

CLIENT ALERT

HHS Proposed Rule Takes Aim at Drug Rebates from Manufacturers to Health Plans/PBMs, Proposes Safe Harbors to Pass Savings to Consumers and Protect Some Manufacturer-PBM Payments

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On January 31, 2019 the Department of Health and Human Services issued a long-awaited notice of proposed rulemaking to implement the Trump Administration's efforts to curb drug price increases, as outlined in the [American Patients First Blueprint](#). The proposed rule attempts to address the issue by eliminating discount safe harbor protection for reductions in price to prescription pharmaceutical products (or rebates) provided by manufacturers to plan sponsors under Medicare Part D and Medicaid managed care organizations (MCOs), whether negotiated by the plan or by pharmacy benefit managers (PBM) or paid through a PBM to the plan or Medicaid MCO. The proposed rules also would increase regulatory risk associated with rebates provided by manufacturers to commercial health plans (if the commercial health plan sponsor also provides Medicare Part D or Medicaid prescription drug coverage), which would result in the rules having an impact across a wider spectrum of the prescription drug coverage market than just federal health care programs.

The proposed rule also would create two new safe harbors: (1) a "point-of-sale reductions in price for prescription pharmaceutical products" safe harbor that would enable manufacturers to offer a reduction in price on particular drugs if the reduction is completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale, is set in advance, and does not involve a rebate unless certain conditions are met; and (2) a "PBM service fees" safe harbor that enables drug manufacturers to pay PBMs fixed fees for providing services to the manufacturer related to pharmacy benefit management services that the PBM furnishes to health plans, so long as certain writing and other requirements are met.

The effective date of revisions to the rebate safe harbor will be January 1, 2020. The Department is specifically soliciting comments on whether the proposed effective date gives affected entities a sufficient transition period to restructure any arrangements that could implicate the Anti-Kickback Statute and no longer would be protected by a safe harbor. The prospect of the rules being implemented within such a short time period creates challenges for Part D plans, as they will need to anticipate the rule's financial impact when preparing bids due in June for the 2020 contract year.

The point of sale safe harbor will go into effect 60 days after final regulations. The Department did not provide a specific effective date for the new PBM service fees safe harbor, which means that it would also likely go into effect 60 days after publication of the final rule.

How would the discount safe harbor change?

The Department proposes to eliminate safe harbor protection for manufacturer reductions in price on prescription pharmaceutical products to Medicare Part D plans operating under section 1860D-1 et seq. of the Act, and Medicaid MCOs, as defined under section 1903(m) of the Act. This would exclude from discount safe harbor protection rebates from manufacturers

to plan sponsors under Medicare Part D and Medicaid MCOs. The method by which this is done is to create an additional exclusion under the discount safe harbor. Thus, the text of the rule will remain largely the same:

§ 1001.952 Exceptions

(h)(1)-(4) are unchanged.

(5) [Unchanged] For purposes of this paragraph, the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include—

(viii) [New] A reduction in price or other remuneration from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product to a plan sponsor under Medicare Part D, a Medicaid Managed Care Organization as defined in section 1903(m) of the Act, or to a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, or Medicaid Managed Care Organization, unless it is a price reduction or rebate that is required by law.

The proposed rule also creates definitions for “manufacturer,” “wholesaler,” “pharmacy benefit manager,” “prescription pharmaceutical product,” and “Medicaid Managed Care Organization.”

As a result of the change, the only reduction in price protected between manufacturers and a plan sponsor or PBM would be those that fit within the new safe harbor that is being proposed to protect manufacturer point-of-sale reductions in price on prescription pharmaceutical products to a plan sponsor or a PBM that would be applied at the point of sale to benefit the beneficiary, the plan, and, by extension, the government. Other remuneration between a manufacturer and a PBM could be protected under a new proposed safe harbor that would protect certain fixed service fees that pharmaceutical manufacturers pay to PBMs.

Preliminary Impact Analysis

1. The proposed rule represents a sea change in the way health plans and PBMs secure discounts for prescription drugs from manufacturers. Most significantly, the Department is removing rebates from the safe harbor without proposing a clear alternative. Although the rule does not *prohibit* rebates, by removing safe harbor protection for reductions in price, the Department has significantly raised the risk profile of discounts for products included in a formulary when those discounts are realized through rebate arrangements.

2. It is also significant that the Department has elected to target rebate arrangements generally, rather than, for instance, continuing to allow safe harbor status for rebates that are passed through to the beneficiary at the point of sale. We believe this is just one indication that the Department would prefer that manufacturers reduce their list prices across the board, which they could do without any risk under the fraud and abuse laws. However, the point of sale safe harbor provides a pathway for manufacturers to continue targeting reductions in price to health plans. The Department does not explain why manufacturers would have any incentive to reduce list prices if plans are able to negotiate comparable discounts to what they receive now through rebates, even if the discount must be reflected in the consumer price at the point of sale.

3. The effective date of January 1, 2020 means that Part D plans will be required to forecast their costs for the 2020 bidding cycle by June of 2019, before they are able to determine the financial and utilization impact of alternative arrangements, let alone negotiate and finalize such arrangements. The prospect of uncertainty alone could magnify the projected impact of the proposed rule in raising Part D premiums, at least for the next plan year.

4. Further, changes set forth in this proposed rule raise a critical administrative law question about the Secretary’s legal authority to eliminate regulatory safe harbor protections for drug rebates. Given that Congress enacted a broad Anti-Kickback Statute discount exception codified in statute, the Secretary’s authority to remove rebate protection through the regulatory process is questionable. Anticipating potential challenges to his authority to remove protections for manufacturer arrangements with plan sponsors and PBMs, the Secretary specifically states that in his view, the statutory exemption for discounts (42 U.S.C. 1320a-7b(b)(3)(A)) does *not* apply to most rebates paid by drug manufacturers to part D plans or to Medicaid managed care plans. However, this remains an open question.

What are the new safe harbors?

New Point of Sale Safe Harbor

Under the proposed new safe harbor (proposed 42 CFR 1001.952(cc)), a manufacturer could offer a reduction in price on a particular prescription pharmaceutical product to a plan sponsor under Medicare Part D, to a Medicaid MCO, or through a PBM acting under contract with either if certain conditions are met.

- The price reduction would have to be set in advance with the plan sponsor or PBM. “Set in advance” would mean that the terms of the reduction in price would be fixed and disclosed in writing to the plan sponsor or PBM by the time of the initial purchase, which, in turn, would be the first purchase of the product at that reduced price by the plan sponsor on behalf of an enrollee.
 - As with the current discount safe harbor, the new safe harbor would exclude from protection price reductions offered to one payor but not to Medicare or Medicaid.
- Second, the reduction in price could not involve a rebate, as defined in 42 CFR 1001.952(h), unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate is required by law.
 - “Chargeback” is defined 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 Plan Sponsor or PBM, and the manufacturer of the prescription pharmaceutical product.
- Third, the reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale. For example, if the discounted rate is set in advance, at the time of dispensing the pharmacy would have the necessary information to appropriately charge a beneficiary who owes coinsurance, even if the manufacturer ultimately tenders the dispensing pharmacy a payment through a chargeback to reflect this negotiated price with the payor.

The proposed safe harbor’s requirements are intended to exclude from its protection conduct that mimics rebates but are referenced in other ways in the contracts between a manufacturer and a PBM, e.g., fees that are based on a percentage of a

prescription pharmaceutical product's list price could be a disguised kickback and would not be protected by this proposed safe harbor unless the requirements created by this rule are met.

New PBM Service Fee Safe Harbor

This proposed safe harbor (proposed 42 CFR 1001.952(dd)) would protect payments pharmaceutical manufacturers make to PBMs for services the PBMs provide to the pharmaceutical manufacturers, for the manufacturers' benefit, when those services relate in some way to the PBMs' arrangements to provide pharmacy benefit management services to health plans. *This safe harbor would protect only a pharmaceutical manufacturer's payment for those services that a PBM furnishes to the pharmaceutical manufacturer, and not for any services that the PBM may be providing to a health plan.*

- Example: PBMs might provide services for pharmaceutical manufacturers to prevent duplicate discounts on 340B claims.

The requirements are similar to the terms that currently exist to qualify for the Anti-Kickback Statute personal services safe harbor, with an additional requirement for disclosure to plan sponsors or the government:

- The PBM and the pharmaceutical manufacturer must have a written agreement that: (i) 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 (ii) specifies each of the services to be provided by the PBM and the compensation for such services.
- The compensation paid to the PBM must: (i) be consistent with fair market value in an arms-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.
- The PBM must *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.

The Department is considering and is requesting comments on whether, and if so under what conditions, PBMs should also be required as an additional condition of safe harbor compliance to disclose the fee arrangements to the health plans.

Impact on Commercial Plans

The Department clearly intends to have an impact on rebate arrangements for commercial plans as well as Medicare Part D and Medicaid. It specifically noted that the proposed rule does not change the discount safe harbor's provision that excludes from protection price reductions offered to one payor but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products.

Thus, arrangements will not be eligible for safe harbor status if they "carve out" referrals of Federal health care program beneficiaries or business generated by Federal health care programs. As the OIG has stated with some frequency, such arrangements implicate, and may violate, the Anti-Kickback Statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business.

Impact on Discounts for Other Parties

The preamble to the proposed rules specifically states that the Department intends 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 payors in other Federal health care programs. The Department is soliciting comments on whether additional or different regulatory text would be necessary to clarify that other types of discounts (*e.g.*, volume or prompt payment discounts to wholesalers) that currently are protected by the discount safe harbor would remain protected if all safe harbor conditions are met.

In addition, to the extent that manufacturers have used rebate arrangements as a way to influence formulary placement decisions by PBMs/health plans, manufacturers will need to determine whether the point of sale arrangements protected by the new safe harbor adequately replace PBM/health plan rebates and, if not, how else they may increase utilization of their products in a compliant manner.

No Specific Rule Related to Value Based Arrangements

The preamble to the proposed rule states that the Department is exploring value-based arrangements and their use in the sale of prescription pharmaceutical products, and furthermore, that it does not “intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCOs.” It does not elaborate on what this means, for instance, whether it refers to other safe harbors such as the risk sharing or managed care price reduction safe harbors. In addition, the preamble notes that the Department is interested in hearing from stakeholders about, and is soliciting comments on, the extent to which the proposed amendment and accompanying proposed safe harbor may affect any existing or future value-based arrangements.

Reasons Given for the Changes

The preamble to the rule provides a lengthy analysis of what the Department sees as problems with current arrangements by which manufacturer discounts almost always take the form of rebates to the plan sponsor or PBM, but the following were given as the key reasons for disfavoring rebates.

1. The Department believes that the rebate-based system harms beneficiaries because beneficiaries do not get the benefit of the net price after rebates, and to the extent that manufacturers raise list prices to offset rebate payments, as the Department believes, many Medicare beneficiaries actually pay a higher price at the point of service than they would without rebates.
2. The Department believes that rebates result in higher list prices that harm Federal health care programs. The Department noted that since the passage of the Anti-Kickback Statute and the establishment of the various safe harbors, the list prices of branded prescription drugs, and the rebates paid by manufacturers to pharmacy benefit managers, have grown substantially. The phenomenon of list prices rising faster than “net prices” is referred to as the “gross to net bubble.”
3. The Department notes that the rebate system is not transparent and that in some or even many instances, plan sponsors under Medicare Part D and Medicaid MCOs have limited information about the percentage of rebates passed on to them and the percentage retained by their PBMs. The terms of rebate agreements manufacturers negotiate with PBMs may be treated as

highly proprietary and, in many instances, may be unavailable to the plans. This makes it challenging for plans to negotiate with PBMs or to compare pricing between PBMs.

The Department is also soliciting comments on (i) the extent to which rebates deter plans or their PBMs from placing lower cost, therapeutically equivalent drugs on their formularies or incentivizes plans or their PBMs to give preferred formulary placement to a higher-cost drug that carries a higher associated rebate, and (ii) how these practices might change if the Department were to eliminate safe harbor protection for rebates and protect only point-of-sale discounts for prescription pharmaceutical products. Comments on the proposed rule are due 60 days after the date of publication in the Federal Register.

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