes, and once spending passes a certain threshold, the federal government is directly subsidizing the Medicare Part D plans' drug costs. Specifically, once a patient reaches the catastrophic zone, the federal government becomes responsible for 80% of a Medicare Part D plan's prescription drug costs, which means that the payor's liability is low.³¹ In the coverage gap, the plan is only paying 5% of the cost, with brand manufacturers paying 70% of costs. Because the plan liability is low in these benefit phases, Medicare Part D plans have an incentive to favor higher priced brand drugs because the rebates that they can obtain exceed its liability.³² Instead of PBMs being incentivized to choose the most expensive drug possible for any given treatment, eliminating rebates will encourage PBMs and payors to use lower-cost brand and generic alternatives, which would save the federal government billions of dollars.

D. How would implementation of the proposed rules affect the commercial market?

We expect that the implementation of the proposed rules will have some impact. And indeed, they may have already had some impact on the commercial market. PBMs such as Express Scripts and OptumRx have recently announced plans to offer point-of-sale rebate sharing to their commercial clients, signifying that the infrastructure and the capacity to implement this policy already exist.³³

³¹ Gabriela Dieguez, Maggie Alston, Samantha Tomicki, *A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices*, Millman, May 21, 2018.

³² Dusetzina, Stacie B. et al. (2017). Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending. *JAMA Internal Medicine* 177.8: 1185–1188.

³³ Adam Fein, *PBM Pricing Overhaul: Express Scripts Prepares for a World Without Rebates-But Employers May Not Change*, Drug Channels, October 25, 2018; Ed Silverman, *UnitedHealth will require drug rebates to be paid to consumers*, Stat/Pharmalot, March 19, 2019.

E. Does the current rebate system incentivize PBMs and payors to give higher-cost drugs preferred formulary placement?

PBMs contribute to higher drug costs through their practice of requiring pharmaceutical manufacturers to pay rebates. PBMs control the drug formularies, which determine what drugs patients are allowed to purchase. PBMs tend to recommend preferred status on the formulary for therapeutically comparable brand-name drugs that offer the highest rebates; this encourages drug manufacturers to focus on offering higher rebates to secure that preferred status. And it gives PBMs incentives to put higher-cost drugs on their formularies, because the rebates are based on a percentage of a drug's list price.

In essence, PBMs are making decisions on inclusion of a drug not based on clinical research, or evidence-based efficacy and safety, but based on which manufacturer offers a higher rebate payment. In pursuit of higher rebates, PBMs routinely change drug formularies, or require prior authorization for drugs that may be best for a patient's condition, even in cases where a more affordable medication is available. These financial incentives interfere with doctor-patient relationships, and harm patients' health when they can't get the drugs they need.

Because the current system favors brand medicines with higher list prices and larger rebates over the use of safe, effective lower-priced generics and biosimilars, taxpayers and consumers are paying more for prescription drugs than they should. In 2017, generics saved consumers \$265 billion overall, \$82 billion in the Medicare Part D program and \$40 billion in Medicaid.³⁴ Those savings could have been higher, but PBMs use rebates to effectively exclude new innovative drugs that may be less expensive and more effective.³⁵ As Professor Robin Feldman puts it, "the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs."³⁶

PBMs secure rebates from drug manufacturers in exchange for exclusivity arrangements and bundle rebates based on volume and/or indications that keep lower-priced generics and biosimilars from competing.³⁷ This contracting practice is known as a "rebate wall." It limits patient choice, slows the adoption of superior

³⁴ Association for Accessible Medicines 2018 Annual Report.

³⁵ Mariana Social and Gerard Anderson, *Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available*, JAMA, March 18, 2018.

³⁶ Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed?*, Washington Post, November 26, 2018.

³⁷ *Id.*

new drugs, and reduces competition.³⁸ Today, a manufacturer with an established product with significant market share has the incentive to make its rebates contingent on preferred or exclusive formulary position for multiple indications.³⁹ The adverse competitive effect is that a new drug cannot get on the formulary. Through rebate walls, PBMs can prevent entry of a newly approved product with superior efficacy in only one indication, even if the new product offers a greater rebate.⁴⁰ That's because the new product has few prescriptions, so even a larger rebate will not overcome the potential loss of the rebate dollars from the market-leading product.⁴¹ According to Professor Feldman, "the name of the game is volume. The more volume a drug company has with a particular PBM or hospital, the better deal it can offer as a temptation to exclude rival drugs."⁴² Moreover, rebate walls and bundled rebates distort the workings of the free market, result in higher drug prices, and reduce patients' access to lower-cost generic and biosimilar alternatives.

F. How would implementation of the proposed rules change the current PBM and payor practice of favoring higher cost drugs over lower cost alternatives?

Eliminating the safe harbor for rebates and encouraging discounts to be reflected at the point of sale will help address perverse incentives and make sure PBMs and payors are focused on the net cost of medicine. Indeed, prohibiting PBMs from being compensated based off the list price and ensuring that the savings from PBM negotiations are passed through to consumers, will change the drug manufacturers', PBMs', and payors' incentives. PBM compensation should be flat, transparent, and connected to the value-added services they provide. Removing some of the perverse incentives that resulted in so much consumer harm should result in lower costs and the elimination of a significant conflict of interest. The rebate wall strategy would disappear, and we expect that PBMs would make formulary decisions based on a drug's superior efficacy and lower price. Drug manufacturers would compete on price. This should result in true competition where competing drug manufacturers would constrain each other's prices. The leading incumbent drug manufacturer would be forced to respond to newly launched drugs that are offering lower prices.

³⁸ *Id.*

³⁹ David Balto, *Rebate Walls Should Be Dismantled by FTC's Antitrust Arm*, STAT News, December 4, 2018.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Feldman, *supra* note 36.

G. Are there possible negative or positive effects on pricing competition that could result from an increase in transparency under the point of sale discount safe harbor?

We fully expect that the proposed rule to create safe harbor protection for discounts to be passed directly to patients in a transparent manner will have a positive effect on pricing competition. Pharmaceutical manufacturers are free to lower the list prices of drugs to where they should be sans the rebate, or to provide the discounts negotiated by PBMs directly to patients at the point of sale. Pricing transparency is a prerequisite for a competitive market, especially in the drug supply chain. Greater transparency is important, because markets typically function better when consumers have the information they need to make choices among available options. For far too long, the rebate system has not been transparent, and consumers have suffered through an unhealthy and uncompetitive market. Moreover, some PBMs and payors have already instituted some initiatives in commercial markets to pass discounts directly to patients so there is no valid concern that an increase in transparency with regards to point-of-sale discounts would have a negative effect on their ability to negotiate with manufacturers over pricing.⁴³

IV. Conclusion

Consumers are currently paying higher prices resulting from the misuse of rebates in the prescription drug supply chain that incentivizes higher list prices and more expensive drugs over less expensive alternatives. Patients and providers must be empowered so as to no longer be at the mercy of PBMs, whose dominance in the supply chain has skewed incentives and hurt consumers. The crucial role of the consumer is paramount to a competitive pharmaceutical market that can truly thrive. Nothing less than the health of our nation, quite literally, is at stake.

We urge the Administration to implement these proposed rules. Their implementation should reduce prescription drug prices, lower patients' out-of-pocket costs, and remove a significant conflict of interest. The prohibition of rebates changes PBM incentives, which should result in the increased usage of biosimilar and generic medicines, which will result in more savings for the Medicare Part D program and even lower out-of-pocket costs to patients.

⁴³ Fein and Silverman, *supra* note 33.

For more information, contact David Balto, The Law Offices of David Balto, at 8030 Ellingson Dr., Chevy Chase, MD 20815, at 202-577-5424 or David.balto@dcantitrustlaw.com.

Respectfully submitted,

Consumer Action
Consumer Federation of America
Consumer Reports
NETWORK Lobby for Catholic Social Justice
U.S. PIRG