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Special Update: HHS Proposes to Exclude Prescription Drug Rebates to PBMs from Safe Harbor Protection

February 1, 2019

Health Care

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) released a new rule yesterday proposing to revise the Anti-Kickback Statute safe harbor at 42 C.F.R. § 1001.952(h) to explicitly exclude manufacturer rebates and other price reductions on prescription drugs paid to Part D plans, Medicaid managed care organizations (MCOs), or pharmacy benefit managers (PBMs) acting on their behalf. The rule also proposes to establish two new safe harbors to protect certain manufacturer discounts on prescription drugs offered at the point-of-sale and to protect certain fixed-fee service arrangements between manufacturers and PBMs.

Elimination of Safe Harbor for PBM Rebates

The rule proposes to amend the existing discount safe harbor to no longer protect rebates or other price reductions from manufacturers to Medicaid MCOs or plan sponsors under Medicare Part D, either directly or through contracted PBMs, unless the price reduction is otherwise required by law (for example, rebates required under the Medicaid Drug Rebate Program). HHS seeks comments on whether this amendment should also apply to prescription drugs covered by other federal health care programs (*e.g.*, Medicare Part B fee-for-service, Medicaid MCOs operating under section 1915 waivers, etc.), and Secretary Azar has suggested that Congress extend this policy into the commercial market.

The preamble to the proposed rule states that the discount safe harbor will continue to protect discounts on prescription drugs offered to other entities such as wholesalers, pharmacies, and third-party payors in other federal health care programs. However, HHS recognizes that some pharmacies and PBMs are related through ownership and seeks comments on any potential issues such ownership interests might create under the proposed rule.

Proposed Safe Harbor for Discounts at Point-of-Sale

The rule proposes a new safe harbor to protect certain price reductions offered by manufacturers on prescription drug at the point-of-sale. Under the safe harbor, manufacturers could offer a price reduction for drugs payable by a Part D plan or Medicaid MCO under the following conditions:

- The reduction in price is set in advance and in writing with the plan sponsor or a PBM acting on behalf of the sponsor;

- The sale does not involve a rebate, unless the full value of the price reduction is provided to the dispensing pharmacy through a chargeback or a series of chargebacks or is required by law; and
- The price reduction is "completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale." *See* Proposed § 1001.952(cc).

Proposed Safe Harbor for Fixed-Fee Service Arrangements with PBMs

HHS also proposes a new safe harbor that would protect arrangements between PBMs and manufacturers for undefined services "related to the pharmacy benefit management services" the PBMs provide to health plans if the following criteria are met:

- There is a written agreement between the PBM and manufacturer covering all of the services and specifying the compensation for services;
- Compensation paid under the agreement is "consistent with fair market value"; is "a fixed payment, not based on a percentage of sales," and does not "take[] 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 in part by" a Federal health care program;
- 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 rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan." *See* Proposed § 1001.952(dd).

HHS proposes that the amendments to exclude price concessions on prescription drugs to Part D plans and Medicaid MCOs take effect on January 1, 2020, while the two new safe harbors would take effect 60 days after publication of the final rule.

HHS also released a fact sheet and a press release summarizing the proposed rule. Comments to the proposed rule will be due 60 days after the rule is published in the federal register. Publication is currently scheduled for February 6, 2019.

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