

HHS Proposes Removal of Safe Harbor Protection for PBMs

On January 31, 2019, the *Department of Health and Human Services* (HHS) released a proposed rule that would eliminate safe harbor protection under the *Anti-Kickback Statute* (AKS) for rebates that prescription drug manufacturers grant to *pharmacy benefit managers* (PBMs), Medicare Part D plans, and Medicaid *managed care organizations* (MCOs).¹ This proposal carries out Congress's directive under the *Medicare and Medicaid Patient and Program Protection Act of 1987*, requiring the HHS Secretary, Alex Azar, to identify payment practices that should not be subject to prosecution under the AKS and to periodically evaluate safe harbor rules in order "to reflect changing business practices and technologies in the health care industry."² This proposed rule addresses the changes of the "modern prescription drug distribution model" to ensure arrangements benefit federal healthcare program beneficiaries.³

PBMs administer prescription programs to Americans who have health insurance through commercial health plans, Medicare Part D plans, managed Medicaid plans, and others, but are experiencing increased scrutiny within the healthcare industry.⁴ Historically, PBMs have been "middlemen" entities that process medication claims for insurance companies and plan sponsors for a small fee per claim.⁵ PBMs have since evolved to manage drug benefits for approximately 95% of the U.S. population, providing drug utilization review and drug plan formulary development, among other services.⁶ Because PBMs make formularies for plan sponsors, they are able to negotiate better prices; however, only a portion of the rebates they receive are shared with the plan sponsor, causing concern within the healthcare industry as patients are paying cost shares that do not reflect the actual, lower cost of the drug.⁷

Drug prices and rebate payments to PBMs have grown substantially in recent years, prompting the revision to the AKS safe harbor.⁸ The *Office of Inspector General* (OIG) released a report indicating that reimbursement for brand-name Part D drugs increased by 77% from 2011 to 2015, despite a 17% decrease in prescriptions of these drugs.⁹ Recently, drug manufacturers announced drug increases at an average of approximately 6.3%.¹⁰ Despite the increase in drug prices that lead to higher rebates, HHS states that many rebates are not seen at the pharmacy counter in the form of price reductions; rather, the rebates are applied as reduced premiums for all enrollees.¹¹

Consistent with the Trump Administration's promise to reduce prescription drug prices and out-of-pocket costs, this proposed rule attempts to encourage manufacturers to pass on discounts directly to patients at the point of sale for products payable under Medicare Part D or by Medicaid MCOs, as well as increase transparency within the overall prescription drug industry.¹² Additionally, the proposed rule outlines new safe harbors for the point-of-sale discounts offered to patients and for fixed service fees that drug manufacturers give PBMs for services that meet specific criteria.¹³ If the rule is finalized, the prescription drug rebates, which are, on average, 26% to 30% of a drug's list price, would be passed on directly to patients, particularly benefiting older Americans and those with chronic conditions who have high drug expenditures.¹⁴

Azar believes that, under the existing structure, Americans often pay more for prescriptions "because of a hidden system of kickbacks to middlemen [i.e., PBMs]."¹⁵ Currently, PBMs and Part D plans favor drugs with higher prices, such as brand-name and biologic prescriptions, rather than lower-cost generics and biosimilars, as rebates tend to be a percentage of the list price.¹⁶ The *Pharmaceutical Research and Manufacturers of America* (PhRMA) supports the proposed rule because it focuses on patients and reduces the incentives for insurers and PBMs to favor drugs with high list prices, ensuring "that the \$150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy."¹⁷ Particularly with insurer-PBM market consolidation, such as the CVS-Aetna and Cigna-Express Scripts deals, drug manufacturers have minimal ability to push back on rebate demand from PBMs.¹⁸

However, the *Pharmaceutical Care Management Association* (PCMA), a PBM lobbying group, emphasizes that this proposed rule would increase drug costs and force Medicare beneficiaries to pay higher premiums and out-of-pocket expenses.¹⁹ PCMA states that drug manufacturers set and raise prices, independent of rebates, and PBMs are part of the solution to these high costs, as they negotiate on behalf of beneficiaries.²⁰ A study by Oliver Wyman Consulting found that rebates have reduced costs by approximately \$35 billion, and without these rebates, premiums would have increased by 52% in 2018.²¹ Further, another study concluded that the price of popular Part D drugs were increasing, but there

was no change in rebate levels to PBMs, from 2012 to 2017, supporting the PCMA statement that drug manufacturers are the entities that set and raise prices.²²

An IHS Markit analysis projects that with negotiated discounts at the point of sale, Medicare beneficiaries with diabetes could save approximately \$350 annually.²³ However, despite the intent to lower out-of-pocket costs, there is a possibility of unintended consequences stemming from the proposed rule, such as beneficiaries paying more in cost-sharing at the pharmacy.²⁴ In addition, according to HHS's analysis, Part D premiums in 2020 could be subject to an increase of \$3.20 to \$5.64 per beneficiary per month (PBPM); however, total cost sharing would decrease, indicating a net decrease in beneficiary spending PBPM.²⁵

Excluding PBMs, Part D plans, and Medicaid MCOs from safe harbor protections, and including safe harbor protection for discounts offered directly to patients, intend to lower drug prices and out-of-pocket costs, increasing transparency in the pharmaceutical industry. Although the proposal only applies to federal plans, it may prompt a similar change in commercial plans. Azar believes that insurers that offer both Medicare and commercial plans may eliminate rebates for their commercial plans, as it may be difficult to “segregate” systems.²⁶ Additionally, Azar mentions that states may eventually adopt safe harbor protections and outlaw rebates to private plans similar to the proposed rule.²⁷

The proposal was published in the Federal Register on February 6, 2019 and will include a 60-day comment period.²⁸

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2 “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” Federal Register, January 31, 2019, <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-01026.pdf> (Accessed 1/31/19).

3 *Ibid.*

4 “What is a PBM and what do they do?” PCMA, <https://www.pcmamet.org/our-industry/> (Accessed 2/1/19).

5 “The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1” By Brittany Hoffman-Eubanks, Pharmacy Times, November 14, 2017, <https://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1> (Accessed 2/1/19).

6 *Ibid.*

7 *Ibid.*; “The PBM Problem” Alliance for Transparent & Affordable Prescriptions, <https://atapadvocates.com/the-pbm-problem/> (Accessed 2/1/19).

8 Federal Register, January 31, 2019.

9 *Ibid.*

10 “Drugmakers Celebrate the New Year by Raising Prices on Hundreds of Drugs an Average of 6.3%” By Kevin Kelleher, Fortune, January 2, 2019, <http://fortune.com/2019/01/02/dozens-drugmakers-celebrate-new-year-raising-prices-hundreds-drugs/> (Accessed 2/1/19).

11 Federal Register, January 31, 2019.

12 Department of Health and Human Services, January 31, 2019.

13 *Ibid.*

14 *Ibid.*; “Trump administration proposes rules for Medicare plans as it seeks to lower drug prices” By Bertha Coombs and Christine Wang, CNBC, January 31, 2019, <https://www.cnbc.com/2019/01/31/cvs-cigna-fall-after-trump-administration-proposes-rule-to-lower-drug-prices.html> (Accessed 2/1/19).

15 Department of Health and Human Services, January 31, 2019.

16 *Ibid.*, p. 2.

17 “PhRMA Statement on the Administration’s Proposed Rule to Reform the Rebate System” Pharmaceutical Research and Manufacturers of America, January 31, 2019, <https://www.phrma.org/press-release/phrma-statement-on-the-administration-s-proposed-rule-to-reform-the-rebate-system> (Accessed 2/1/19).

18 Coombs and Wang, January 31, 2019.

19 “PCMA Statement on the Administration’s Prescription Drug Rebate Proposed Rule” Pharmaceutical Care Management Association, January 31, 2019, <https://www.pcmamet.org/pdma-statement-on-the-administrations-prescription-drug-rebate-proposed-rule/> (Accessed 2/1/19).

20 *Ibid.*

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