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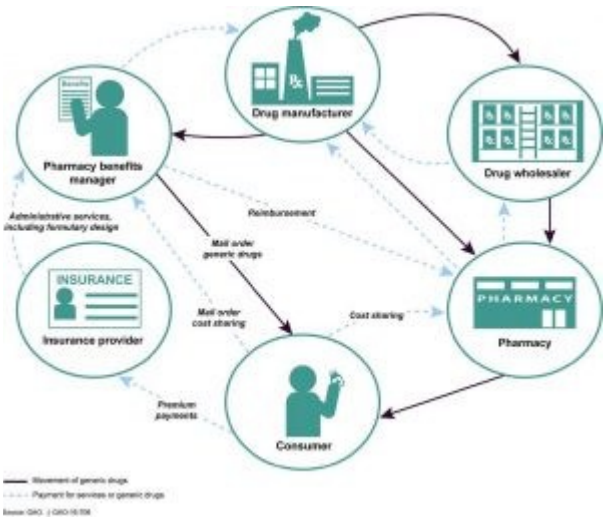
Drug Rebates Threatened Under Proposed Anti-kickback Rule

February 6, 2019 – Dorsey Health Law
by Ross C. D'Emanuele, Alissa Smith, and Benjamin Fee

The Office of Inspector General of the Department of Health and Human Services ("OIG") released a proposed rule to eliminate safe harbor protection under the anti-kickback statute for drug price reductions that pharmaceutical manufacturers pay to Medicare and Medicaid plan sponsors and their pharmacy benefit managers ("PBMs"). The OIG proposed replacing the current safe harbor protection for drug price discounts and rebates with a new safe harbor to protect only those drug price reductions that are set in advance and are applied fully to the price of the product charged to the Medicare or Medicaid beneficiary at the point of sale.

In addition, the OIG proposed a new safe harbor to protect compensation from pharmaceutical manufacturers to PBMs for services provided to the manufacturer, but only if those payments are fixed, fair market value payments not tied to volume or value, and the PBM discloses such payments to its health plan customers.



The OIG's proposals could have a significant impact on the drug discount and rebate arrangements that are commonly in place between manufacturers and Medicare Part D plans/Medicaid managed care organizations (and PBMs acting on behalf of these plans). The OIG's proposals would also impact Medicare and Medicaid beneficiaries who would be entitled to receive any such discounts directly at the point of sale.

The proposed rule release can be found here and is expected to be published in the

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Federal Register on February 6. The proposed effective date of the new rules is January 1, 2020, with an earlier effective date of 60 days after the final rule is published, for the new point of sale safe harbor.

I. Discount Safe Harbor – Changes to Focus on Point-of-Sale Reductions in Drug Prices

The federal anti-kickback statute (Social Security Act § 1128B(b)) makes it a criminal offense for anyone knowingly and willfully to pay, solicit, or receive anything of value to induce referrals of items or services that are reimbursable under any federal health care program. Violation of the statute is a felony, and can carry civil fines, imprisonment, exclusion from federal health care programs, and be the basis for liability under the False Claims Act.

An existing safe harbor protects from anti-kickback statute liability discounts and rebates on drug prices that pharmaceutical manufacturers pay to health plans or their PBMs. The OIG's proposal would revise the discount safe harbor to exclude from protection any reduction in price or other compensation in any form paid from a pharmaceutical manufacturer to a Medicare Part D or Medicaid managed care organization or their PBM in connection with the sale or purchase of a prescription drug.

The proposal reflects OIG's concern that the current manner in which drug price discounts and rebates are structured does not result in lower drug costs to federal programs and federal program beneficiaries, and in fact may be a cause of rising drug costs, and may be contrary to the purposes of the anti-kickback statute.

In its place, the OIG proposes to add a new safe harbor focused narrowly on point-of-sale reductions in prescription drug prices. That safe harbor would protect reductions in the price charged by a manufacturer for drug products that are payable by a Medicare Part D or Medicaid managed care organization or their PBM, but only if that price reduction meets three conditions (the "Point of Sale Safe Harbor"):

First, the reduced price must be set in advance. OIG intends this to mean that the terms of the price reduction are fixed and disclosed in writing to the plan sponsor by the time of the initial purchase.

Second, the sale may not involve a rebate unless the full value of the price reduction is provided to the dispensing pharmacy through chargebacks. This means that when a pharmacy dispenses a drug to a beneficiary, the total payment to the pharmacy (including the beneficiary co-payment, payment from the health plan, and any chargeback payment from the manufacturer) must be no less than the drug price agreed between the manufacturer and the health plan sponsor or their PBM.

Lastly, the reduction in price must be completely applied to the price charged to the beneficiary at the time of sale. This means that the drug price to which the beneficiary's

cost-sharing obligations apply at the point of sale must be the same price (taking into account all discounts) that the manufacturer charges to the plan sponsor or their PBM.

The OIG also noted that the discount safe harbor would continue to not apply if a manufacturer offered a price reduction to payors other than Medicare and Medicaid payors (i.e., situations in which parties "carve out" referrals of federal health care program beneficiaries or business from otherwise "questionable" financial arrangements). The OIG is especially concerned with these "carve out" arrangements if the offer of a discount on products would serve as an inducement for the purchase of products that are reimbursable by federal healthcare programs (e.g., offering a discount to a private health plan that is conditioned, even implicitly, on a product's favorable formulary placement in the health payor's Part D plans).

II. New PBM Service Fee Safe Harbor

In addition, the OIG proposed a new safe harbor to protect compensation from pharmaceutical manufacturers to PBMs for services rendered to the manufacturers that relate to PBMs' arrangements to provide PBM services to health plans (the "PBM Service Fee Safe Harbor").

The OIG did propose three specific conditions that must be met in order for compensation to be protected under the PBM Services Fee Safe Harbor.

The first proposed condition of the safe harbor would require the PBM and the pharmaceutical manufacturer to have a written agreement 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 for such services.

Notably, the OIG declined to propose a specific definition for PBM services but did provide a list of examples of services that it generally considers to be PBM services, including: contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.

The second proposed condition requires that compensation paid to the PBM must: (i) be consistent with fair market value in an arm's-length transaction; (ii) be a fixed payment, not based on a percentage of sales; and (iii) 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 Medicare, Medicaid, or other Federal health care programs.

Finally, the Department proposes that the PBM disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services it rendered to each pharmaceutical manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for such services.

Other than the proposed revisions to the discount safe harbor, and the new PBM Service Fee Safe Harbor, the OIG did not propose to modify any other existing safe harbors which PBMs may use to protect payments from manufacturers. The OIG specifically noted the possibility that certain types of remuneration that manufacturers might pay to PBMs could continue to be protected under another existing safe harbor. For example, PBMs could presumably continue to rely on the Group Purchasing Organization (GPO) safe harbor to protect certain administrative fees paid by drug manufacturers to PBMs for GPO services, even if those fees are based on the total prescription volumes of health plans on behalf of which the PBM contracts with the manufacturers.

III. Conclusion

The OIG proposal reflects a clear intent to substantially alter many of the current drug discount and services compensation practices among pharmaceutical manufacturers and Part D/Medicaid MCO payers and their PBMs. The proposal also reflects the OIG's skepticism that current drug discount and compensation practices among manufacturers and PBMs are sufficiently transparent to health plans to ensure that all appropriate cost reductions and value is passed through to health plans and reflected in lower health plans costs and lower premiums for beneficiaries.

The proposal to exclude drug price reductions to Part D and Medicaid MCO health plan sponsors and PBMs is proposed to be effective on January 1, 2020. The OIG is also proposing that the new Point-of-Sale Safe Harbor will take effect in a shorter time frame of sixty (60) days after the rule is finalized. Comments to the proposed rule may be submitted 60 days after publication in the Federal Register.

There are a number of steps that parties to the type of arrangements covered by the proposed rule should take, including reviewing their current discount and rebate agreements to determine whether there will need to be amendments to these contracts in order to comply with the proposed rule, if it is finalized. Parties will also need to evaluate what compliance measures are needed in order to operationalize the changes in these arrangements to ensure compliance with the new safe harbor requirements. Finally, in light of the attention OIG is giving to these type of arrangements, now would be an opportune time to review arrangements for compliance with the current safe harbor restrictions, such as the carve out restriction described above.

If you have further questions about this proposed rule, please contact the authors or any other health care transaction and regulatory attorneys at Dorsey & Whitney.