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Lowering Prescription Drug Costs: A Small Regulatory Change with a Large, Lasting Impact

Nicole Mouzakiotis

LOWERING PRESCRIPTION DRUG COSTS: A SMALL, REGULATORY CHANGE WITH A LARGE, LASTING IMPACT

I. INTRODUCTION

"*We have access to the greatest medicines in the world, but access is meaningless without affordability*."[1]

This quote from former Department of Health and Human Services (HHS) Secretary Alex Azar describes the current healthcare system in the United States, with specific reference to the challenges this country faces regarding the cost of prescription drugs.[2] In response to this issue, former President Trump created a plan in 2018 aimed to reduce soaring prescription drug prices and save consumers out-of-pocket drug costs.[3] This blueprint began as a proposal (Proposed Rule) by HHS proposed on February 6, 2019, titled 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in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees[4] but was publicly withdrawn only months later in July 2019 (although, HHS never officially withdrew the Proposed Rule from the Federal Register).[5] A year later, though, nearing the conclusion of former President Trump's term in November 2020, the Proposed Rule was finalized (Final Rule).[6]

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1. HHS, AMERICAN PATIENTS FIRST 5 (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf [hereinafter AMERICAN PATIENTS FIRST]; Jacqueline LaPointe, *HHS Secretary Alex Azar Resigns, Effective Jan. 20*, REVCYCLE INTELLIGENCE (Jan. 19, 2021), https://revcycleintelligence.com/news/hhs-secretary-alex-azar-resigns-effective-jan.-20 ("Alex Azar has resigned as head of HHS to make room for President-elect Joe Biden's pick for HHS Secretary following his inauguration on Jan. 20, 2021.").

2. LaPointe, *supra* note 1.

3. *Id.*

4. *See generally* 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, 85 Fed. Reg. 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

5. HHS, FACT SHEET: TRUMP ADMINISTRATION FINALIZES PROPOSAL TO LOWER DRUG COSTS BY TARGETING BACKDOOR REBATES AND ENCOURAGING DIRECT DISCOUNTS TO PATIENTS 5 (2020), https://www.hhs.gov/about/news/2020/11/20/fact-sheet-trump-administration-finalizes-proposal-to-lower-drug-costs.html [hereinafter FACT SHEET: TRUMP ADMINISTRATION FINALIZES PROPOSAL]; *see infra* King & Spalding, note 89 and accompanying text.

6. *See generally* 85 Fed. Reg. 76,666.

As the title of the Proposed Rule states, and as was kept in the title of the Final Rule, this rule establishes four changes to the regulatory safe harbor protections to the federal Anti-Kickback statute (AKS) of the Social Security Act.[7] The AKS is a criminal law that "prohibits transactions intended to induce or reward referrals for items or services reimbursed by the federal healthcare programs."[8] The purpose of the AKS is to protect federal healthcare program beneficiaries from being influenced by monetary bribes for referral decisions and, in effect, is intended to prevent overutilization, increased costs, and poor quality services.[9] However, there are currently safe harbor regulations in place that permit discounts from manufacturers for prescription drugs provided to plan sponsors under Medicare Part D.[10] Thus, the Final Rule excludes from the definition of safe harbor protection certain reductions in price or other remunerations offered by a prescription drug manufacturer to Medicare Part D plan sponsors or pharmacy benefit managers (PBM).[11]

These offerings are similar to a bribe, discussed in further detail below, and the costs were previously reflected in the amount that Medicare Part D beneficiaries paid for their prescriptions. Thus, eliminating these bribes from safe harbor protection effectively lowers prescription drug prices since those hidden costs can no longer be tagged onto the price that beneficiaries pay. Although amending this regulation may seem like a minor change, its effect can have a large impact on creating more transparency in prescription drug costs for Americans and can effectively lower those costs.

Part II of this Comment reviews the many components involved in understanding this Final Rule and its effect. First, it discusses Medicare in general and then more specifically, Medicare Part D and its intended beneficiaries. Next, Part III provides a summary of the PBM life cycle and rebates under the AKS. Finally, all of this background information leads to the main focus of this Comment: the Proposed Rule, which later turned into the Final Rule, and the effect that it will have on lowering prescription drug prices for Medicare Part D beneficiaries. This Comment concludes by examining the positive effects the Final Rule will have on beneficiaries.

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7. *Id.* at 76,666; *see* Social Security Act, 42 U.S.C. § 1320a-7b (2018).

8. Thomas S. Crane et al., *What Is the Anti-Kickback Statute?*, A.B.A., https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/ (last visited Mar. 27, 2021); *see* 42 U.S.C. § 1320a-7b(b).

9. Crane et al., *supra* note 8.

10. *See* 85 Fed. Reg. at 76,666.

11. *Id.*

II. Background

A. What is Medicare?

Medicare is a federal health insurance plan program.[12] It was enacted in 1965 as "Health Insurance for the Aged" under Title XVIII of the Social Security Act, originally intended as health coverage for those over the age of sixty-five.[13] Seven years later, in 1972, Medicare expanded to additionally cover individuals under the age of sixty-five who have disabilities and those with end-stage renal disease, which is permanent kidney failure.[14] It is evident through these three categories of people who qualify for coverage that Medicare is intended to benefit the elderly, those who suffer from a health issue, or both. Thus, each part of Medicare, Parts A, B, C, and D, provides different types of health insurance to its beneficiaries.

Medicare Part D is a voluntary prescription drug plan for citizens that use Medicare for their health insurance.[15] Although Medicare Part D is offered as a way for beneficiaries to obtain their necessary prescription drugs at a lower cost, Part D beneficiaries endured higher out-of-pocket costs in 2020 and 2021 than they have in previous years.[16] The Proposed Rule, introduced in February of 2019, was designed to combat these soaring prices for beneficiaries as an attempt to provide more transparency by eliminating the hidden, additional cost of rebates that gets added into the cost which consumers pay for their prescription drugs.[17] Initially, the Proposed Rule was withdrawn.[18] This withdrawal was unfortunate for Medicare Part D beneficiaries because the Proposed Rule would have allowed seniors and individuals with disabilities who rely on Medicare Part D to obtain the prescription drugs they need, and it would have increased access to

12. Medicare.gov, *What's Medicare?*, https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare (last visited Apr. 12, 2022).

13. Presentation from Ctrs. for Medicare & Medicaid Servs., Introduction to Medicare 5 (Apr. 4, 2022).

14. *Id.*

15. Kaiser Fam. Found., *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 13, 2021), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit.

16. *Id.*

17. HHS, Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients 2 (2019), https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf [hereinafter Fact Sheet: Trump Administration Proposes to Lower Drug Costs].

18. Yasmeen Abutaleb et al., *Trump Kills Key Drug Price Proposal He Once Embraced*, Wash. Post (July 11, 2019), https://www.washingtonpost.com/business/economy/white-house-kills-key-drug-pricing-rule-to-eliminate-hidden-rebates/2019/07/11/ff595192-a3de-11e9-bd56-eac6bb02d01d_story.html.

more affordable healthcare. Although the Proposed Rule was finalized in 2020, implementation has been delayed until 2023; thus, beneficiaries cannot reap the benefits of the Final Rule for another year and will continue paying inflated drug costs until then.

B. Medicare Part D: Prescription Drug Coverage

Among the sixty-two million Medicare users across the United States, over forty-eight million are enrolled in Medicare Part D plans.[19] Part D was not originally a part of the Medicare plan enacted in 1965. It was not until 2003 that former President George W. Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act, which added a prescription drug plan to Medicare and is now known as Medicare Part D.[20]

The Medicare Part D plan covers many of the prescription drugs commonly taken by people with Medicare, including drugs in certain protected classes, such as drugs to treat cancer or HIV/AIDS.[21] To obtain Medicare Part D prescription drug coverage, beneficiaries have two options.[22] One option is to select a Medicare drug plan, which essentially adds drug coverage to the beneficiary's existing plan, such as Original Medicare.[23] Obtaining a separate Medicare drug plan requires pre-existing Medicare Part A or Medicare Part B coverage.[24] The second option to get Part D coverage is through a Medicare Advantage Plan, which is Part C, or some other Medicare health plan with drug coverage included.[25] Similar to the first option, this requires being enrolled in both Parts A and B.[26]

The price of prescription drugs can be costly, especially for those who qualify for Medicare, since they are of older age or may have disabilities, both of which can lead to an increased risk of additional health problems that require additional prescription drugs.[27] Prior to

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19. KAISER FAM. FOUND., *supra* note 15.

20. Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 283 (2004).

21. MEDICARE.GOV, *How to Get Prescription Drug Coverage*, https://www.medicare.gov/drug-coverage-part-d/how-to-get-prescription-drug-coverage (last visited Apr. 14, 2022).

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. HEALTH POL'Y INST., *Prescription Drugs*, https://hpi.georgetown.edu/rxdrugs (last visited Mar. 27, 2021). Out-of-pocket prescription drug costs are much higher for older beneficiaries:

> Annual average out-of-pocket prescription drug expenditures for all adults are $177, but people age 65 and older pay much more for their medications. People age 65 to 79 pay $456 out-of-pocket. People age 80 and older pay even more . . . . Consumers who

the enactment of Part D, tens of thousands of Medicare beneficiaries had little assistance with drug costs, spending up to thousands of dollars each year out-of-pocket for prescription drugs.[28] Thus, Medicare Part D is insurance that covers these prescription drug costs and alleviates some of the burden on those who need these drugs.[29] Although Medicare Part D is a great resource, the high cost of prescription drugs in the United States still remains a major issue.[30]

C. Pharmacy Benefit Manager Life Cycle

PBMs play an important role in the life cycle of prescription drugs by acting as a middleman between the drug manufacturer and the consumer, who, for purposes of this Comment, is the Medicare Part D beneficiary.[31] PBMs are "companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers."[32] Essentially, PBMs serve as the middleman in the distribution chain of prescription drugs between the drug manufacturers, insurers, pharmacies, and consumers, such as Medicare Part D beneficiaries.

PBMs work for insurance companies, big employers, and government agencies, and a large part of their job is to decrease the cost of drugs for their employers.[33] However, while PBMs aim to lower drug costs for their employers, they simultaneously raise prices for consumers. Under the current PBM business model, "PBMs' profit incentive often conflicts with efforts to minimize drug costs for drug plans and beneficiaries and, instead, can lead to higher drug prices for all pa-

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> have common chronic conditions have substantial prescription drug expenses. Since their total prescription drug expenditures are very high, their total out-of-pocket expenditures are also high. They pay about half of the cost of prescription drugs out-of-pocket.

Id.

28. BOOMER BENEFITS, *What is Part D?*, https://boomerbenefits.com/medicare-part-d-plans/what-is-part-d/ (last visited Apr. 14, 2022); MEDICARE.GOV, *Costs in the Coverage Gap*, https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap (last visited Apr. 14, 2022) (out-of-pocket costs are defined as "[h]ealth or prescription drug costs that you must pay on your own because they aren't covered by Medicare or other insurance").

29. *See* BOOMER BENEFITS, *supra* note 28; MEDICARE.GOV, *supra* note 21.

30. *See* HEALTH POL'Y INST., *supra* note 27.

31. Michael Bihari, *Pharmacy Benefit Managers Help Fill Your Prescriptions*, VERYWELL HEALTH (June 2, 2020), https://www.verywellhealth.com/pharmacy-benefit-manager-1124201.

32. COMMONWEALTH FUND, *Pharmacy Benefit Managers and Their Role in Drug Spending* (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.

33. Ydejesus, *How Drug Prices Work*, WALL ST. J. (May 28, 2019, 6:00 AM), https://www.wsj.com/video/how-drug-prices-work/C9D3F950-DFE3-4E37-9120-836D411A9A66.html.

tients."[34] To put into perspective how large of an impact this adverse business model has on consumers, PBMs currently manage drug benefits for over ninety percent of Americans with prescription drug coverage, meaning nearly all Medicare Part D beneficiaries are impacted by this.[35]

There are three general ways that a PBM gets paid.[36] A PBM can either charge for administering benefits to a defined group of enrollees; collect rebates by negotiating with pharmaceutical manufacturers; or receive the difference between what their clients pay for a drug and what the pharmacy receives, which is known as "the spread."[37] The focus of this Comment is on the second avenue: rebates. Pharmaceutical drug manufacturers pay rebates to PBMs for many of the drugs they sell, and in turn, the PBM sometimes keeps a portion of the rebate or immediately distributes it to their employer, explained further below.[38]

PBMs use formularies, which is a list of both brand name and generic prescription drugs, that are covered by a given health insurance plan.[39] These formularies determine which drugs individuals under that health insurance plan will use, and they also determine the individuals' out-of-pocket costs.[40] Thus, drug manufacturers want to ensure that their drugs are covered by these formularies in order to reach consumers that need them.[41]

D. How Rebates Work

The PBM formularies are where rebates come into play. Formularies have tiers of drugs that determine different levels of payment for the consumer depending on the tier: "drugs in the lowest tier have the smallest patient cost-sharing, while the drugs in the highest tier have

34. Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 YALE L. & POL'Y REV. 360, 361 (2020).

35. *Id.* at 361.

36. Ike Brannon et al., *INSIGHT: Constraining Pharmacy Benefit Managers Will Not Reduce Drug Prices*, BLOOMBERG L. (Jan. 6, 2020, 3:00 AM), https://news.bloomberglaw.com/pharma-and-life-sciences/insight-constraining-pharmacy-benefit-managers-will-not-reduce-drug-prices.

37. *Id.*

38. Ydejesus, *supra* note 33.

39. *Id.*

40. *Id.*; *See* Elizabeth Davis, *Why Isn't This Prescription Drug on My Health Plan's Drug Formulary*?, VERYWELL HEALTH (May 16, 2021), https://www.verywellhealth.com/why-isnt-my-rx-drug-on-my-health-plan-drug-formulary-1738477 ("Many people are shocked to learn their health plan has a list of drugs it will pay for . . . . [I]f your drug isn't on that list, your health insurance won't pay for it.").

41. *What Is a Pharmacy Benefit Manager (PBM) and How Does a PBM Impact the Pharmacy Benefits Ecosystem?*, TRUVERIS (Feb. 17, 2021), https://www.truveris.com/resources/what-is-a-pbm-and-how-does-a-pbm-impact-the-pharmacy-benefits-ecosystem.

the highest patient cost-sharing."[42] In other words, consumers pay more for the lowest tier drugs and pay less for the highest tier drugs because plans cover a greater portion of the drug cost as the tier level increases.[43] Due to the lack of transparency in this current PBM-controlled system, "payers are left out of the equation while expensive, yet highly rebateable, drugs are placed in preferred positions on the PBM formulary."[44]

When a drug manufacturer offers a higher rebate to the PBM, the PBM will move the drug up on the formulary to a higher tier, which manufacturers desire because patients are more likely to choose the drugs in higher tiers that will cost them less.[45] This demonstrates how status on the formulary can greatly increase the sales of a drug, which creates competition among manufacturers to offer the largest rebates to PBMs to ensure their drug gets listed on the formulary.[46]

For example, if a consumer wants a drug that is either in a lower tier or not on the formulary at all, the consumer must pay a higher co-pay for that drug.[47] Thus, a manufacturer that pays a rebate to the PBM in order to be placed higher on the PBM's formulary will likely increase sales of that drug since drugs in higher tiers cost the consumer less money, resulting in the consumers being more likely to purchase those drugs, as opposed to purchasing a lower tier drug which will cost the consumer more out-of-pocket. To compensate for the cost of this rebate paid to the PBM, the drug manufacturer inflates the list price of its drugs.[48] And who bears the burden of this additional cost? The consumer.

There is a positive correlation between rebates and the list price of a drug.[49] "On average, a $1 increase in rebates is associated with a $1.17 increase in list price."[50] Some argue that PBMs are to blame for rising drug prices since the PBMs' increase in demand for rebates in

42. *A Consumer Guide to Drug Formularies: Understanding the Fundamentals of Behavioral Health Medications*, PARITYTRACK, https://www.paritytrack.org/issue-briefs/a-consumer-guide-to-drug-formularies-understanding-the-fundamentals-of-behavioral-health-medications/#part-i:—prescription-drug-formulary-overview (last visited Apr. 14, 2022).

43. *Id.*; Ydejesus, *supra* note 33.

44. Lindsey Roberts, *How Expensive Prescription Drugs Make It to the PBM Formulary*, RXBENEFITS (Oct. 20, 2020), https://www.rxbenefits.com/blogs/how-expensive-rx-drugs-make-formulary/.

45. Ydejesus, *supra* note 33.

46. *See* Shepherd, *supra* note 34, at 361.

47. *Id.*

48. *Id.*

49. Neeraj Sood et al., *The Association Between Drug Rebates and List Prices*, USC SCHAEFFER (Feb. 11, 2020), https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.

50. *Id.*

turn causes manufacturers to increase list prices to remain profitable due to the higher costing rebates.[51] Hence, it is a continuous cycle. Due to the positive correlation between rebates and drug list prices, "reducing or eliminating rebates could result in lower list prices, thereby decreasing out-of-pocket costs for uninsured patients and for insured patients with deductibles or coinsurance," such as Medicare Part D beneficiaries.[52] Therefore, by excluding rebates from safe harbor protection under the AKS, this rule will benefit consumers as well as drug manufacturers because it will save both parties the additional cost that rebates are currently imposing on the list price of prescription drugs.[53] This is especially true for consumers such as Medicare Part D beneficiaries, who might enroll in such a program specifically for the purpose of obtaining lower prescription drug prices.[54]

E. The Proposed Rule

On February 6, 2019, the Office of Inspector General (OIG) and HHS proposed a rule titled 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 to amend the safe harbor regulation regarding discounts under the AKS, which is section 1128B(b) of the Social Security Act.[55] The Proposed Rule subsequently was withdrawn on July 10, 2019, according to the White House Office of Management and Budget,[56] but the Proposed Rule was never withdrawn from the Federal Register.[57]

The AKS is a law that, among other functions, criminalizes soliciting or receiving any remuneration, including rebates.[58] Remuneration

51. *Id.*

52. *Id.*

53. *Id.*

54. MEDICARE.GOV, *supra* note 12.

55. *See generally* 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, 85 Fed. Reg. 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

56. Debra A. McCurdy, *HHS Scraps Pending Rule to Remove Anti-Kickback Safe Harbor Protection for Drug Rebates to Health Plans, PBMs*, REED SMITH (July 12, 2019), https://www.healthindustrywashingtonwatch.com/2019/07/articles/other-health-policy-developments/other-oig-developments/hhs-scraps-pending-rule-to-remove-anti-kickback-safe-harbor-protection-for-drug-rebates-to-health-plans-pbms/; *OIRA Conclusion of EO 12866 Regulatory Review*, OFF. OF INFO. & REG. AFF. (July 10, 2019), https://www.reginfo.gov/public/do/eoDetails?rrid=129208.

57. FACT SHEET: TRUMP ADMINISTRATION FINALIZES PROPOSAL, *supra* note 5, at 5.

58. Social Security Act, 42 U.S.C. § 1320a–7b (2018).

can include "anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies."[59] Essentially, remuneration is similar to a bribe, where something is either offered or received due to a benefit incurred in return. While some industries permit rewarding others for providing a benefit, paying for referrals is a crime in the federal healthcare programs.[60] Violations of this statute are not taken lightly; penalties include fines, jail terms, and exclusion from participation in the federal healthcare program.[61]

Upon announcing the Proposed Rule, HHS indicated that its intention was for drug "manufacturers to lower their list prices, replace rebates with discounts, or do both."[62] For example, beneficiaries who do not fill some of their prescriptions because of expensive out-of-pocket costs would be more likely to fill them if their prices were lower, which would occur under the Proposed Rule.[63]

Although it appears that the AKS should apply to the rebates that PBMs charge drug manufacturers, since rebates are essentially a bribe to get higher up on the PBM's formulary, there are currently regulatory safe harbor protections in place which preclude the rebates from criminal liability.[64] Thus, the Proposed Rule was designed to "expressly exclude from safe harbor protection under the Anti-Kickback statute (AKS) rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations."[65] Essentially, the Proposed Rule, as well as the Final Rule, amend the safe harbor regulation by excluding certain reductions in price or other remuneration from a manufacturer to plans under Medicare Part D, or PBMs under contract with them, from the definition of a discount eligible for safe harbor protection.[66]

In sum, the Proposed Rule was an attempt to provide more transparency in prescription drug pricing by eliminating the hidden, addi-

59. *Fraud & Abuse Laws*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ (last visited Apr. 14, 2022).

60. *Id.*

61. *Id.*

62. CONG. BUDGET OFFICE, INCORPORATING THE EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS FOR PHARMACEUTICAL REBATES IN CBO'S BUDGET PROJECTIONS—SUPPLEMENTAL MATERIAL FOR *Updated Budget Projections: 2019 to 2029* 2 (2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf [hereinafter INCORPORATING THE EFFECTS OF THE PROPOSED RULE].

63. *Id.* at 4.

64. Crane et al., *supra* note 8.

65. FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS, *supra* note 17, at 1.

66. 42 C.F.R. § 1001.952 (2020).

tional cost of rebates that get added into the price that consumers pay for their prescription drugs. Additionally, the Proposed Rule provided for two new safe harbor provisions.[67] The first would protect certain point-of-sale reductions in price on prescription drugs, and the second would protect certain PBM service fees.[68] These proposed safe harbor provisions were added as an incentive to offer prescription drug discounts directly to consumers and to create a fixed fee service arrangement between drug manufacturers and PBMs to provide transparency in fees involved in transactions that have been kept secret from public knowledge for far too long.[69] Therefore, the Proposed Rule should never have been withdrawn so that it could rid the system that is designed to provide more affordable drugs from inflating prescription drug prices.

F. Issues with the Current Rebate System that Final Rule Seeks to Combat

There are three main problems with the current rebate system in place that the Proposed Rule, and subsequently, the Final Rule, seek to correct.[70] First and foremost, some beneficiaries undergo increased financial burdens.[71] This is because the current system rewards higher list prices for prescription drugs; thus, the Final Rule seeks to protect upfront discounts in order to combat the incentives for higher list prices.[72]

The second problem is that the rebates which drug manufacturers pay to PBMs to get on their formularies are not reflected in the price of the out-of-pocket cost the Medicare beneficiary pays.[73] Therefore, the Final Rule amends the safe harbor regulations "to offer protection for reductions in price that are reflected at the point of sale," thus, the rule "provide[s] a strong incentive for drug manufacturers to offer discounts that will directly benefit patients by lowering their out-of-

67. 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, 85 Fed. Reg. 76,666, 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

68. *Id.*

69. FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS, *supra* note 17, at 1.

70. 85 Fed. Reg. at 76,668.

71. *Id.*

72. *Id.* at 76,666; With the current rebate system in place, if the negotiation between manufacturers and PBMs favors higher rebates over lower drug costs, then it results in higher list prices, which is detrimental to Part D beneficiaries.

73. *Id.*

pocket costs at the pharmacy counter."[74] This problem contributes to the lack of transparency in prescription drug prices that the Final Rule aims to correct.

Finally, a third problem of the current rebate system is that it discourages consumers' use of low-priced generic drugs or biosimilars.[75] This is due to the fact that insurers and Medicare Part D plan sponsors can often receive higher rebates from brand name drugs and biologics, which minimizes their incentive to use biosimilars.[76] One solution to this problem is for manufacturers of brand name drugs to decrease generic or biosimilar competition by offering larger rebates when they pay for a drug or group of drugs and make the payment of those rebates contingent upon maintaining their exclusive formulary position. In effect, this would not only alleviate out-of-pocket costs for consumers, but it would also promote a free market system by increasing the availability of drug options, rather than limit sources to only brand name drugs.

G. Reasons the Proposed Rule was Withdrawn

When the Proposed Rule was initially introduced in February 2019, it was withdrawn by July of that year, and "its advancement was hotly contested."[77] The decision to withdraw the Proposed Rule was made in July 2019 by former President Trump himself, nearly seven months

74. FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS, *supra* note 17, at 2. For example, if the consumer is spending out-of-pocket up to his deductible, then the consumer pays the amount agreed to between the plan and the pharmacy, which is usually based at least partially on the drug's list price without regard for the rebates. Further, when a patient is using coinsurance, the patient pays for the drug as a percentage of the amount agreed to between his plan and the pharmacy, which is also based on the plan's list price for the drug. Additionally, in some instances, the consumer's cost sharing may be higher than the net price paid by his plan after rebates.

75. *Id.*; According to the Food and Drug Administration, a biosimilar is a biological product which is a "[l]arge and generally complex molecule[ ]," that is "[p]roduced from living organisms," and that is "[c]arefully monitored to ensure consistent quality." *What is a Biosimilar?*, FDA, https://www.fda.gov/media/108905/download (last visited Apr. 15, 2022). Biosimilars are distinct from, but often confused with, generic drugs. "But biosimilar drugs and generic drugs are very different, mainly because while generic drugs are identical to the original in chemical composition, biosimilar drugs are 'highly similar,' but close enough in duplication to accomplish the same therapeutic and clinical result." CANCER TREATMENT CTRS. OF AM., *What's the Difference? Biosimilar and Generic Drugs* (Dec. 25, 2018), https://www.cancercenter.com/community/blog/2018/12/whats-the-difference-biosimilar-and-generic-drugs.

76. FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS, *supra* note 17, at 2; FACT SHEET: TRUMP ADMINISTRATION FINALIZES PROPOSAL, *supra* note 5, at 2.

77. Rachel Sachs, *Administration Finalizes Drug Pricing Rebate Rule at The Last Minute*, HEALTH AFFS. (Nov. 23, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201122.985836/full/.

after releasing the proposal.[78] This begs the question: what changed? Why would former President Trump, who vehemently advocated[79] to reduce the cost of prescription drugs, make the decision to withdraw the proposal but then finalize it at the eleventh hour of his presidency?[80]

The Proposed Rule was withdrawn in 2019 for two main reasons: concerns regarding a substantial increase in federal spending, upwards of nearly $180 billion over the following ten years, and the potential risk of increasing Medicare beneficiaries' premiums.[81] According to the Congressional Budget Office (CBO), this projection reflects the assumption that pharmaceutical manufacturers would refuse to give approximately fifteen percent of the discounts currently given to PBMs in Medicare Part D, which would no longer be allowed under the Proposed Rule.[82] In effect, the CBO predicted that instead of decreasing the list price of the drugs, these manufacturers would offer the renegotiated discounts as a chargeback.[83]

A pharmaceutical chargeback occurs in two scenarios.[84] In the first, a wholesaler purchases drugs from the pharmaceutical company at a specified contract price and sells them to consumers at a different contract price.[85] When the consumer contract price is less than the pharmaceutical price, the wholesaler will charge the pharmaceutical company this difference in price to prevent loss of profit.[86] The second scenario involves a chargeback resulting from a failed transaction in which the entire payment made by the consumer must be returned to the consumer.[87] The Proposed Rule aimed to eliminate Medicare Part D beneficiaries' current cost-sharing obligation, which is related to the list price of the drug and does not include the rebates paid by the

78. Abutaleb et al., *supra* note 18.

79. AMERICAN PATIENTS FIRST, *supra* note 1, at 9.

80. *See generally* 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, 85 Fed. Reg. 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

81. Sachs, *supra* note 77; INCORPORATING THE EFFECTS OF THE PROPOSED RULE, *supra* note 62, at 1.

82. INCORPORATING THE EFFECTS OF THE PROPOSED RULE, *supra* note 62, at 2 (These projections were made prior to the rule being finalized in 2020).

83. *Id.* at 2–3. "Manufacturers could offer discounts to beneficiaries either by reducing their list price or by making a payment to the pharmacy of the full amount of the negotiated discount (referred to as a chargeback)." *Id.* at 2.

84. Tyler Lacoma, *What Is a Pharmaceutical Chargeback?*, BIZ FLUENT (Nov. 21, 2018), https://bizfluent.com/info-8783464-pharmaceutical-chargeback.html.

85. *Id.*

86. *Id.*

87. *Id.*

manufacturer to either the PBM or private plan.[88] Rather, the Proposed Rule replaced it with a cost-sharing model that instead is based on an overall lower list price for the drug or on a post-chargeback price.[89] Therefore, Part D beneficiaries would be provided with more transparency as well as lower drug prices.

H. The Final Rule

The Final Rule was created on November 20, 2020, shortly before former President Trump's term ended and shortly after the presidential election, and it is essentially the Proposed Rule from February 2019 with some modifications.[90] Although the government publicly withdrew the rule, an official notice of withdrawal was never listed in the Federal Register.[91] Therefore, HHS's OIG finalized the Proposed Rule, establishing the Final Rule.[92] The rebate system in place prior to the enactment of the Final Rule has been described as "opaque," which is evidenced by the issues discussed above.[93] This is because the old rebate system did not reflect to consumers the hidden costs in the price they were paying at the point of sale for their prescription drugs; therefore, the new system under the Final Rule will offer true discounts.[94] Thus, the Proposed Rule was initially created, and later finalized,[95] to combat this issue by "expressly excluding rebates on

88. INCORPORATING THE EFFECTS OF THE PROPOSED RULE, *supra* note 62, at 2. This is part of the problem. Although this cost is not directly reflected in the price, the inflation of the costs represents the hidden fees consumers are unknowingly paying to compensate for the rebates.

89. *Id.*

90. King & Spalding, *HHS Finalizes Rule Challenging Drug Manufacturer Rebates to PBMs and Payors*, JD SUPRA (Nov. 30, 2020), https://www.jdsupra.com/legalnews/hhs-finalizes-rule-challenging-drug-89523/; Angelica LaVito, *White House Drops Proposal to Eliminate Drug Rebates. Health Stocks Soar*, CNBC (July 11, 2019, 8:06 AM), https://www.cnbc.com/2019/07/11/white-house-pulls-proposal-to-eliminate-drug-rebates-politico.html ("[T]he Congressional Budget Office found the rule would cost $177 billion through 2029."); Sachs, *supra* note 77 ("Another point is worth making about the differences (or, really, lack thereof) between the NPRM and final rule.").

91. Sachs, *supra* note 77.

92. *See generally* Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 86 Fed. Reg. 5864 (Jan. 19, 2021) (to be codified at 42 C.F.R. pts. 405, 417, 422–23, 255, 460).

93. FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS, *supra* note 17, at 1.

94. *Id.*

95. Two rules regarding drug-pricing were actually finalized:

> One rule creates a Most Favored Nation ("MFN") Model that seeks to lower prices by indexing Medicare Part B payments for the top 50 physician-administered drugs to prices paid by other countries. The second rule focuses on the Medicare Part D program, replacing the current federal anti-kickback safe harbor protection for manufac-

prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs) and Part D plans from safe harbor protection under the Anti-Kickback Statute (AKS)."[96] The current rebate system in place, outlined in Trump's May 2018 drug pricing blueprint, has a domino effect by incentivizing higher list prices for prescription drugs, which benefits the PBMs and, in turn, increases the costs for patients.[97]

Initially, the Final Rule was supposed to go into effect on January 29, 2021, except for the amendments to 42 C.F.R. 1001.952(h)(5), which were to become effective on January 1, 2022.[98] The Final Rule retains the same title as the Proposed Rule.[99] But as of current, the entire Final Rule will not go into effect until January 1, 2023, prolonging implementation for an additional two years.[100]

There were several significant changes made to the Proposed Rule before it was finalized, which are demonstrated in the Final Rule. As previously mentioned, prescription drug prices have been described as "opaque,"[101] and according to Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma, the changes made from the Proposed Rule to the Final Rule "provide desperately needed transparency on the out-of-pocket costs for prescription drugs that

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turer rebates to Part D plan sponsors and their contracted Pharmacy Benefit Managers ("PBMs") with a new safe harbor limited to rebates that benefit patients at the pharmacy counter.

Michael Gallagher & Kevin C. Adam, *Trump Administration's Eleventh-Hour Drug Pricing Regulations Face an Uncertain Path Forward*, WHITE & CASE (Dec. 3, 2020), https://www.whitecase.com/publications/alert/trump-administrations-eleventh-hour-drug-pricing-regulations-face-uncertain-path.

96. *The New Regulation for Drug Rebates in Medicare Part D*, ENSURE DATA SOLUTIONS, https://ensuredatasolutions.com/the-new-regulation-for-drug-rebates-in-medicare-part-d/ (last visited Apr. 12, 2022).

97. AMERICAN PATIENTS FIRST, *supra* note 1, at 12.

98. 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; Delayed Effective Date, 86 Fed. Reg. 10,181, 10,181 (Feb. 19, 2021).

99. 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, 85 Fed. Reg. 76,666, 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

100. 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; Additional Delayed Effective Date, 86 Fed. Reg. 15132, 15132–33 (Mar. 22, 2021) (to be codified at 42 C.F.R. pt. 1001).

101. FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS, *supra* note 17, at 1.

have been obscured for seniors."[102] This demonstrates the importance of the Proposed Rule being finalized and one of its most positive effects: to provide Medicare Part D beneficiaries, who are primarily senior citizens, with information on what they are actually paying for when they pick up their prescriptions from the pharmacy.

First, the Final Rule's effective date changed, pushing it back two years to allow entities affected by the rule to properly prepare.[103] Additionally, the Final Rule offers protection to the price reductions that are offered to Medicare Part D plan sponsors or Medicaid Managed Care Organizations (MCOs), contingent upon where the drug is placed on the PBM formulary.[104] This protection is offered under the new safe harbor for point-of-sale reductions in price under 42 C.F.R. § 1001.952(cc).[105] Further, these reductions in price offered to Medicaid MCOs that are also contingent upon where the drug is placed in the formulary will remain protected by the discount safe harbor at 42 C.F.R. § 1001.952(h).[106] Therefore, despite the Final Rule's efforts to primarily benefit the Part D beneficiaries, the Final Rule still includes benefits for plan sponsors and MCOs. Another change is that the Final Rule does not amend 42 C.F.R. § 1001.952(h) to exclude rebates offered to Medicaid MCOs, which is the discount safe harbor provision, with the caveat that rebates that are offered by pharmaceutical manufacturers to Medicaid MCOs satisfy all other safe harbor requirements.[107] The final major change from the Proposed Rule to the Final Rule is a change in the definition of a "chargeback."[108] This revi-

102. *Changes to Medicare Advantage and Part D Will Provide Better Coverage, More Access and Improved Transparency for Medicare Beneficiaries*, CMS.GOV (Jan. 15, 2021), https://www.cms.gov/newsroom/press-releases/changes-medicare-advantage-and-part-d-will-provide-better-coverage-more-access-and-improved.

103. 86 Fed. Reg. at 15132–33.

104. Epstein Becker & Green, *Finalized HHS Drug Formulary Rebate Rule Faces Uncertain Future Under Biden Administration and Current Legal Challenge*, JD SUPRA (Jan. 18, 2021), https://www.jdsupra.com/legalnews/finalized-hhs-drug-formulary-rebate-5473810/.

105. AMERICAN PATIENTS FIRST, *supra* note 1, at 22; 42 C.F.R. § 1001.952(cc).

106. 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, 85 Fed. Reg. at 76,667 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

107. *Id.* at 76,717.

108. FACT SHEET: TRUMP ADMINISTRATION FINALIZES PROPOSAL, *supra* note 5, at 6. For further explanation on this change in definition under the Final Rule:

> We proposed to define a "chargeback" as a payment from a manufacturer to a dispensing pharmacy that would be at least equal to the discounted price of the drug agreed to by the manufacturer and the Part D Plan sponsor or Medicaid MCO. We agree with commenters who noted that our proposed definition could lead to gaming and that the chargeback should be equal to the reduction in price, not the discounted price of the drug, so we define a chargeback in the final rule as a payment equal to the reduction in

sion was in response to commenters, and the Final Rule will rename it a "point-of-sale chargeback."[109]

In response to concerns of increased federal spending and premiums for Medicare Part D beneficiaries, former HHS Secretary Alex Azar stated his belief that these increases would not occur, which follows from HHS's expectation that manufacturers will lower list prices of drugs in response.[110] This belief is also supported by CMS, which explained that the changes between the Proposed Rule and Final Rule "are expected to result in an estimated $75.4 million savings to the federal government over ten years, arising exclusively from Drug Management Program (DMP) savings on reduced prescription drug spending."[111]

III. Analysis

Finalizing the Proposed Rule was the proper decision made in order to rid a system that is designed to provide more affordable drugs from ever-inflating prescription drug prices. The Final Rule and its various amendments to 42 C.F.R. § 1001.952 may seem like minor changes, but the impact those changes will have on Medicare Part D beneficiaries is major.

A. PBM Opposition to the Final Rule

Some potential roadblocks to implementing the Final Rule have already been flagged by various sources.[112] While figures from both political parties demonstrated support and excitement for the Final Rule passing, other politicians expressed concern for the rule being passed

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price. This definition ensures that the pharmacy is made whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment.

Id.

109. 85 Fed. Reg. at 76,697–98.

110. Sachs, *supra* note 77.

111. *Contract Year 2022 Medicare Advantage and Part D Final Rule (CMS-4190-F2) Fact Sheet*, CMS.gov (Jan. 15, 2021), https://www.cms.gov/newsroom/fact-sheets/contract-year-2022-medicare-advantage-and-part-d-final-rule-cms-4190-f2-fact-sheet.

112. *See* Gallagher & Adam, *supra* note 95. Many believe that the Final Rule is going to be subject to lawsuits from industry stakeholders and other political challenges from those such as the pharmaceutical industry, the PCMA, and America's Health Insurance Plans (the insurance industry trade association); Sachs, *supra* note 77. Ricardo Alonso-Zaldivar, *Trump Makes Late-Term Bid to Lower Prescription Drug Costs*, AP News (Nov. 20, 2020), https://apnews.com/article/donald-trump-medication-prescription-drug-costs-medicare-prescription-drugs-e17119840 2445755b920842ded293b59 ("[I]n a time of political uncertainty, it's hard to say whether the rules will withstand expected legal challenges from the pharmaceutical industry or whether President-elect Joe Biden's administration will accept, amend or try to roll them back entirely.").

so late in former President Trump's term.[113] In fact, the Pharmaceutical Care Management Association (PCMA), a trade group that represents PBMs, filed suit against joint defendants which includes HHS, OIG, Counsel to OIG, Department of Justice, and individuals working under all of those organizations, such as former HHS Secretary Alex Azar, to challenge implementation of the Final Rule.[114] The complaint filed by the PCMA sought declaratory and injunctive relief, including asking the U.S. District Court for the District of Columbia to declare the Final Rule unlawful and to vacate and set aside the Final Rule.[115] Amidst the many allegations cited in this complaint, the PCMA claimed that the Final Rule would "increase prescription drug premiums, federal spending, and aggregate spending on prescriptions—ultimately harming the American seniors and disabled citizens the Rule purports to help."[116] On January 30, 2021, the court issued an order stating that the PCMA and HHS must both "submit a joint status report identifying whether and how this case should proceed by not later than April 1, 2021."[117] Eventually, the PCMA pulled their lawsuit after coming to a resolution with the Biden administration.[118]

In addition to filing this complaint, the PCMA created a report in 2019, before the Proposed Rule was withdrawn, conducted by Matrix Global Advisors that "suggests there is limited evidence supporting the claim that rebates are tied to higher list prices and that the plan does not properly target the [sic] Department of Health and Human Services' (HHS) stated goals."[119] Amongst other criticisms in this report, the Matrix Global Advisors note that HHS strayed from its typical practice by relying on its own actuarial analysis conducted by the

113. Gallagher & Adam, *supra* note 95; Yasmeen Abutaleb, *Trump Pushes Last-Minute Drug Pricing Rules Likely to Face Big Legal Challenges*, WASH. POST (Nov. 20, 2020), https://www.washingtonpost.com/health/2020/11/20/trump-drug-price-rules/. Senator Mark R. Warner called the Final Rule "a significant step in the right direction for improving patient care." *Id.* On the other hand, Representative Lloyd Doggett referred to the Final Rule as an "invitation to legal challenges" due to how late in his presidency Trump finalized the rule. *Id.*

114. Complaint at 1, Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health and Human Servs., No. 1:21-CV-02161 (D.D.C. Dec. 1, 2021).

115. *Id.* at 78.

116. Complaint at 2, Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health and Human Servs., No. 1:21-CV-00095 (D.D.C. Jan. 12, 2021).

117. Order at 1, Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health and Human Servs., No. 21-95 (D.D.C. Jan. 30, 2021).

118. Robert King, *PCMA Pulls Lawsuit Over Rebate Disclosure Rule After Reaching Deal with Biden Admin,* FIERCE HEALTHCARE (Dec. 2, 2021), https://www.fiercehealthcare.com/payer/pcma-pulls-lawsuit-over-rebate-disclosure-rule-after-reaching-deal-biden-admin.

119. Jacqueline Renfrow, *PCMA Report Says HHS Rebate Rule Would Significantly Boost Drug, Part D Spending*, FIERCE HEALTHCARE (Apr. 8, 2019, 6:42 AM), https://www.fiercehealthcare.com/payer/pcma-calls-proposed-drug-rebates-rule-poorly-conceived.

CMS Office of the Actuary and also by contracting with two private-sector firms to determine the impact of the Proposed Rule.[120] This report insinuates that HHS, by deviating from its standard practice and, additionally, by having two private-sector firms formulate the impact of the Proposed Rule, bent the rules and thus utilized inaccurate data to support the Proposed Rule. The claims in this report created by Matrix Global Advisors for the PCMA are baseless since they do not state what standard practice is in either case or what alternative method HHS should have used to determine the Proposed Rule's impact.

In addition to the litigation that has ensued, there is uncertainty surrounding the Final Rule and what the Biden administration may do with it now that he has been inaugurated. President Biden nominated Xavier Becerra as the new Secretary of the HHS.[121] The Senate voted to confirm Becerra for this role on March 18, 2021, despite opposition from Republicans.[122] This will add another interesting wrinkle in former President Trump's decision to finalize the rule at the conclusion of his presidential term. However, Becerra has actually "openly expressed concerns with the impact of formulary rebates on competition and drug prices."[123] Therefore, the Final Rule may be subject to stay under his new direction, following former HHS Secretary Alex Azar.

B. Arguments that Withdrawal Should Preclude Finalization

In further opposition of the Final Rule, some have argued that since the Proposed Rule was withdrawn, an agency "cannot proceed directly to the final rule stage (as it did here) if it changes its mind about the withdrawal."[124] This is because once withdrawn, a rule can only recommence by issuing another notice of proposed rulemaking before

120. ALEX BRILL, CONCERNS REGARDING THE PROPOSED RULE TO RESTRICT DRUG MANUFACTURER REBATES IN MEDICARE PART D AND MEDICAID MCOS 2 (2019), http://getmga.com/wp-content/uploads/2019/04/MGA-Report-on-Proposed-Rebate-Restriction-3.pdf (This report and claims were made regarding the Proposed Rule and not the Final Rule; thus, some numbers may not be an accurate reflection of the impact of the Final Rule due to changes made from when it was initially proposed.).

121. Lois M. Collins, *Xavier Becerra's Future Role in Your Family Life*, DESERETNEWS (Jan. 23, 2021, 10:00 PM), https://www.deseret.com/indepth/2021/1/23/22226637/what-role-will-xavier-becerra-play-in-family-health-human-services-secretary-biden-administration. Becerra has had several roles throughout his career, including providing legal aid services to low-income families, serving in Congress for twenty-four years, and serving as the Attorney General of California. *Id.* Notably, as President Biden's nominee, Becerra would be the first Hispanic to head HHS. *Id.*

122. Allison Pecorin, *Xavier Becerra confirmed as HHS Secretary over Republican Opposition*, ABC NEWS (Mar. 18, 2021, 12:19 PM), https://abcnews.go.com/Politics/xavier-becerra-confirmed-hhs-secretary-republican-opposition/story?id=76518625.

123. Epstein Becker & Green, *supra* note 104.

124. Sachs, *supra* note 77.

being finalized.[125] Essentially, once a rule is officially withdrawn, it is as if the rule never existed, and lawmakers must start from the very beginning again before proceeding.

This claim is also baseless. The Proposed Rule was never officially withdrawn since it was never reported in the Federal Register.[126] Thus, this combats the claim that once a rule is withdrawn it cannot be finalized because, here, the Proposed Rule was never subject to an official withdrawal noted in the Federal Register.[127] Therefore, it was unnecessary to reintroduce the Proposed Rule before finalization since it was never officially listed as withdrawn. In response, those opposing the Final Rule further argue that the actions of the administration constitute a withdrawal and should thus be treated as one, regardless of whether it was officially recorded in the Federal Register.[128] Regardless of whether the Proposed Rule was actually withdrawn, many are also concerned about the precedent this may set, citing instances in which administrations claim to withdraw a controversial rule and then finalize the rule immediately after an election.[129]

Despite some opposition to the Final Rule, finalizing the Proposed Rule was the correct choice made by HHS. There are numerous potential benefits that can result from the Final Rule not only for Medicare Part D beneficiaries, but also for the prescription drug market as a whole. As described in the blueprint created by the Trump administration prior to the Proposed Rule, the Final Rule can have the effect of boosting competition and enhancing negotiation in addition to the primary goals of creating incentives for lower list prices and reducing out-of-pocket spending.[130] Thus, the Final Rule can actually benefit

125. *Id.*

126. John O'Brien & Kelly Cleary, *Are We Gearing Up for a Drug Rebate Rule Instant Replay?*, EVIDENCE BASE (July 21, 2020), https://healthpolicy.usc.edu/evidence-base/are-we-gearing-up-for-a-drug-rebate-rule-instant-replay/ ("The decision to withdraw a proposed rule after a notice and comment period is considered 'final agency action.'. . . Interestingly, there was no such notice for the rebate rule.").

127. *See generally* Bridget C.E. Dooling, *Going Through Regulatory Withdrawal*, YALE J. ON REG. (Oct. 13, 2020), https://www.yalejreg.com/nc/going-through-regulatory-withdrawal/.

128. *Id.*

129. Dan Bosch, *Zombie Rebate Rule Could Create Troubling Precedent*, INSIGHT (Aug. 25, 2020), https://www.americanactionforum.org/insight/zombie-rebate-rule-could-create-troubling-precedent/. The finalization of this rule is the first time in recent history that a rule was announced as withdrawn then came back without being re-proposed. *Id.* As a result, finalizing this rule sets precedent that could "destabilize the regulatory process," and in the future there may be similar occurrences in which similar moves are made for political gain. *Id.*

130. 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, 85 Fed. Reg. 76,666, 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

drug manufacturers as well and incentivize innovation in the prescription drug market due to increased efforts in competition and negotiations.

IV. Impact

A. The Final Rule's Lasting Effect

The Final Rule makes four small regulatory changes to 42 C.F.R. § 1001.952 that will widely benefit Medicare Part D beneficiaries once the Final Rule goes into effect in 2023.[131] The amendment to 42 C.F.R. § 1001.952(h)(5) that removes from safe harbor protection reductions in price for prescription pharmaceutical products provided to Part D plan sponsors will likely have the greatest impact for consumers.[132] This will increase transparency in drug pricing by preventing manufacturers from offering discounts to PBMs and compensating for those discounts by increasing the list price of their drugs, which consumers have no choice but to pay under the current rebate system. Although this amendment seems like a small, technical change, its effect on prescription drug pricing overall will save Medicare Part D beneficiaries money on drugs, which is the purpose of a Part D plan.[133]

In addition to saving beneficiaries money, this Final Rule can also potentially decrease government spending in Medicare Part D.[134] For example, plan sponsors subtract rebates from their plan bids, and lower bids result in lower premiums, which in turn can result in lower government spending on premium subsidies.[135]

B. Positive Effects of Final Rule on Medicare Part D Beneficiaries

Despite the few groups that are unhappy with the Final Rule, which primarily consist of the PBMs, the Final Rule carries great benefits to Medicare Part D beneficiaries. As mentioned in Part I, Medicare Part D is intended to benefit those who are either elderly or suffer from a

131. 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; Additional Delayed Effective Date, 86 Fed. Reg. 15132, 15133 (Mar. 22, 2021) (to be codified at 42 C.F.R. pt. 1001).

132. 42 C.F.R. § 1001.952(h)(5).

133. *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 15.

134. 86 Fed. Reg. at 15133.

135. 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, 85 Fed. Reg. 76,666, 76,667 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

health issue.[136] The Final Rule requires drug manufacturers to give Medicare rebates to the Medicare beneficiaries rather than to insurers or PBMs, which is where the rebates currently end up.[137] In other words, the discount will be reflected in the price that consumers, the Medicare beneficiaries, pay, rather than the insurers or PBMs, who currently benefit from the rebates. Although the CBO claims this would increase taxpayer costs by nearly $180 billion over the next decade, the Trump administration supported the rule and estimated that it could actually result in thirty percent savings for Medicare Part D beneficiaries.[138]

At the time of this writing and prior to the Proposed Rule being finalized, Medicare Part D premiums were already predicted to increase nine percent from thirty-eight dollars in 2020 to forty-one dollars in 2021.[139] These numbers are demonstrated further in a bar chart that shows a steady increase in the price of premiums from the year 2006 through 2021.[140]

V. Conclusion

So, what exactly does all of this mean for Medicare Part D beneficiaries? The Final Rule's more transparent discounts are anticipated to lead to decreased spending for Part D beneficiaries overall.[141] This is due to the projected decrease in out-of-pocket costs for the beneficiaries being greater than the potential increase in premiums.[142] Further, while savings will vary by beneficiary, beneficiaries who are the sickest or who have more expensive prescription drugs are likely to save the most.[143] This means that Medicare Part D will fulfill its intended goal: to benefit those who are sick and/or the elderly, a group that can be interchangeable with those who pay higher drug costs.[144]

After reviewing average prescription drug prices in the United States, it is easy to see why former President Trump took the initiative

136. *See supra* Part II.

137. Alonso-Zaldivar, *supra* note 112.

138. *Id.*

139. Juliette Cubanski & Anthony Damico, *Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2021*, Kaiser Fam. Found. (Oct. 29, 2020), https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2021/.

140. *Id.* at fig. 3.

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*; Fact Sheet: Trump Administration Proposes to Lower Drug Costs, *supra* note 17, at 3 ("The new system would work as insurance is intended to: where those with especially high out-of-pocket drug costs will be most likely to benefit.").

to lower prescription drugs.[145] What is still unclear, though, is why this proposal was made, debatably withdrawn, and subsequently finalized the following year, which happened to be immediately following the 2020 presidential election. Regardless of the resulting litigation and other potential effects of this Final Rule discussed in this Comment, the goal remains the same: to decrease prescription drug prices for Medicare Part D beneficiaries, as they are members of a program designed to perform this objective.

Nicole Mouzakiotis

145. Robert Langreth, *Drug Prices*, BLOOMBERG (Sept. 16, 2020, 12:13 PM), https://www.bloomberg.com/quicktake/drug-prices (highlighting how on average, Americans spend more on prescription drugs than any other country in the world, which is due to higher prices in the United States than other countries worldwide); *Report: U.S. Drug Prices Far Exceed Average for 11 Similar Countries*, AM. HOSP. ASS'N (Sept. 23, 2019, 2:58 PM), https://www.aha.org/news/headline/2019-09-23-report-us-drug-prices-far-exceed-average-11-similar-countries ("U.S. drug prices are nearly four times higher than the combined average price for 11 other similar countries.").