PUBLICATION

HHS/OIG Finalizes Rule Stripping PBM Rebates of Safe Harbor Protection

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UPDATE (February 19, 2021): The Pharmaceutical Care Management Association filed suit on January 12, 2021, challenging the final rule as it relates to PBM rebates (*Pharmaceutical Care Management Association v. United States Department of Health & Human Services et al.*, No. 1:21-cv-00095 (D. DC.)). On January 30, 2021, the court postponed the effective date of the PBM rebate provisions until January 1, 2023. OIG issued a Federal Register Notice on February 19, 2021, implementing the court-ordered delayed effective date.

UPDATE (February 1, 2021): On January 29, 2021, HHS issued a notice to be published in the February 2, Federal Register, delaying the effective date of those provisions of the regulation that were to take effect on January 29, 2021. The new effective date is March, 22, 2021. The notice was issued in accordance with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," and in light of the pendency of litigation challenging the final rule. The provisions of the rule relating to PBM rebates scheduled to take effect on January 1, 2022, are not affected by this notice.

Original Alert: On November 20, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) issued a Final Rule to finalize a February 6, 2019 proposal stripping rebates received from drug manufacturers by pharmacy benefit managers (PBMs) from safe harbor protection under the Anti-Kickback Statute (AKS), creating new safe harbors to incentivize point-of-sale (POS) discounts passed on to patients, and protecting certain PBM fees. While HHS/OIG made some modifications to the proposed rule, the main thrust of the proposal was unchanged.

The proposed regulation was controversial, with significant objections raised by the PBM sector. Beneficiary advocates also expressed concern that the proposed rule, if finalized, would increase premiums for beneficiaries under Medicare Part D. It is likely that the Final Rule will be challenged in court, and it is not clear whether the incoming Biden administration will take steps to prevent implementation.

The Final Rule has three main components, which are discussed below.

Removal of Safe Harbor Protection for PBM Rebates

Currently manufacturers often pay rebates to PBMs in return for favorable formulary placement. Manufacturers typically pay the rebates retrospectively, after initially selling a drug at a wholesale list price substantially higher than the net price, post-rebate. In the Preamble, HHS/OIG states its view that this rebate framework incentivizes manufacturers to increase list prices and provide larger rebates. Although this may ultimately result in lower net drug prices, these lower prices are often not passed on to beneficiaries or to the Medicare program. This occurs because both patient responsibility payments and federal health care program expenditures are often tied to list prices, which do not reflect the amount of the rebates. The Preamble further states that this may create "perverse incentives" that reward manufacturers for increasing list prices while increasing patient out-of-pocket costs.

Historically, drug manufacturers have relied on a statutory exception and an HHS/OIG safe harbor for "discounts" to protect PBM rebates from AKS enforcement action. The final rule strips such payments from

safe harbor protection by explicitly excluding from the definition of protected "discounts," any rebate or other reductions in price "in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law."

HHS/OIG did not implement its proposal to extend this provision to rebates related to Medicaid Managed Care Organizations (MCO). The stated basis for this decision is that rebates in the Medicaid MCO context have minimal impact on beneficiaries because of the way in which Medicaid cost-sharing obligations are structured. The Preamble also makes clear that sales covered by Medicare Part B are not covered by the new definition.

The Preamble states that the AKS is not implicated in arrangements involving only commercial, private pay or self-pay sales. Notwithstanding that, HHS/OIG noted its longstanding concern about arrangements that purport to relate only to commercial or private pay patients, but in fact are part of a broader arrangement that include Medicare Part D reimbursed sales. HHS/OIG notes that such arrangements can violate the AKS.

HHS/OIG also stated that discount safe harbor protection continues for drug discounts offered to entities such as wholesalers, hospitals, physicians, pharmacies and third-party payors in other federal health care programs. Importantly, the Preamble states that certain PBM rebates may still be protected by the safe harbor for group purchasing organizations (GPO), provided the PBM meets the regulatory definition of a GPO.

The effective date of this change to the safe harbor regulation will be January 1, 2022, in order to provide sufficient time to restructure arrangements that will no longer be protected by the discount safe harbor.

New Safe Harbor for Point-of-Sale Discounts

The rule also finalized the proposed new safe harbor to protect certain POS discounts passed on to beneficiaries. The new safe harbor protects drug price reductions payable under Medicare Part D or by a Medicaid MCO, so long as the price reduction: (1) is set in advance in writing with a Part D plan sponsor, Medicaid MCO or PBM; (2) does not involve a rebate, unless the full value discount is provided to the pharmacy at the point of sale, through a chargeback or is required by law; and (3) is completely applied to the price charged for the drug to the beneficiary at the point of sale.

This new safe harbor is effective 60 days from date of publication in the Federal Register.

New Safe Harbor for PBM Service Fees

HHS/OIG also finalized a new safe harbor to protect certain service fees paid by manufacturers to PBMs. The new safe harbor protects payments by a manufacturer to a PBM for services the PBM provides to the manufacturer "related to the pharmacy benefit management services that the PBM furnishes to one or more health plans." It applies so long as: (1) the PBM has a written agreement with the manufacturer that covers and specifies the services and associated compensation; (2) the payment to the PBM is consistent with fair market value in an arm's-length transaction, is a fixed payment, and does not take into account volume or value of referrals or business between the parties; and (3) the PBM at least annually discloses the arrangement in writing to each contracted health plan, and to HHS upon request, the services rendered to manufacturers.

Importantly, the new safe harbor only protects services provided to a manufacturer, not to a health plan. The Preamble specifically states that formulary placement is considered to a be a service to a plan, not a manufacturer and that payments for formulary placement are *not* protected by this safe harbor.

The Preamble further notes that many service fees paid by manufacturers to PBMs may not even implicate the AKS or could be protected by other existing safe harbors. This new safe harbor is effective 60 days from date of publication in the Federal Register.

Implications

The removal of Anti-Kickback safe harbor protection for retrospective rebates paid by drug manufacturers to PBMs, if it stands, will likely cause a significant transformation of the current prescription drug payment system. Simply put, it arguably effectively criminalizes core aspects of the current PBM business model. Much can happen between now and the January 1, 2022 effective date. It seems likely that there will be both court challenges to the regulations, as well as efforts to convince the incoming Biden administration to retract or modify the rule.

Legal challenges may focus on procedural issues. The Trump administration indicated plans to withdraw the proposed rule after stakeholders expressed concerns over increased premiums, which raises questions as to whether HHS/OIG was allowed to move forward with issuing a final regulation. In addition, after indicating plans to not move forward with finalizing the proposal, on July 24, 2020 the White House issued an Executive Order instructing HHS/OIG to complete the rulemaking, but only if HHS/OIG could publicly confirm that the regulation was not projected to increase federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs. On November 20, 2020, the Secretary of HHS, Alex Azar, issued a statement in response to the Executive Order with a "projection" that the Final Rule will not increase federal spending, patient out-of-pocket costs or Part D premiums. The statement does not reference any analysis of the Final Rule to support the projection, and in the Preamble to the Final Rule, HHS/OIG acknowledges the possibility of increased premiums, which raises questions as to whether the Final Rule follows the instructions laid out in the Executive Order.

Baker Donelson will continue to monitor developments related to Anti-Kickback safe harbors and the use of prescription drug rebates. For questions, please contact Craig Holden or any member of the Baker Ober Health Law Group.