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CLIENT ALERT

# Finalized HHS Drug Formulary Rebate Rule Faces Uncertain Future Under Biden Administration and Current Legal Challenge

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**January 2021**

On November 30, 2020, the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") published a final rule ("Final Rule") that removes safe harbor protection under the discount safe harbor to the federal Anti-Kickback Statute ("AKS") for certain pharmaceutical rebates and creates two new safe harbors governing certain pharmaceutical manufacturer price reductions at the point of sale ("POS") and certain pharmacy benefit manager ("PBM") service fees.[1] While the new safe harbors become effective January 29, 2021, the removal of the discount safe harbor has a delayed effective date of January 1, 2022.[2] The Final Rule, if fully implemented, will have a significant impact on drug supply chain stakeholders operating under Medicare Part D, including health plans, PBMs, pharmaceutical manufacturers, drug wholesalers, and pharmacies.

## Regulatory Background Leading to the Final Rule

In recent years, the federal government has called for increased scrutiny over pharmaceutical manufacturer rebates. In our February 2019 Client Alert,[3] we outlined

[1] *See* Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76666 (Nov. 30, 2020), *available at* https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals [hereinafter "Final Rule"].

[2] *Id.* at 76691. The later effective date was designed to minimize disruption and to allow more time for compliance.

[3] *Epstein Becker Green Health Care & Life Sciences Client Alert,* "HHS OIG Proposes Anti-Kickback Safe Harbor Amendments to Regulate and Restrict the Provision of Manufacturer Remuneration to Plan Sponsors and PBMs" (Feb. 5, 2019), *available at* https://www.ebglaw.com/news/hhs-oig-proposes-anti-

government concerns regarding the impact of rebates on drug prices and costs and summarized preceding policy and legal developments, including the Trump administration's May 2018 *American Patients First* Blueprint[4] and the corresponding January 31, 2019, proposed rule ("Proposed Rule")[5] to amend the AKS safe harbors regarding rebates. Subsequent reports from the Office of the Actuary ("OACT") for the Centers for Medicare & Medicaid Services ("CMS"), Milliman, Inc., and the Wakely Consulting Group concluded that, if implemented, the Proposed Rule would significantly increase federal government drug spending and Medicare Part D premiums.[6]

Due to concerns about cost, negative stakeholder feedback, and the reduced likelihood of bipartisan legislation to address drug prices, the Trump administration appeared to have abandoned the Proposed Rule.[7] Nevertheless, on July 24, 2020, the Trump administration breathed new life into the proposed policy by issuing the "Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen" ("Executive Order"), which directed HHS to finalize the Proposed Rule with modifications.[8] Significantly—and likely in response to reports on the anticipated costs of the Proposed Rule—the Executive Order mandated that finalization of the Final Rule be contingent upon the Secretary of HHS's confirmation that it would "not be projected to increase Federal spending, Medicare beneficiary premiums, or patients' out-of-pocket costs."[9]

In compliance with the Executive Order's mandate, on November 20, 2020, the Secretary issued a confirmation.[10] Notably, however, in reaching this determination, the Secretary did not cite to any new studies or data to support his spending projections. Rather, the projections were based on his evaluation of the prior analyses in light of his industry experience.[11]

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[4] U.S. DEP'T OF HEALTH & HUMAN SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT REFERENCE BLUEPRINT (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[5] *See* Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019).

[6] *Id.* at 2358.

[7] *See, e.g.,* Dan Diamond, *White House kills drug rebate rule*, POLITICO (July 11, 2019), *available at* https://www.politico.com/newsletters/politico-pulse/2019/07/11/white-house-kills-drug-rebate-rule-678684; Caroline Humber & Bryan Pietsch, *White House scraps key plan to lower U.S. drug prices; may target drugmakers*, REUTERS (July 11, 2019), *available at* https://www.reuters.com/article/us-usa-healthcare-rebates/white-house-scraps-key-plan-to-lower-u-s-drug-prices-may-target-drugmakers-idUSKCN1U61J1?feedType=RSS&feedName=topNews.

[8] Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, Exec. Order No. 13939, 85 Fed. Reg. 45759 (July 24, 2020), *available at* https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/.

[9] *Id.*

[10] Press Release, U.S. Dep't of Health & Human Servs., Secretary Azar Confirmation In Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen (Nov. 20, 2020), https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html.

[11] *Id.*

## THE FINAL RULE

### Key Provisions and Differences from the Proposed Rule

*Removal of the "Discount Safe Harbor"*

As with the Proposed Rule, the Final Rule expressly removes AKS discount safe harbor protection for rebates in connection with the sale or purchase of drugs from manufacturers to Part D plans, either directly from the health plan or indirectly through a PBM contracted with the health plan, unless the price reduction would have been required by law.[12] The Final Rule accomplishes this goal by specifically excluding rebates from the definition of a "discount" within the discount safe harbor in 42 C.F.R. § 100.952(h). HHS makes clear in the preamble, however, that the discount safe harbor will continue to protect drug discounts to other entities such as "wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs."[13]

One significant difference between the Proposed Rule and the Final Rule is that the latter continues to allow AKS discount safe harbor protection for price reductions offered to Medicaid managed care organizations ("MCOs") contingent on formulary placement.[14] According to the OIG, to do otherwise would impose unnecessary costs on states, thereby undermining the policy goal of lowering out-of-pocket spending for beneficiaries.[15]

*New Safe Harbor for "Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products"*

Consistent with the Proposed Rule, the OIG finalized the addition of the new "Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products" ("POS reductions") safe harbor, which protects POS rebates offered by manufacturers for prescription drugs payable under Part D or Medicaid MCOs.[16] The POS reductions safe harbor specifically excludes from the definition of AKS "remuneration" any price reductions from manufacturers to plan sponsors for drugs payable in whole or in part by Part D or a Medicaid MCO if the arrangement meets the following three criteria:

- the price reduction is negotiated in advance, in writing, before the first purchase of the product at the reduced price;

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[12] *See* Final Rule, *supra* note 1, at 76690.
[13] *Id.* at 76694.
[14] *Id.* at 76683. *See also* HHS Fact Sheet, Trump Administration Finalizes Proposal to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Nov. 20, 2020), *available at* https://www.hhs.gov/about/news/2020/11/20/fact-sheet-trump-administration-finalizes-proposal-to-lower-drug-costs.html.
[15] Final Rule, *supra* note 1, at 76675.
[16] *Id.* at 76667 (to be codified at 42 C.F.R. §1001.952(cc).

- the price reduction may not involve a rebate unless the full value of the price reduction is "provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or series of point-of-sale chargebacks" or unless required by law; and

- the price reduction must be reflected in the dispensing price of the drug.

The Final Rule also clarified that POS price reductions given to Part D plan sponsors or Medicaid MCOs conditioned on formulary placement may qualify for safe harbor protection if the reduction requires no services, such as marketing or switching, and if all conditions of the POS reductions safe harbor are met. Moreover, with regard to value-based arrangements, the OIG provided that such arrangements would be analyzed, for purposes of the POS reductions safe harbor, on a case-by-case basis.[17]

In contrast to the Proposed Rule, the Final Rule altered the definition of a "chargeback"[18] to allow flexibility for parties to "structure back-end, point-of-sale chargeback processes that result in fully passed-through point-of-sale discounts."[19]

*New Safe Harbor for "PBM Service Fees"*

Also consistent with the Proposed Rule, the Final Rule creates the PBM Service Fees safe harbor, which excludes from the definition of AKS "remuneration" any payment from a manufacturer to a PBM for PBM services furnished to a plan if all the following conditions are met:

- The PBM must have a signed, written agreement with the manufacturer that:
    - covers all the services the PBM will provide in connection with the plans for the term of the agreement,
    - specifies each service to be provided, and
    - specifies the compensation of such services.
- The payment to the PBM:
    - must be "consistent with fair market value in an arm's-length transaction";
    - must be fixed and not be based on the percentage of sales; and

[17] *Id.* at 76678.
[18] "Chargebacks" or "point-of-sale chargebacks" are defined as payments by manufacturers "made directly or indirectly (through a PBM or other entity) to a dispensing pharmacy equal to the reduction in price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product**."** *Id.* at 76731 (to be codified at 42 C.F.R. § 1001.952(cc)(2)(ii)).
[19] *Id.* at 76698.

  - may not be determined in a manner that takes into account the volume or value of referrals or business generated between the PBM and the manufacturer or between the PBM and the health plans if the payment may be made, in whole or part, under any federal health care program.

- At least annually, the PBM must disclose in writing to the health plans with which it contracts the services rendered to each manufacturer. Upon the Secretary's request, the PBM must also disclose this information and the fees paid for each service.[20]

- The PBM services may not "involve counseling or promotion of a business arrangement or other activity that violates state or Federal law."[21]

The final element above was added to the Final Rule and was not included in the Proposed Rule. Additionally, the OIG clarified, within the preamble to the Final Rule, that the safe harbor applies only to services that are "legitimate," and not to arrangements for services that are "not necessary, are worthless, or are duplicative."[22]

**Other Final Rule Highlights**

*Swapping Arrangements by Private Plans*

In the Final Rule, the OIG warned against "swapping" or similar arrangements involving commercial plans, in which remuneration is structured as part of a "broader arrangement to induce referrals of federal health program business or patients."[23] The OIG cited its "long-standing concern" with questionable arrangements in which referrals are "carved out" for federal health care program beneficiaries or business.

*Application of the Discount Safe Harbor to PBMs*

Both the Proposed Rule and the Final Rule expressly confirm that any portion of a payment paid by the manufacturer to a PBM and retained by the PBM is not protected by the discount safe harbor.[24] The OIG does not consider (i) a PBM to be a buyer or (ii) the portion of payment retained by the PBM to be a price reduction.[25] Accordingly, even though the discount safe harbor provides protection to Medicaid MCOs, the OIG emphasized that neither the discount safe harbor nor the new safe harbor would protect rebates or other price reductions retained by a PBM from a manufacturer, even if that PBM is operating on behalf of a Medicaid MCO.

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[20] *Id.* at 76731 (to be codified at 42 C.F.R. § 1001.952(dd)(1)).
[21] *Id.* (to be codified at 42 C.F.R. § 1001.952(dd)(1)(ii)).
[22] *Id.* at 76713.
[23] *Id.* at 76678.
[24] *Id.* at 76679.
[25] *Id. citing* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 2020), https://www.federalregister.gov/citation/56-FR-35952.

**Impact on Stakeholders**

While the Final Rule removes AKS safe harbor protection for Part D rebates, the ripple effect of shifting to a POS rebate system would require stakeholders throughout the supply chain to reconsider their contractual and business arrangements.

*PBMs and Health Plans*

If implemented, PBMs and health plans would likely suffer the brunt of negative financial repercussions from the Final Rule. CMS's OACT has predicted that the shift to a POS rebate system will result in a loss of rebate revenue to plans, triggering an increase in premiums.[26] PBMs provide significant value by negotiating formulary rebates on behalf of health plans, and any reduction in formulary rebate dollars passed on to health plans would likely require PBMs to find other cost-saving strategies for their customers, such as more restrictive formulary designs or by lowering reimbursement to, or increasing fees payable by, pharmacies.[27]

*Drug Manufacturers*

Many brand drug manufacturers have supported the Final Rule.[28] To the extent the rulemaking lowers patient co-payments, it would improve patient drug access. Moreover, as an unintended consequence, removal of safe harbor protection could result in drug manufacturers retaining a portion of price concessions, which otherwise would be paid as formulary rebates.[29] Even so, drug manufacturers will still seek to secure preferred formulary status for their products, and, therefore, they will have a strong incentive to work with PBMs to restructure contracts to offer the lowest POS costs.

*Pharmacies and Wholesalers*

The Final Rule would require stakeholders to develop a new "charge back" system to make a pharmacy whole for discounts provided at the POS. Since the POS reductions safe harbor contemplates that the full value of the price reduction be paid to the pharmacy, pharmacies have a significant interest in the development of a "charge back" system that will make pharmacies whole and will do so without pharmacies being left waiting for reimbursement. Because wholesalers are the primary sellers of products to pharmacies, they may be in the best position to pay chargebacks to the pharmacies under a new "charge back" system.

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[26] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., OFF. OF THE ACTUARY, PROPOSED SAFE HARBOR REGULATION (Aug. 30, 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf.

[27] *See* Jake Laisner, Kaite Holcomb, & Troy Filipek, *Impact of Potential Changes to the Treatment of Manufacturer Rebates*, Milliman, Inc. (Jan. 31, 2019), https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf.

[28] *See* Tom Wilbur, *Final Rebate Rule Represents Right Way to Change Medicare*, PhRMA (Dec. 1, 2020), https://catalyst.phrma.org/final-rebate-rule-represents-right-way-to-change-medicare.

[29] CMS estimated that drug manufacturers would retain 15 percent of existing price concessions and stand to gain up to $17 billion to $40 billion over 10 years. *See* Final Rule, *supra* note 1 at 76725.

**Potential Actions by the Biden Administration and the 117th Congress**

*Biden Administration*

The Biden administration has announced that it will issue a memorandum, to be published in the *Federal Register* and effective Inauguration Day, which will block actions taken by the outgoing Trump administration that have not yet become official.[30] While the informal announcement only addressed new regulations that have yet to be published in the *Federal Register,* historically, certain prior memoranda have directed agencies to extend the effective dates of the published and final regulations, or to reopen such regulations and solicit comments in anticipation of publishing new proposed regulations to modify or rescind the final regulation.[31] If the effective dates of the Final Rule are similarly extended, stakeholders may wait to expend resources on restructuring their business arrangements in response to the Final Rule.

At some point in the future, the Biden administration will need to either rescind, amend, or proceed with the Final Rule. Amending or rescinding the Final Rule will require notice with a comment period. Stakeholders should not assume that the Biden administration will rescind the Final Rule, as President-Elect Biden's nominee for HHS Secretary, California Attorney General Xavier Becerra, has openly expressed concerns with the impact of formulary rebates on competition and drug prices.[32] In the end, the Biden administration may decide to work with the Final Rule through amendments, rather than rescinding it outright.

To the extent that the Biden administration opposes the Final Rule, it could also instruct HHS and the Department of Justice not to defend legal challenges to the Final Rule, such as the recent lawsuit discussed below.

*Congress*

In conjunction with the Biden administration, the incoming Congress may decide to use its legislative powers to overturn the Final Rule. Under the Congressional Review Act, a new Congress may pass a joint resolution, signed by the President, to overturn any major final rule that has been released in the recent past.[33] This may be an attractive option for the new Congress and President to address last-minute rulemaking of the prior outgoing administration, such as the Final Rule.

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[30] *See* Emma Kinery and Jennifer A. Dlouhy, *Biden to Block Still-Pending Trump Administration Regulations*, BLOOMBERG LAW NEWS (December 31, 2020).

[31] *See* Memorandum for the Heads of Executive Departments and Agencies; Regulatory Freeze Pending Review, 82 Fed Reg. 8346 (January 24, 2017); Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 4435 (January 26, 2009); Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7702 (January 24, 2001).

[32] *See* Letter from Xavier Becerra, Att'y Gen., State of California, to Sec. April Tabor, Acting Sec'y, Federal Trade Commission, on AbbVie and Allergan, 6 (June 11, 2020).

[33] Enacted as a part of the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121) and codified at 5 U.S.C. §§ 801-808.

**PCMA Lawsuit**

At least one stakeholder, the Pharmaceutical Care Management Association ("PCMA"), has recently challenged the legality of the Final Rule.[34] PCMA has alleged that the Final Rule exceeds HHS and the OIG's statutory authority, violates the Administrative Procedures Act's ("APA's") notice-and-comment-rulemaking requirement, and is arbitrary and capricious.[35] PCMA has argued that the Final Rule marked a new rulemaking process, following the withdrawal of the Proposed Rule, and, therefore, HHS and the OIG violated the APA by failing to provide for a new comment period prior to publishing the Final Rule.[36] PCMA also argues that HHS lacks authority to subject retrospective manufacturer rebates to AKS liability, given that the statutory discount exception, within the AKS, arguably applies to such rebates.[37] Finally, PCMA argues that the Final Rule is arbitrary and capricious insofar as the Final Rule rests on a premise that changes to the treatment of rebates will not increase premiums or federal spending, when, according to PCMA, all evidence is to the contrary, allegedly undermining HHS's publicly stated goal of promoting value-based arrangements, and the effective date of the Final Rule is not aligned with the CMS schedule for implementing Part D program bid requirements.[38]

**Conclusion**

Due to the new political landscape of 2021 and expected legal challenges, the fate of the Final Rule is in question. Regardless of whether the Final Rule stands or falls, retroactive formulary rebates and their impact on out-of-pocket costs will continue to be a focus of attention, including possible future regulatory or legislative action. In the meantime, drug manufacturers, Part D plan sponsors, and PBMs need to consider whether to restructure their rebate arrangements based on the rule as it currently stands in advance of the January 1, 2022, effective date of its key provision. Given the scrutiny of retroactive drug formulary rebates, stakeholders in the commercial arena will likely continue to experiment with modified forms of price concessions, including POS rebates. Finally, all players in the drug supply chain will need to closely monitor legal and operational developments regarding rebates, which are likely to evolve further in upcoming years.

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[34] Complaint, *Pharmaceutical Care Management Association v. United States Department of Health and Human Services, et al.*
[35] *Id.* at 2.
[36] *Id.* at 6 and 8.
[37] *Id.* at 7.
[38] *Id.*at 8-9.

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