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HHS Proposes Changes to Rx Rebates for Medicare Part D Programs

HHS has issued a proposed rule that, if implemented, would significantly limit the current safe harbor protection for prescription drug rebates offered to Medicare Part D plans, including employer-sponsored EGWPs.

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Background

The federal Anti-Kickback Statute imposes criminal penalties for knowingly offering remuneration to induce or reward the referral of business reimbursable by Medicare and other federal health care programs. Regulations promulgated by the Department of Health and Human Services (HHS) include a safe harbor for certain types of price discounts, including pharmaceutical manufacturer rebates. However, HHS recently issued a [proposed rule](#) that, if implemented, would significantly limit the current safe harbor protection for rebates offered to Medicare Part D and managed Medicaid prescription drug plans. HHS also released a [Fact Sheet](#) on the proposed rule. The comment period on the proposed rule ended April 8, 2019. HHS will also conduct hearings on the proposal.

Proposed rule

Typically, pharmaceutical manufacturer rebates are paid retrospectively to the pharmacy benefit managers (PBMs) that administer Medicare Part D and managed Medicaid plans. For self-funded plans, PBMs generally pass on these rebates to plan sponsors, who use them to offset total plan costs or lower premiums.

Under HHS' proposed rule, these retrospective rebate payments to PBMs would no longer qualify for the safe harbor – only rebates used to lower member out-of-pocket prescription drug costs at “point of sale” (POS) — i.e., at the pharmacy counter, would qualify. According to HHS, this draft rule would redirect an estimated \$29 billion in rebates from PBMs and insurers to Medicare beneficiaries in the form of lower out-of-pocket prescription drug costs at POS.

This proposed rule would also modify the safe harbor so that only fully disclosed fixed-fee service arrangements between the PBMs and pharmaceutical manufacturers for Medicare Part D and managed Medicaid plans would qualify.

The effective date of the proposed rule is January 1, 2020, pending the results of the public comment period.

Buck Comment. On April 5 the Centers for Medicare & Medicaid Services (CMS) released guidance concerning the HHS proposal and the impact on 2020 bids. The guidance states that “plan sponsors will submit bids for CY2020 in a form and manner that is consistent with the Anti-Kickback Statute law and regulations in effect as of the bid submission deadline, including, for the purposes of bid development, the treatment of manufacturer rebates per our existing rules and guidance related to Direct and Indirect Remuneration.”

The most likely beneficiaries of lower prescription drug costs, net of rebates, will be those participants with chronic conditions, who require expensive, rebate-eligible brand-name medications on an ongoing basis. POS rebates will not lower out-of-pocket costs for the majority of beneficiaries who use generic drugs, for which there are no rebates, or brand-name drugs that are not rebate-eligible.

According to outside consultants retained by HHS and Medicare actuaries, redirection of rebates to the POS is expected to increase monthly Medicare Part D premiums for individual marketplace plans by 13% to 19%. Thus, while POS drug costs will be lowered for beneficiaries who are high utilizers of expensive brand drugs, premium costs are expected to increase for all insureds.

Buck Comment. Although the proposed rule does not specifically address its application to Employer Group Waiver Plans (EGWPs), we expect that it will apply. Further, we also expect that it will affect EGWPs with flat-dollar copayment designs and those with coinsurance plan designs differently.

What is an EGWP?

An employer/union-sponsored group waiver plan, or EGWP, is a Medicare Advantage or Medicare Part D plan offered to retirees of the entity sponsoring the EGWP.

What group health plan sponsors need to know HHS’ proposed rule is limited to Medicare and managed Medicaid prescription drug programs. With the exception of EGWPs, the rule does not directly affect employer-sponsored pharmacy benefit plans. No one can predict with certainty whether any changes in the Medicare safe harbor will be implemented, and if they are, when any changes would be effective — January 1, 2020 or later.

Changes in the treatment of pharmacy rebates for commercial plans (including employer-sponsored plans) would require federal legislation. On March 6 Senator Mike Braun (R-Ind) introduced the Drug Price Transparency Act (S. 657) which would make similar changes to the treatment of rebates in the commercial market. This type of legislation could significantly alter the economics of the employer-PBM-pharmaceutical manufacturer relationship. Currently, most employer-sponsored plans elect to

retain pharmaceutical manufacturer rebates they receive from PBMs to offset total plan costs and premiums. Curtailment of this practice would have a profound impact on employer-sponsored pharmacy benefit plans.

In closing

Employers with EGWPs should monitor the potential changes to the treatment of rebates. Additionally, plan sponsors should also monitor legislation that may be considered by Congress that would affect rebates for non-Medicare commercial plans and be prepared to respond to these and other marketplace forces that could impact employer-sponsored pharmacy benefit plans.

Marketplace Response.

On March 12 OptumRx announced that it will require all new self-funded pharmacy plan clients to offer point of sale rebates, effective January 1, 2020. This change could have a significant impact on how rebates are offered in the employer marketplace.

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