

HHS OIG Proposes Anti-Kickback Safe Harbor Amendments to Regulate and Restrict the Provision of Manufacturer Remuneration to Plan Sponsors and PBMs

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On January 31, 2019, the Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) issued a proposed rule (“Proposed Rule”) that would restrict safe harbor protection under the federal Anti-Kickback Statute (“AKS”) for pharmaceutical rebates, while permitting certain pharmaceutical manufacturer price reductions at the pharmacy point of sale (“POS”) and certain pharmacy benefit manager (“PBM”) service fees.¹ As rebates paid by pharmaceutical manufacturers to health plan sponsors and PBMs are a central feature of the U.S. drug distribution and reimbursement system, the Proposed Rule represents a groundbreaking reform measure that could dramatically impact consumers and supply chain stakeholders. If finalized, the Proposed Rule would go into effect on January 1, 2020. OIG will be accepting public comments on the Proposed Rule until 5 p.m. EDT on April 8, 2019.

Background on Drug Rebates and Related Issues and Reforms

In the preamble to the Proposed Rule, OIG explicates its view that the provision of pharmaceutical manufacturer rebates and price concessions has distorted drug distribution and reimbursement in the United States. In particular, OIG maintains that rebate payments under the federal health care programs, such as Medicare and Medicaid, have conflicted with the purposes of the AKS and have increased costs for federal health care program beneficiaries and for the federal and state governments.

Pharmaceutical manufacturers typically provide price concessions to health plan sponsors and PBMs to achieve more favorable formulary status for their drugs and to promote market share for certain branded drug products. While they have been

¹ HHS-OIG, Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019).

successful in extracting substantial amounts of price concessions from manufacturers, many health plan sponsors and PBMs have been allocating large portions of these pricing concessions to lower plan costs and premiums rather than to lower prices at the pharmacy POS. This phenomenon has contributed to the so-called “gross-to-net bubble,” or spread between drug list prices and the net costs borne by health plan sponsors after accounting for manufacturer price concessions. OIG notes that, while this dynamic favors many beneficiaries through reduced premiums, it negatively impacts sicker beneficiaries who often must pay substantial cost sharing based on undiscounted list prices for expensive drugs.

OIG identifies drug rebates as having contributed to the complexity and lack of transparency in drug pricing, which has engendered public confusion and opportunities for stakeholder gaming. Also, OIG maintains that PBMs’ receipt of percentage-based service fees from manufacturers has created conflicts of interest that undermine PBMs’ duty to reduce drug costs for their health plan sponsor clients. Finally, OIG posits that the industry’s reliance upon rebate-based remuneration may serve to incentivize manufacturers to inflate drug list prices, skew formulary placement decisions, and thwart competition from lower-cost drugs.

The Proposed Rule is the latest manifestation of the federal government’s evolving reform efforts that target drug manufacturer rebates. In November 2017, the Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule and Request for Information (“November 2017 RFI”) announcing its plan to require Medicare Part D plan sponsors to pass through a certain portion of rebates and other price concessions to beneficiaries through lowered drug prices at the pharmacy POS.² CMS contended that, by failing to pass through significant portions of price concessions in an effort to keep premiums low, Part D plan sponsors have been gaming the Part D system and shifting drug costs to beneficiaries, drug manufacturers, and the government. In its May 2018 *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (“*Blueprint*”), the Trump administration highlighted the widening gap between list and net drug prices. In the *Blueprint*, the Trump administration proposed to restrict manufacturer price concessions under Medicare Part D and to remove AKS safe harbor protection for rebates. Following the *Blueprint*’s release, Secretary of HHS Alex Azar and Food and Drug Administration Commissioner Scott Gottlieb have publicly criticized the role of rebates and hinted at future reform initiatives.³ Due to these developments, many industry observers have anticipated the sort of dramatic regulatory reforms that directly govern drug rebates that are now set forth in the Proposed Rule.

² See Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. 56336 (Nov. 28, 2017).

³ See, e.g., Alex M. Azar II, Fixing Healthcare: Driving Value Through Smart Purchasing and Policy (May 16, 2018) (proposing to “eliminate rebates and forbid remuneration from pharmaceutical companies”), available at: <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/fixing-healthcare-driving-value-through-smart-purchasing-and-policy.html>.

Proposed AKS Safe Harbor Amendments

The AKS provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives “remuneration” to induce or reward the referral of business reimbursable under any federal health care programs.⁴ Additionally, the AKS explicitly identifies rebates, along with kickbacks and bribes, as remuneration.⁵

The Proposed Rule outlines three interrelated changes to the AKS safe harbors that are designed to regulate remuneration paid among manufacturers, plan sponsors, and PBMs under Medicare Part D and the Medicaid managed care organization (“MCO”) programs.

First, the Proposed Rule proposes to amend the existing discount safe harbor to carve out price reductions made by manufacturers to Medicare Part D plan sponsors and Medicaid MCOs and their contracting PBMs.⁶ To this end, the Proposed Rule would expressly exclude such activity from the safe harbor definition of “discount,” which is then incorporated into the related definition of “rebate.”

Second, the Proposed Rule would create a new safe harbor to protect “point-of-sale price reductions” on drugs offered by manufacturers to Medicare Part D plan sponsors or Medicaid MCOs that satisfy the following three criteria:

- (1) The price reduction is “set in advance,” meaning that the price is fixed and disclosed in writing to the plan sponsor or PBM at the time of initial purchase.
- (2) The price reduction does not involve a rebate unless its full value is provided to the dispensing pharmacy through a chargeback or series of chargebacks, or if the rebate is required by law. OIG proposes to define a “chargeback” as a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Part D plan sponsor, Medicaid MCO, or PBM and the manufacturer.
- (3) The price reduction is completely reflected in the price the pharmacy charges the beneficiary at the POS.

Third, the Proposed Rule would introduce another safe harbor for “PBM service fees” that protects fixed fees paid by manufacturers to PBMs for PBM services⁷ that satisfy the following three criteria:

⁴ 42 U.S.C. § 1320a-7b.

⁵ 42 U.S.C. § 1320a-7b(1).

⁶ 42 C.F.R. § 1001.952(h).

⁷ OIG declined to define “pharmacy benefit management services” because such services could evolve over time. However, OIG noted that such services include contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and

- (1) A manufacturer and a PBM have a written agreement that (a) covers all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans for the term of the agreement and (b) specifies each of the services to be provided by the PBM and the compensation for such services.
- (2) Compensation paid to the PBM must (a) be consistent with fair market value in an arm's length transaction; (b) be a fixed payment, not based on a percentage of sales; and (c) not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole or in part under a federal health care program.
- (3) PBMs must disclose in writing to each health plan with which they contract at least annually, and to the Secretary of HHS upon request, the services they rendered to each manufacturer that are related to the PBMs' arrangements with that health plan and the associated costs for such services.

If the proposed changes are implemented, stakeholders operating under the Medicare Part D and the Medicaid MCO programs would no longer be able to rely upon the discount safe harbor to protect drug rebates from liability under the AKS. Instead, these arrangements would likely need to be structured to fit within the narrower bounds of the new POS price reductions safe harbor by ensuring that any discounts are set in advance and passed through to patients at the pharmacy POS. In addition, manufacturers and PBMs would have a new pathway for safe harbor protection for PBM service fees. OIG recognizes that certain remuneration paid by manufacturers to PBMs might not implicate the AKS or otherwise be protected under other safe harbors. Nevertheless, percentage-based PBM service fees tied to drug sales would be deemed suspect under the AKS because they pose a higher risk of abuse and conflicts of interest. In addition, OIG is considering whether to require PBMs to demonstrate that such manufacturer service fee arrangements do not result in duplicative payments ("double dipping") for PBM services that a PBM already is providing on behalf of health plan sponsor.

The Proposed Rule's Scope of Application

Although the Proposed Rule would have far-reaching consequences, its scope of application is more circumscribed than the overall AKS, which, in its broadest application, can affect activities under all of the federal health care programs. As written, the AKS safe harbor amendments would directly affect rebates and other forms of remuneration paid by drug manufacturers to plan sponsors and PBMs under Medicare Part D and Medicaid MCO programs in connection with purchases of prescription drugs and biologics. Notably, the safe harbor amendments in the Proposed Rule would not directly affect medical

managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.

devices or supplies that do not fall within the definition of “drug” or “biological” under the Social Security Act.⁸ Nor would the Proposed Rule’s changes affect drug discounting activities conducted under other federal health care programs (e.g., Medicare Part B, TRICARE, etc.) or by other supply chain stakeholders (e.g., hospitals, physicians, and wholesalers). However, OIG is accepting comments on whether the amendments to the safe harbors should be extended to apply to other federal health care programs, such as Medicare Part B.

The Proposed Rule also would not directly affect drug discounting activities under commercial health care plans. In its accompanying Fact Sheet,⁹ OIG noted that “Congress has more power to prohibit rebates in commercial insurance,” thereby implying that OIG may lack authority to implement reforms of this nature in the commercial space, which could only be effectuated through federal legislation.¹⁰ Nevertheless, OIG cited its longstanding policy view that discounts “offered to one payor but not to Medicare or Medicaid” are unlawful where they comprise disguised remuneration that “serve as inducements for the purchase of federally reimbursable products.” This statement serves as a pointed reminder for stakeholders to avoid creating any real or perceived unlawful nexus between discounting activities under commercial programs and the referral of federal health care program business. Finally, the Proposed Rule and similar drug rebate reforms will likely have substantial indirect effects in the commercial arena. Such impacts already have been observed following publication of the November 2017 RFI on Part D drug rebate pass-through and the *Blueprint*, as commercial plans have begun to voluntarily engage in rebate pass-through, and PBMs are experimenting with no-rebate formulary and reimbursement models. Given the size of the Medicare Part D and Medicaid MCO programs—which have experienced substantial enrollment growth in recent years—dramatic reforms in these areas will likely have redounding effects on health plans operating in the commercial space.

Projecting the Impacts of the Proposed Rule’s Safe Harbor Amendments

The Proposed Rule’s stated objective is to “curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs.” OIG is soliciting comments on whether the Proposed Rule’s safe harbor amendments would support these goals and on their

⁸ Social Security Act, section 1927(k)(2)(A), (B), and (C). OIG is also soliciting comments on the definition of the terms “manufacturer,” “wholesaler,” “distributor,” “pharmacy benefit manager,” and “prescription pharmaceutical product” in the Proposed Rule’s safe harbor amendments.

⁹ HHS, Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Jan. 31, 2019), available at: <https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html>.

¹⁰ To this end, Congress would need to create a new statutory scheme or modify existing laws, such as the Employee Retirement Income Security Act of 1974 (or “ERISA”), the Internal Revenue Code, and the Public Health Services Act, which are federal statutes that govern the commercial insurance markets.

projected effects on the range of stakeholders, including beneficiaries, manufacturers, the federal government, plan sponsors, PBMs, and pharmacies.

While the amendments would likely have large and widespread impacts on the U.S. drug distribution and reimbursement system, OIG acknowledges that there is significant uncertainty about the nature and extent of these impacts. This stems primarily from the difficulty of predicting how pharmaceutical manufacturers, PBMs, and health plan sponsors will adjust their strategic behavior. To shed light on these issues, OIG is releasing, in combination with the Proposed Rule, the results of three studies conducted by the CMS Office of the Actuary and independent actuarial firms Milliman and the Wakely Consulting Group.¹¹ The Proposed Rule summarizes these studies' findings regarding the effects of the AKS safe harbor amendments, which varied considerably based on the studies' behavioral assumptions. OIG is inviting comments on the propriety of the studies' analyses and their underlying assumptions.

Despite the range of findings, the AKS safe harbor amendments in the Proposed Rule are projected to lead to decreases in cost-sharing amounts paid by beneficiaries with coinsurance or deductible plans at the pharmacy POS for rebated brand-name drugs. In addition, plan premiums are projected to increase for beneficiaries, with Part D premium increases ranging from \$3.20 to \$5.64 per beneficiary per month in 2020. The studies generally found that savings from reduced cost sharing would exceed the costs from increased beneficiary premiums. However, more beneficiaries would pay more for premiums than they would save in cost sharing. This indicates that the individual cost benefits will vary and that a large portion of savings would be enjoyed by beneficiaries who purchase more expensive brand-name drugs. Due to the safe harbor amendments, federal government payments to plan sponsors for direct subsidies, subsidies for low-income enrollees' premiums, and cost sharing are slated to increase but be partially offset by reduced reinsurance payments. The studies found that net government payments would increase by 2 to 14 percent in the absence of behavior changes but would increase by only 1 to 3 percent if manufacturer and plan behavior caused net prices to decrease; on the other hand, if net drug prices increase, government payments would increase to a greater extent.

Practical, Legal, and Policy Issues Raised by the Proposed Rule

For stakeholders impacted by the Proposed Rule, perhaps the most pressing issue is the anticipated timing of the proposed AKS safe harbor amendments, which are scheduled to become effective on January 1, 2020. OIG is soliciting comments on whether that compliance deadline would afford stakeholders sufficient time to make necessary contractual adjustments, while acknowledging that the proposed AKS safe harbor amendments in the Proposed Rule may require the restructuring of existing discount arrangements. Many commenters will likely take issue with the aggressive transition

¹¹ The three actuarial studies will be posted as supplementary material in the docket for the Proposed Rule at www.regulations.gov.

timeline, given that plan sponsors must engage in manufacturer negotiations and submit plan bids well in advance of the 2020 benefit year. As an alternative, OIG is offering to delay the compliance deadline from January 1, 2020, to January 1, 2021, to lower transition costs for affected entities.

The Proposed Rule also raises a series of legal issues that could dramatically influence future stakeholder actions and impacts. First and foremost, the question arises as to whether, in the wake of the amendments, the provision of manufacturer drug rebates under Medicare Part D and Medicaid MCO programs could receive protection under the AKS's statutory exception for discounts¹² or any of the other AKS exceptions or regulatory safe harbors. Although OIG does not expansively address this question in its preamble discussion, it notes the "Secretary's view" that "[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price" and therefore would not qualify for protection under the AKS discount exception.

In addition to fraud and abuse issues under the AKS, the Proposed Rule could generate antitrust concerns regarding the form and nature of manufacturer price concessions. The industry's reliance upon rebates as the primary form of remuneration paid by manufacturers to plan sponsors and PBMs largely stems from the terms of a settlement agreed to by drug manufacturers to resolve class action antitrust claims filed under the Sherman and Robinson-Patman Acts.¹³ Following the 1996 settlement, many manufacturers have maintained that rebates are preferable from a practical and legal standpoint due to antitrust concerns. Stakeholders will need to reassess these antitrust questions in light of the Proposed Rule's safe harbor amendments, which narrow protections to POS price concessions that are set in advance.

The Proposed Rule's safe harbor amendments could likewise disrupt value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCO programs. Acknowledging this issue, OIG noted that it "does not intend for this proposal to have any effect on existing protections for value-based arrangements" in this setting. However, many value-based arrangements rely on rebates and similar price concession mechanisms. Therefore, stakeholders will need to carefully analyze the extent to which existing and future value-based arrangements could be impacted by the proposed POS price concessions. Manufacturers, plan sponsors, and PBMs that interpret the proposed regulatory language as creating barriers may need to advocate for additional safe harbor amendments that would explicitly address and protect value-based arrangements.

In view of the Proposed Rule's potentially disruptive consequences, OIG offers the public in the Proposed Rule, as regulatory alternatives, the options of taking no action and maintaining the status quo or finalizing the drug rebate pass-through reforms under Medicare Part D that are outlined in the November 2017 RFI. Notably, the latter reform

¹² 42 U.S.C. § 1320a-7b(b)(3)(A).

¹³ See generally *In re Brand Name Prescription Drugs Antitrust Litigation*, No. 94-C-897 (N.D. Ill. 1994).

would address many of the same concerns cited by OIG in relation to the “gross-to-net bubble.” Therefore, stakeholders may seek to opine on whether the November 2017 RFI’s pass-through mandate or the Proposed Rule’s AKS safe harbor amendments would serve as the optimal means to achieve the government’s goals, or whether either of these avenues would only serve to exacerbate underlying challenges.

Stakeholders should take the time to review the Proposed Rule and consider commenting where they deem appropriate by 5 p.m. EDT on April 8, 2019.

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