Health Law Alert: HHS Proposes Rule to Bring Transparency to PBM Pricing

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The Department of Health and Human Services (HHS) has recently proposed to amend the discount safe harbor of the Federal Anti-Kickback Statute (AKS) and to establish two new safe harbors. These changes, should they be adopted, mark the first updates to the discount safe harbor since the Medicare Part D program was established. Click here to view the Proposed Rule.

Noting the lack of transparency of manufacturer rebates paid to Pharmacy Benefit Managers (PBMs), and the impact these rebates have on the ultimate cost of drugs, the proposed rule seeks to amend the discount safe harbor so that: (1) rebates paid to a sponsor of a prescription drug plan, as well as a Medicare Advantage organization offering a prescription drug plan (collectively "Plan Sponsors") and PBMs by drug manufacturers will be excluded from the safe harbor; (2) there will be a safe harbor for rebates at the point of sale to consumers; and (3) services provided by PBMs to drug manufacturers could be covered under a safe harbor if they are offered on a flat fee and other criteria are met. The proposed rule contains detailed discussion about some of the problems HHS has seen involving percentage-based payments in the pharmaceutical industry.

These changes are in line with earlier Requests for Information published in June 2018 (for the Stark Law) and August 2018 (for the Anti-Kickback Statute) under which the Department of Health and Human Services solicited stakeholder input on ways to simplify the fraud and abuse laws and make them more consistent with the HHS push toward quality- and performance-based reimbursement programs. They appear to reflect a broader effort by HHS to bring longstanding fraud and abuse laws more in allignment with new payment programs.

The Discount Safe Harbor

The discount safe harbor was designed to protect discounts or reductions in the price of a good or service that is received by providers. Notably, protection extends to discounts that are offered in the form of a rebate. "Rebate" is defined to include any discount that has fixed terms, which are disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

Certain items are excluded from safe harbor protection, such as cash or reductions that are applicable to one payer but not to Medicare, Medicaid, or other Federal health care programs.

Problems with the Current System

The price of prescription drugs continues to rise. Some industry observers contend that these increases are due in large part to a system in which drug manufacturers offer greater discounts to PBMs (under the protection of the discount safe harbor), and then increase the price of the drug to cover this extra cost.

The proposed rule outlines how PBMs receive rebates from drug manufacturers, which have the potential to make the PBM more likely to promote use of that drug in its benefit structure. Manufacturers then start competing over who can offer the higher rebate. In order to increase rebates payable to PBMs, manufacturers could be incentivized to increase the list price that is ultimately paid by the consumer.

For example, assume a manufacturer sells a medication for $105.00 and then pays a $5.00 rebate to the PBM. If the manufacturer wanted to increase the rebate payable to the PBM by another $5.00, it could simply charge the consumer $110.00. This would make the drug more profitable for the PBM to promote in its formulary and would likely lead to greater sales volume for the manufacturer.

The Proposed Rule

HHS seeks to amend the discount safe harbor to address problems it has identified in the current rebate system. Under the proposed rule:

- Rebates paid to Plan Sponsors or PBMs by drug manufacturers will be excluded from the safe harbor;
- Rebates provided at the point of sale to consumers will be protected; and
- Services provided by PBMs to drug manufacturers could still be protected under the safe harbor, but only if the services are offered on a flat fee and other criteria are met.

HHS stated that its goal is to better align protected discount arrangements so that consumers (not PBMs or Plan Sponsors) benefit from these discounts, and ultimately pay less for prescription drugs. HHS also hopes that this improves transparency in the Medicare program and better enables HHS to ensure that drug manufacturers, PBMs, and other parties comply with the program's rules.

Who is impacted?

Payors and PBMs are the primary industry groups most likely to be impacted by the proposed rule. Although the safe harbor only applies to federally reimbursed healthcare programs, HHS made it clear that it expects this to impact commercial health plans as well (noting that attempts to avoid implication of the AKS by limiting initiatives to commercial programs often, in itself, implicates the AKS).

From the consumer side, the intended impact is a reduction in prices across the board, including both deductible and coinsurance costs. There would also be greater incentive to offer discounts and rebates directly to consumers at the point of sale.

The impact on drug manufacturers is unclear. The proposed rule removes, at least in part, the incentive to increase drug prices. This is because there is no longer an incentive to offer PBMs the highest possible rebate to secure preferable placement in PBM formularies.

The Unknowns

There are many questions about whether the proposed regulations will influence behavior in the way that HHS intends. HHS requests comments in this area and on the impact the proposed rule will have on competition within the pharmaceutical industry. Specifically, HHS requests comments as to whether these changes inadvertently exclude proper price reductions from protection, and whether additional language or commentary is needed to clarify protection of other types of arrangements.

HHS is accepting comments on this proposed rule until April 8, 2019.

Upcoming Health Law Roundtable

Due to the complex nature of the Anti-Kickback Statute and other health laws and regulations, even well-run, highly conscientious health care organizations can unexpectedly find themselves in the crosshairs of a regulator. Please join us for a roundtable on March 19, 2019 where a slate of seasoned Gray Plant Mooty attorneys will discuss how to best navigate the initial stages of an investigation or enforcement action. Click here to register and to learn more about the event.

If you have questions about the Anti-Kickback Statute, please contact Julia Reiland at julia.reiland@lathropgpm.com (612.632.3280), Tony Fricano at antonio.fricano@lathropgpm.com (612.632.3236), or Jesse Berg at jesse.berg@lathropgpm.com (612.632.3374).