# OIG FINALIZES REBATE RULES: REMOVAL OF SAFE HARBOR PROTECTIONS FOR REBATES AND CREATION OF NEW SAFE HARBORS FOR OTHER DISCOUNTS AND SERVICE FEES

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**Health Care and FDA Alert**

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On 20 November 2020, the United States Department of Health and Human Services (HHS) Office of the Inspector General (OIG) released its final rule on drug rebates entitled "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."[1] As the title implies, this final rule clarifies and amends the discount safe harbor at 42 C.F.R. § 1001.925(h) under the federal Anti-kickback statute (AKS) such that rebates paid from drug manufacturers to Medicare Part D prescription drug plan sponsors or their pharmacy benefit managers (PBMs) are not protected from liability under the discount safe harbor. The rule also adds a new safe harbor for point-of-sale reductions in price that are passed on directly to a buyer (a defined term under the rule) and an additional safe harbor for "legitimate" service fees paid to PBMs by drug manufacturers.

The rule had a non-linear path to issuance. The proposed rule[2] was released in February of 2019, but was ultimately withdrawn on 10 July 2019.[3] However, the rule was resurrected when, on 24 July 2020, President Trump issued an Executive Order[4] directing Secretary Azar of HHS to resume and complete the rulemaking that the proposed rule initiated. (For more on this Executive Order, please read our analysis linked here.)

HHS' stated rationale behind the rule is that it intends "to create incentives to lower list prices and reduce out of pocket spending on prescription drugs by delivering discounts directly at the pharmacy counter."[5] Specifically, HHS identified three "harms" from this current rebate structure.[6] These include:

- financial burdens experienced by some Medicare beneficiaries, such as "if a beneficiary is paying coinsurance on a drug subject to a rebate, the beneficiary pays a percentage of a price that more closely resembles the list price than the net price;"[7]
- "increasing list prices, preventing competition to lower drug prices, discouraging the use of lower-cost brand or generic drugs, and skewing formulas used to determine pharmacy reimbursement or Medicaid rebates;"[8] and
- transparency in the current system.[9]

Thus, HHS enacted three reforms to address these three identified harms. Overall, key takeaways include:

- The incoming Biden administration may pause or unwind the implementation of such rules, given the potential to increase federal healthcare spending. HHS acknowledges that given the dynamic nature of potential stakeholder responses to the rule, it could result in savings of $100 billion or increased costs of up $196 billion.
- Stakeholders, including pharmacies, manufacturers, PBMs, and wholesalers, must establish chargeback procedures to implement the new point-of-sale safe harbor.
- Pharmaceutical manufacturers and PBMs now have a new safe harbor around which to structure any fixed service fees paid between the entities.

## AMENDMENTS TO THE DISCOUNT SAFE HARBOR

The amendment to the discount safe harbor is specifically targeted to rebates paid between drug manufacturers and PBMs. Currently, Medicare beneficiaries—and generally all consumers—pay coinsurance for prescription drugs that is generally calculated as a percentage of the list price. However, Medicare Part D plan sponsors sometimes negotiate a rebate on many drugs with the drug's manufacturer so that the plan pays less for the drug than what the Medicare beneficiary was required to pay at the point-of-sale. Alternatively, PBMs often negotiate such rebates on behalf of the Medicare Part D plan and may pass all or a portion of the rebate on to the sponsor. Sponsors have maintained, whether received directly or through a PBM, that such rebate payments lower premiums for Medicare beneficiaries. However, it is HHS' position that these rebates result in increased prices paid by Medicare beneficiaries.

Therefore, to address HHS' concerns regarding financial burdens for Medicare beneficiaries and largely in line with the proposed rule, the final rule “remove[s] safe harbor protection for reductions in price in connection with the sale or purchase of prescription pharmaceutical products from manufacturers to plan sponsors under Part D, either directly or through PBMs acting under contract with them, unless the reduction in price is required by law.”[10] Importantly, as opposed to the proposed rule, the final rule did not finalize HHS' “proposal to exclude from protection those reductions in price from pharmaceutical manufacturers to Medicaid MCOs.”[11] These changes take effect 1 January 2022, requiring that plan sponsors and manufacturers negotiate these prices in 2021 for plans that will be effective in 2022.

## NEW POINT-OF-SALE SAFE HARBOR

Coinciding with the removal of the discount safe harbor protections for rebates between Medicare Part D plan sponsors, PBMs, and manufacturers, the final rule also creates a new safe harbor, to be codified at 42 C.F.R. § 1001.952(cc), that exempts from the definition of remuneration “certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations (MCOs) that meet certain criteria.”[12] Specifically, the rule states, in relevant part:

(1) As used in section 1128B of the Act, “remuneration” does not include a reduction in price from a manufacturer to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization, provided the following conditions are met with regard to that reduction in price:

(i)The manufacturer and the plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either, set the reduction in price in advance, in writing, by the time of the first purchase of the product at that reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee;

(ii)The reduction in price does not involve a rebate unless the full value of the reduction in price 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 is required by law; and

(iii)The reduction in price must be completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary.[13]

Importantly, as the rule states, the discount must be reflected in the price charged to the patient at the point-of-sale. Importantly, HHS reiterates that "as stated in the preamble to the proposed rule . . . any portion of a payment (whether it is called a "rebate" or something else) that a manufacturer pays to a PBM that is retained by the PBM and not passed through to the buyer never was protected under the discount safe harbor."[14] It states further that "[t]he discount safe harbor protects a reduction in price to a buyer. A PBM is not a buyer, and the portion of a payment from a manufacturer to a payor that is retained by a PBM is not a reduction in price."[15]

Furthermore, HHS clarifies that "reductions in price given to Part D plan sponsors or Medicaid MCOs that are conditioned on formulary placement of a particular drug can qualify for protection under the new safe harbor for point-of-sale reductions in price,"[16] as they frequently increase competition between manufacturers and, therefore, benefit Medicare beneficiaries. However, there cannot be any required services, such as marketing or switching, in connection with such formulary placement.[17]

The new safe harbor will become effective 60 days after becoming finalized.[18] While some comments objected to this early effective date as compared to January 2022 effective date for the elimination of the discount safe harbor protections for certain rebates, HHS noted that this new safe harbor "does not require any party to take any action within a particular timeframe. The safe harbor may be used starting 60 days after the final rule is published, but it is just another option for protecting discounts."[19]

## FIXED FEE SAFE HARBOR

Additionally, the final rule also creates another new safe harbor, to be codified at 42 C.F.R. § 1001.952(dd), "for fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet specified criteria."[20] Specifically, the rule permits the payment of a "flat, fixed fee" from manufacturers to PBMs for the services the PBM provides the manufacturer.[21] Specifically, the following conditions must be met:

(i) The PBM has a written agreement with the pharmaceutical manufacturer, signed by the parties, that 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 specifies each of the services to be provided by the PBM and the compensation associated with such services.

(ii) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(iii) The compensation paid to the PBM:

(A) Is consistent with fair market value in an arm's-length transaction;

 

(B) Is a fixed payment, not based on a percentage of sales; and

(C) Is not 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 Medicare, Medicaid, or other Federal health care programs.

(iv) The PBM discloses in writing (A) to each health plan with which it contracts at least annually the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan; and (B) to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan and the fees paid for such services.[22]

OIG—in a deviation from its usual position—permits per transaction fees when the fee is set in advance and even if the number of transactions is not known when the fee is set. However, it does not permit the fee to change with the value or volume of transactions that occur between the parties.[23]

This new safe harbor will also become effective 60 days after the rule's publication in the Federal Register.

## SCOPE OF AMENDMENTS AND NEW SAFE HARBORS

As noted above, although the *proposed rule* included Medicaid MCO's in its purview as the elimination of discount safe harbor protection for rebate payments, the final rule did not include Medicaid MCOs and applies only to Part D plan sponsors. However, Medicaid MCO's are included in the new safe harbor for point-of-sale rebates should they wish to take advantage of this safe harbor.

Additionally, HHS notes that it “intended for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payers in other Federal health care programs.”[24] Furthermore, the amendments to the discount safe harbor do not apply to Part B drugs, as “Part B drugs are reimbursed under Medicare fee-for-service based on the average sales price (ASP), which already accounts for rebates and other price concessions.”[25]

For commercial plans, OIG reiterated that the scope of the AKS is limited to federal health care program business.[26] OIG, however, cautions that the scope of the AKS does implicate swapping arrangements, in which discounts are given on private pay business to induce the referral of business for federal health care program beneficiaries.[27]

## CHARGEBACKS

As contemplated under the proposed rule, the final rule recognizes that the fees pharmacies collect from consumers at the point-of-sale will include the discount price, but that this is unlikely to be the price that the pharmacy paid the manufacturer for the drug. Therefore, the pharmacies will have to be “made whole” through the chargeback process. Called a “point-of-sale chargeback” under the rule, OIG declined to set a formal process for reconciling these chargebacks, but noted that wholesalers may be in the best position to effectuate the chargeback process because of their position in the supply chain distribution channel.[28]

 

## MEDICARE BENEFICIARY COST SHARING OBLIGATIONS AND ULTIMATE PRICES

HHS' examples for calculation of the point-of-sale rebates recognizes that, while the overall goal is to reduce Medicare beneficiaries' spending on prescription drugs, it intends for these individuals to keep some cost sharing obligations and cannot be applied to eliminate all such expenses, unless they are in the deductible phase of their plan.[29] However, the beneficiary may still see a reduction in price as the pharmacy counter, as their coinsurance or full price paid for the drug will reflect the discount at the point-of-sale, which previously was not captured in any of the beneficiary's payments. Specifically, HHS provided the following example:

[A] PBM has negotiated a rebate with the manufacturer, of 30 percent of the WAC/list price ($30), which is passed on entirely to the plan sponsor. This rebate does not reduce the price charged at the pharmacy counter or the beneficiary's out-of-pocket cost, and the beneficiary's $26 coinsurance is actually 35 percent of the net cost of the drug ($104-$30), compared to the 25 percent coinsurance described in the benefits summary (which is based on negotiated pharmacy reimbursement and not net price). Thus, in this example, the plan receives back $30 in rebates, reducing the net cost for the drug to $74 (i.e., $104-$30).

[Using this example] if the rebate were fully reflected in the point-of-sale price, the beneficiary's cost-sharing obligations would drop from $104 to $74 if the beneficiary were still in the deductible phase, and from $26 to $18.50 if she had a coinsurance obligation of 25 percent. The plan's share of the discount would be proportional to the coinsurance: the plan would get no share of the discount if the beneficiary were to pay full cost, but it would get 75 percent of the discount if the beneficiary had 25 percent coinsurance.[30]

Thus, HHS is hopeful that these measures will result in increased cost savings for Medicare beneficiaries at the point-of-sale.

## CONCLUSION

Any cost savings to the federal government is still unknown. As a practical matter, OIG notes that the actuarial impact analysis swings broadly on one end from a potential $100 billion in reduced federal spending if all rebates are converted into “list price concessions and Part D plans exert greater formulary control” to the other extreme of an increase in $196 billion “if manufacturers reduce price concession in Part D.”[31]

Two significant hurdles to these rules and their implementation may be the upcoming Biden administration's as-of-yet unknown response to these rules, including whether there is potential that they may be withdrawn or their implementation delayed while the incoming leadership reviews their effects. (For more on the Biden administration's potential responses, please read our analysis linked here.)

K&L Gates' health care practice regularly advises clients on pharmaceutical pricing matters and will continue monitoring the impact of these new regulations. Contact the authors of this article or your K&L Gates lawyer for assistance or to learn more about the potential impact of the changes outlined in this alert.

# FOOTNOTES

[1] Department of Health and Human Services, Office of Inspector General, HHS, 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, RIN 0936-AA08, at 1, *available here* (Final Rule).

[2] 84 Fed. Reg. 2340 (Feb. 6, 2019).

[3] OIRA Conclusion of EO 12866 Regulatory Review, here.

[4] Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, Whitehouse.gov (July 24, 2020), *available here*. *See* 85 FR 45,759 (July 29, 2020).

[5] HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter, Press Release, here.

[6] Final Rule at 14.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id*. at 7.

[11] *Id*. at. 272.

[12] *Id*. at. 8.

[13] *Id*. at 341–42.

[14] *Id*. at 74.

[15] *Id*.

[16] *Id.* at 93–94.

[17] *Id*. at 94.

[18] The final rule has not yet been published in the Federal Register.

[19] *Id*. at 168.

[20] *Id*. at 8.

[21] *Id*. at 231.

[22] *Id*. at 342–44.

[23] *Id*. at 244–45.

[24] *Id*. at 145.

[25] *Id*. at 146.

[26] *Id*. at 61.

[27] *Id*.

[28] *Id*. at 183.

[29] *Id*. at 88.

[30] *Id*. at 220–22.

[31] *Id*. at 289.

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