A First Look At New HHS Prescription Drug Safe Harbors

By Tom Bulleit, Sarah Ferranti, Hyesu Grace Kim, Lillian Maguire and Gideon Palte

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On Jan. 31, 2019, the Office of Inspector General of the U.S. Department of Health and Human Services released a proposed rule that would narrow the existing regulatory discount safe harbor under the Anti-Kickback Statute and create two new safe harbors.


Tom Bulleit

If finalized, the proposed rule would (1) exclude from the existing discount safe harbor discounts provided to Medicare Part D plans (including Medicare Advantage plans with a drug benefit), Medicaid managed care organizations (MCOs), and pharmacy benefit managers (PBMs); (2) add a new safe harbor to protect certain discounts passed along to federal health care program beneficiaries; and (3) add a new safe harbor to protect certain fees prescription drug manufacturers pay to PBMs.


Sarah Ferranti

The stated purpose of the proposed rule is to update the discount safe harbor to address the modern prescription drug distribution model and protect federal health care programs and beneficiaries. Taken together, the proposed changes do not directly affect the price-setting activities of pharmaceutical manufacturers, but instead appear designed to affect pharmaceutical prices indirectly by increasing transparency through requiring that any discounts be provided at the point of sale. At present, however, it is not clear what the ultimate effect of the proposed rule on beneficiary prescription drug costs will be.


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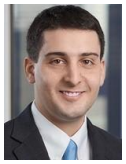
Amendments to the Discount Safe Harbor Under the Proposed Rule, and Potential Legal Challenges


Lillian Maguire

The AKS broadly prohibits the exchange of anything of value intended to induce or reward referrals for or purchases of items and services reimbursed by federal health care programs. The AKS' prohibition can include discounts or other reductions in price offered to buyers on such items or services.


Gideon Palte

However, discounts are permitted if they comply with the regulatory safe harbor at 42 C.F.R. § 1001.952(h) (and, though OIG disagrees, arguably if they comply with the statutory exception for discounts at 42 U.S.C. § 1320a-7b(b)(3)(A) on which the safe harbor is based). While the regulatory discount safe harbor was intended to encourage price competition that would ultimately benefit the Medicare and Medicaid programs,[1] the proposed rule suggests that the safe harbor has not translated into cost savings for federal health care programs when used in the modern prescription drug distribution model.

In the preamble to the proposed rule, OIG notes that rebate arrangements in the prescription drug supply chain may create incentives for manufacturers to keep list prices (and rebates) high, in order to gain preferred status from PBMs and health plans. Often, a portion of PBM compensation is derived from the difference between the list price and the price actually paid after accounting for rebates (the net price).

Thus, an incentive exists for PBMs and health plans (which generally share the value of rebates) to encourage the use of drugs with higher list prices and rebates, typically by preferred formulary placement, because of the higher fees such drugs generate. A manufacturer that lowered list prices would reduce the difference between the list price and the net price, thereby lowering PBM and health plan fees, potentially causing the drug to be removed from the formulary or placed in a less-preferred tier. OIG argues that these incentives to keep list prices high result in higher out-of-pocket costs for beneficiaries and do not translate into lower federal health care spending per beneficiary.

The proposed rule narrows the existing regulatory discount safe harbor by excluding from protection discounts on prescription pharmaceuticals offered to Medicare Part D plans (including Medicare Advantage plans with a drug benefit), Medicaid MCOs and PBMs dealing on behalf of such entities. More specifically, the proposed rule amends the definition of “discount” provided at 42 C.F.R. § 1001.952(h) by carving out “reduction[s] in price or other remuneration from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product” to Medicare and Medicaid plans and PBMs.

Notably, the proposed rule would not affect discounts provided to entities other than plan sponsors and PBMs (such as hospitals, clinics, physician practices, pharmacies or wholesalers); nor would it alter supplemental rebates between states and drug manufacturers.

Additionally, although the proposed rule would not directly affect discounts offered to commercial plans, HHS noted in its commentary to the proposed rule that, consistent with OIG's historic concern regarding the "pull-through" effect of remuneration provided for services payable by nonfederal health care payors, continued rebates in the commercial insurance market also could be subject to scrutiny under the AKS. The "pull-through" concern here is driven by a fear on the part of OIG that private pay-only rebates are intended to induce purchases of federal government program reimbursable drugs (for example, private pay rebates are provided in exchange for favorable formulary treatment of Medicare/Medicaid-covered drugs).

In support of its authority to issue the proposed rule, OIG points to Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, which tasks the HHS secretary with creating new AKS safe harbors through rule-making. Insurers, PBMs and others might mount a legal challenge by arguing that the protected status of rebate arrangements cannot change without action by Congress because the statutory exception under which the regulatory discount safe harbor is based protects "a discount or other reduction in price obtained by a provider of services *or other entity* under a Federal health care program" (emphasis added).

It is difficult to see how MCOs that contract with Medicare or Medicaid do not satisfy this definition. PBMs likely would argue that when they act on behalf of Medicaid MCOs and Medicare Part D sponsors, they should be considered an "other entity" under the statute and thus within the ambit of the exception created by Congress, which the secretary cannot unilaterally change through notice-and-comment rule-making.

New Proposed Safe Harbor: Point of Sale Drug Price Reductions

The proposed rule introduces a new safe harbor that would protect a new form of reduction in price on prescription drugs offered to Medicare Part D plans, Medicaid MCOs or PBMs acting on behalf of either. In order to qualify for protection, drug price reductions would need to satisfy the following conditions:

1. The price reduction must be set in advance with the plan sponsor. The proposed rule provides that "set in advance" means fixed and disclosed in writing by the time of the initial purchase. Initial purchase means the first purchase of the product at the reduced

price by the Medicare Part D plan sponsor or Medicaid MCO on behalf of the enrollee. Like the current discount safe harbor, this proposed safe harbor would exclude price reductions offered to one payor, but not to Medicare or Medicaid.

2. Rebates must take effect through chargebacks or be required by law. The proposed definition of "chargeback" is a payment that a manufacturer makes directly or indirectly to a dispensing pharmacy such that the total payment to the pharmacy is at least equal to the price agreed upon in writing between the manufacturer and the Medicare Part D plan sponsor, Medicaid MCO or PBM.

3. The point of sale, or POS, price charged by a pharmacy to a beneficiary must completely reflect the price reduction, even if the pharmacy only later receives the chargeback. As currently drafted, it is unclear how this provision will affect a beneficiary's cost-sharing obligation. The proposed rule's preamble suggests that the beneficiary's cost-sharing obligation should be calculated based on a reduced price, such as a coinsurance calculated as a percentage of the standard plan reimbursement amount minus the manufacturer rebate.

   However, the text of the proposed rule requires that the reduction in price be applied to the price "charged to the beneficiary at the point of sale" and thus could be read to require elimination of the beneficiary's cost-sharing obligation, since that is the amount charged to the beneficiary at the point of sale. It is not clear what happens to the "excess" if the amount of the chargeback exceeds the beneficiary's cost-sharing obligation.

These requirements are intended to exclude from protection arrangements that resemble rebates, whether or not they are explicitly labeled as such. The safe harbor is satisfied only if all three of the conditions listed above are satisfied. Notably, a pharmaceutical manufacturer will not be able to ensure compliance with all three conditions since compliance with certain of the conditions is dependent on the actions of plans and third-party pharmacies that are downstream in the prescription drug distribution model.

This is in contrast to the existing discount safe harbor, which enumerates different obligations for buyers, sellers and offerors, recognizing the fact that different parties can control different portions of a discount arrangement. The proposed rule also does not address situations in which PBMs and pharmacies are related through ownership, and OIG

has requested comments on how to address such scenarios.

New Proposed Safe Harbor: PBM Service Fees

The proposed rule introduces a second new regulatory safe harbor that would protect fixed fees that a drug manufacturer pays to a PBM for services that the PBM provides to the manufacturer that relate to the PBM's arrangements with any health plan. OIG envisions this safe harbor as providing additional fraud and abuse protection for services that PBMs provide to drug manufacturers, such as using health plan claims data to help manufacturers avoid duplicate discounts on claims for 340B drugs.[2]

The safe harbor would not protect services that the PBM furnishes to a health plan that are not for the benefit of the health plan rather than the manufacturer. In order to fall under the safe harbor, the fees would need to satisfy the following conditions:

1. ***Written Agreement:*** The PBM and the manufacturer must have a written agreement that (1) covers all of the PBM's services for the manufacturer that relate to the PBM's relationships with health plans, and (2) specifies each of the services that the PBM will provide and the compensation it will receive for providing them.

2. ***Proper Terms for Compensation:*** The PBM's compensation must (1) be consistent with fair market value in an arm's length transaction, (2) be a fixed payment not based on a percentage of sales, and (3) not be based on the volume or value of referrals or business generated between the parties or between the manufacturer and the PBM's health plans for which payment may be made under a federal health care program.

3. ***Annual Written Disclosures:*** The PBM annually must disclose in writing to its contracted health plans the services it provides to each manufacturer related to services that the PBM provides to the health plan, and the associated costs for those services. PBMs also must provide this information, as well as information regarding fee arrangements with manufacturers, to the secretary upon request.

Conclusion

If finalized as proposed, the rule would significantly transform prescription drug reimbursement by Medicare Part D and Medicaid MCOs. Although it is difficult to predict

how manufacturers, PBMs and health plans would react to the changes, OIG anticipates that enrollees' out-of-pocket costs for prescriptions drugs would fall. Sicker enrollees who fill more prescriptions would therefore benefit most.

However, the actuarial studies that the proposed rule cites indicate that premiums may rise as a result of narrowing the existing safe harbor, because the rebates as they currently stand under the discount safe harbor serve to lower premiums. Amending the discount safe harbor would reduce the rebates available, and thus may adversely affect federal health care program beneficiaries through increased premiums, as well as lead to increased federal spending.

Interested parties may submit comments by 5 p.m. eastern time on April 8, 2019.

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[1] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback, 56 Fed. Reg. 35,799, 35,953 (July 29, 1991) (codified at 42 C.F.R. pt. 1001).

[2] Section 340B of the Public Health Service Act imposes drug ceiling prices on covered outpatient drugs reimbursed by Medicaid.