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HHS Proposes Rule Challenging Drug Manufacturer Rebates to PBMs and Payors

The Proposed Rule Would Make Clear that the Anti-Kickback Statute's Discount Safe Harbor Does Not Protect Manufacturer Rebates to PBMs or Payors, But Would Create New Safe Harbors for Rebates Passed Through to the Point-of-Sale and for Fixed Payments for PBM Services

On January 31, 2019, the U.S. Department of Health and Human Services (HHS or the Department) released a Proposed Rule that would modify the scope and reach of the federal Anti-Kickback Statute (AKS) discount safe harbor in an effort to eliminate many PBM rebates and reduce patient drug costs. The Proposed Rule, if adopted, could cause major changes to the current drug sale and distribution system.

The Proposed Rule is set to be published in the Federal Register on February 6th. Comments will be due 60 days from publication in the Federal Register. King & Spalding stands ready to assist its clients and friends in interpreting and reacting to the Proposed Rule.

The Proposed Rule would make explicit that the AKS discount safe harbor does not protect manufacturer rebates on prescription drugs paid to Medicare Part D plan sponsors, Medicaid managed care organizations (MCOs), or pharmacy benefit managers (PBMs) in the context of these government programs. The Proposed Rule would create new safe harbors for certain point-of-sale price reductions on prescription drugs and for certain PBM service fees paid by manufacturers.

The proposed changes are part of President Trump's larger "American Patients First" strategy for lowering prescription drug prices and out-of-pocket costs. The Department's position is that the current drug rebate system between manufacturers and Medicare Part D plan sponsors and



Medicaid MCOs (and the PBMs that negotiate on their behalf) can lead to payments that are “disguised kickbacks,” misalign the priorities of stakeholders, and increase costs throughout the system (i.e., for both commercially and publicly insured patients). The preamble to the Proposed Rule describes the perceived flaws in the current payment and rebate system, as well as in the application of the current discount safe harbor. Among the goals of the Proposed Rule is to:

improve[] alignment of incentives among the[] parties that may curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs.

PROPOSED REVISIONS TO THE DISCOUNT SAFE HARBOR

The Secretary of HHS asserts that neither the statutory exception for discounts nor the discount safe harbor should apply to most rebates paid by drug manufacturers to PBMs or payors, including specifically Part D plans and Medicaid MCOs. To the extent these rebates are paid to or through PBMs to establish formulary position, HHS indicates that such payments should not be protected discounts. The Department asserts that PBM rebates in these programs may contribute to drug prices increasing at a faster rate, encourage PBMs to favor higher-cost drugs over lower cost drugs, and discourage the adoption of lower-cost brand drugs and biosimilars. HHS suggests that the result of these effects is a higher price paid by patients and the government.

To combat these effects and make clear that these discounts are not safe harbor protected, HHS proposes to amend the existing AKS regulatory discount safe harbor to exclude from the definition of a “discount” (and therefore make clear the lack of safe harbor protection) price reductions on prescription drugs from manufacturers to plan sponsors under Medicare Part D or Medicaid MCOs, either directly or through PBMs, unless the price reduction is required by law (e.g., rebates under the Medicaid Drug Rebate Program). The Proposed Rule defines “plan sponsor under Medicare Part D” to include the sponsor of a prescription drug plan as well as a Medicare Advantage organization offering a Medicare Advantage prescription drug plan.

The Department seeks comments on proposed definitions of the terms “manufacturer,” “wholesaler,” “distributor,” “pharmacy benefit manager” or “PBM,” and “prescription pharmaceutical product” for purposes of the discount safe harbor. These definitions would also be used in the two proposed new safe harbors discussed below.

The impact of this proposed change on manufacturer rebates offered to commercial health plans – either directly or through PBMs – is not yet clear. On one hand, HHS notes that it does not intend for the proposed change to impact discounts to parties other than Medicare Part D plan sponsors, Medicaid MCOs, and the PBMs that negotiate on their behalf. For example, the Department specifically states that it intends the discount safe harbor to continue to protect price reductions to “other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs.” On the other hand, the preamble also states:

nothing in this proposed rule changes 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. OIG has a long-standing concern about arrangements under which parties ‘carve out’ referrals of Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. 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. This concern would extend to certain pharmaceutical rebate arrangements.”



Thus, while it does not appear to be the Department's intent to expressly prohibit rebates to commercial plans, there is an indication that such arrangements could be subject to scrutiny under the AKS, irrespective of the currently proposed changes. Specifically, to the extent that rebates furnished to PBMs and/or payors relating to commercial plans and formularies would also be intended to influence plan decisions and formularies with respect to Medicare Part D plans or Medicaid MCO plans administered by the same PBM/payor, the AKS could be implicated.

In an attempt to give impacted parties time to revise agreements, HHS proposed that this change, if made final, would not take **effect until January 1, 2020**. The Department seeks comment on whether that timing would be sufficient.

PROPOSED NEW SAFE HARBOR FOR POINT-OF-SALE PRICE REDUCTIONS

The Proposed Rule also would create new AKS protections for certain price reductions designed to benefit the patient, not the PBM or health plan. Specifically, HHS proposes to create a new safe harbor to protect point-of-sale price reductions from manufacturers on certain prescription drugs that are payable under Medicare Part D or by Medicaid MCOs that meet the following criteria:

- The **price reduction is set in advance** with the plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM – meaning that the price reduction is effective at the time of the initial purchase (*i.e.*, the first purchase of the product at the reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee).
- The price reduction cannot include a rebate (as defined in the discount safe harbor), unless the full value of the price reduction is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate is required by law. The Proposed Rule defines a “chargeback” 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 under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.” The Agency's use of “chargeback” in this context is puzzling. Industry understands a chargeback to be a true up payment from a manufacturer to a wholesaler in the context of a discounted indirect sale. The Agency appears to be using “chargeback” to avoid using the term “rebate”, which is what a utilization-based payment like this really is. It would be inefficient for pharmacies to make indirect purchases generating chargebacks at each beneficiary price that may be required at the counter, and simultaneously maintain segregated inventories to permit dispense based on the patient's coverage position. We believe what the Agency may be seeking is a “rebate” to the dispensing pharmacy to be paid on units dispensed out of common inventory, varying by coverage rules as presented by each patient.
- The price reduction must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale.

The above conditions are meant to ensure that arrangements that “mimic rebates”, but that are referenced in other ways in agreements between a manufacturer, a plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM (*e.g.*, reductions in price that are not reflected in the price paid by the actual purchaser and/or service fees that are based on a percentage of a prescription pharmaceutical product's list price), do not receive AKS safe harbor protection.

The proposed effective date for the new safe harbor would be **60 days after publication of a final rule**.

PROPOSED NEW SAFE HARBOR FOR PBM SERVICES FOR MANUFACTURERS

The Department also proposes a new AKS safe harbor to protect fixed fee payments from manufacturers to PBMs for services rendered to the manufacturers (or for the manufacturers' benefit) when certain conditions are met. The conditions of the proposed safe harbor include:

- A **written agreement** between the manufacturer and the PBM 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.
- The **compensation** paid to the PBM must:
 - Be consistent with **fair market value** in an arm's-length transaction;
 - Be a fixed payment, **not based on a percentage of sales**; and
 - **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.
- The PBM must disclose in writing to each health plan with which it contracts at least annually, and to the Secretary of HHS 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.

HHS specifically chose not to create a definition for “pharmacy benefit management services” but provided some examples, 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.”

Manufacturers should note that the test for this PBM services safe harbor is different from the *bona fide* service fee test employed for government price reporting which utilizes different criteria. Qualification for the safe harbor does not mean that a PBM fee is a *bona fide* service fee, or vice versa.

The protection of the proposed safe harbor is limited to payment for services the PBM provides to the manufacturer and does not extend to services for health plans. The Department noted, however, that the safe harbor would not preempt contractual terms between a PBM and a health plan that limits or delineates the PBM's use of the health plan's data.

We note that, unlike the other proposed new safe harbor above, the Department did not specifically state when this proposed safe harbor would take effect. It is most likely, however, that the two new safe harbors would become effective at the same time – 60 days after the publication of a final rule in the Federal Register.

PRACTICAL IMPLICATIONS

HHS recognizes that the impact of the Proposed Rule is “difficult to accurately quantify ... due to the complexity and uncertainty of stakeholder response,” but believes that the Proposed Rule could prompt manufacturers to lower “sticker prices” or slow drug price increases. The reality is likely significantly more complicated.

Critics argue that eliminating these types of rebates could result in higher costs for patients. Rebates to Part D sponsors are generally used to help lower patient premiums, and without such rebates the premiums will likely rise. The Department feels that these increased costs will be offset by savings realized on drug prices, but HHS acknowledges that the true impact will vary and will depend upon whether manufacturers reduce list prices for their drugs, and that some patients will likely bear higher overall costs. Those beneficiaries currently paying more in drug costs are likely to benefit most from the proposed changes.

Importantly, the Department highlights that the Proposed Rule is not intended to impact the application of any other AKS safe harbors on relationships between manufacturers, Medicare Part D plan sponsors, Medicaid MCOs, or PBMs, meaning these entities can still structure arrangements that fit within one of the other safe harbors and receive protection (e.g., the personal services safe harbor or the group purchasing organizations safe harbor). Nonetheless, at the same



time HHS is also signaling the potential for new and increased scrutiny of such arrangements, if they may also have an impact on federal health care programs.

If the proposal were finalized, at a minimum, it would require revisions to thousands of existing PBM and payor rebate arrangements relating to drugs reimbursed by Medicare Part D and Medicaid MCOs. There is no assurance, however, that any of these market changes will bring lower prices. Accordingly, the primary objective of the Department appears to be to foster greater transparency in the discounting process applicable to Medicare Part D and Medicaid MCOs.

The Department does not propose to alter manufacturer obligations relating to Medicaid prescription drug rebates, including requirements regarding best price, additional “inflation penalty” rebate amounts, or the treatment of state supplemental rebates. Interestingly, the Proposed Rule suggests that PBM rates are currently excluded from Best Price. In our experience, many manufacturers consider PBM rates to “affect the price at the ... provider level” and therefore already include them in Best Price. 42 C.F.R. §447.505(c)(17). We expect this disconnect will be explored in the comments to the Proposed Rule.

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Throughout the Proposed Rule, HHS identified areas in which it is specifically seeking public comments. These topics range from the impact of the proposals to potential loopholes that the Department did not yet identify to definitions of key terms in the proposed regulation. Comments on the Proposed Rule will be due 60 days after the Proposed Rule’s publication in the Federal Register on February 6, 2019.

King & Spalding’s fraud and abuse and drug pricing and reimbursement experts are ready to assist in the preparation of comments to this Proposed Rule at every stage—evaluation, consideration and articulation. We have extensive experience in interpreting Proposed Rules and in drafting agency comments. Given the extraordinary complexities raised by this Proposed Rule and the lack of any certainty on the financial impact that it would have on any of the stakeholders, including health plans and patients, we strongly encourage effective, thoughtful, coherent and persuasive comments. For more information, please contact any of the team members on the first page of this Client Alert.

ABOUT KING & SPALDING

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