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Trump administration proposes ambitious AKS rewrite on drug rebates, but needs answers to big questions

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In a significant step towards implementing its American Patients First blueprint for lowering prescription drug prices and patient out-of-pocket costs, the Trump administration has proposed a series of changes to the anti-kickback statute's (AKS) safe harbor rules that seek to eliminate the use of rebates in Medicare Part D and Medicaid managed care plans.

The stated goals of the highly anticipated proposed rule from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) are to realign incentives among drug manufacturers, health plans, and pharmacy benefit managers (PBMs) to reduce list prices or curb price increases, reduce financial burdens on patients, lower federal expenditures by encouraging the use of lower-cost brand or generic drugs, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce Medicare Part D and Medicaid managed care business. But in seeking to use the blunt instrument of the anti-kickback statute to achieve broad drug pricing reform, even the administration has recognized that it's uncertain whether the proposed rule can meet these stated goals.

Three new safe harbor provisions

The proposed rule takes the form of three changes to the regulatory safe harbors to the anti-kickback statute, which broadly prohibits financial arrangements that are intended to induce federal health care program business. Because the anti-kickback statute's prohibition applies only to federal health programs, such as Medicare and Medicaid, the proposed rule's reach is limited to these programs. Specifically, OIG proposes the following changes:

- **Elimination of safe harbor protection for certain drug rebates**. The proposed rule would exclude from the current discount safe harbor to the anti-kickback statute manufacturer rebates paid to Medicare Part D plans (including Medicare Advantage organizations), to Medicaid Managed Care Organizations (MCOs), or to PBMs for Part D plan or Medicaid MCO business. The rationale for this change is outlined in an HHS fact sheet that accompanied the proposed rule, which criticizes the current "rebate-based system" for prescription drugs for rewarding "ever-increasing list prices" (on which rebates typically are based), enriching PBMs, distorting formulary decisions, and driving up patient out-of-pocket costs (which also are usually calculated on the basis of list price). By eliminating safe harbor protection for rebates, the administration hopes to remove them as a barrier to lowering drug

costs. Notably, this aspect of the proposed rule is limited to Part D, Medicaid MCO, and PBM rebates, and would not extend to other kinds of rebates that would remain protected under the discount safe harbor, including:

- Rebates that are required by law, specifically including rebates under the Medicaid Drug Rebate Program.
- Rebates paid to wholesalers, hospitals, physicians, and pharmacies.
- Rebates paid to other federal health care programs, such as the Department of Veterans Affairs (VA), the Department of Defense, the Indian Health Service, or Medicare Part B fee-for-service, though OIG requests comment on whether the amendment should be extended to apply to these other federal health care programs.

To give manufacturers, plans, and PBMs sufficient time to restructure their existing arrangements, OIG has proposed that this aspect of the proposed rule would become effective on January 1, 2020.

- **New safe harbor for point-of-sale discounts to patients**. To take the place of rebates, the proposed rule would create a new safe harbor protecting prescription drug discounts that (a) are set in advance with a Part D plan, a Medicaid MCO, or a PBM; (b) do not involve rebates (although chargebacks may be used to provide the full value of the price reduction to pharmacies); and (c) are completely applied to the price charged to the patient at the point of sale. Because the administration would like patients to receive the benefits of these point-of-sale discounts as soon as possible, OIG proposes that this aspect of the proposed rule would take effect 60 days after the issuance of a final rule. This may signal that the administration plans to issue a final rule in relatively short order.
- **New safe harbor for PBM service fees**. The proposed rule also would create a new safe harbor for payments by a manufacturer to a PBM for services rendered to the manufacturer and "related to" the pharmacy benefit management services that the PBM furnishes to plans, as long as (a) there is a written agreement specifying the services and compensation; (b) the compensation paid to the PBM 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 federal health program business generated between the parties; and (c) the PBM discloses the arrangement to each federal health plan with which it contracts at least annually and to the HHS secretary on request. As an example, the preamble suggests that the safe harbor could protect manufacturer payments for PBM services that depend on or use data gathered by PBMs from their health plan customers, such as providing data to help manufacturers prevent duplicate discounts on 340B claims. In contrast, the safe harbor would not protect manufacturer payments for what OIG apparently considers to be the core services that PBMs provide to health plans themselves, such as 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. The proposed rule is silent on what impact this new safe harbor would have on prior OIG guidance that safe harbor-like protection is available for PBM administrative fees that are structured to fit in the group purchasing organization (GPO) safe harbor. Unlike the proposed new safe harbor, the GPO safe harbor expressly permits percentage-based fees, although OIG could take the view that adoption of a more specific safe

harbor for service fees paid by manufacturers to PBMs would make the GPO safe harbor inapplicable in that context.

Two big questions

In the HHS fact sheet and other statements accompanying its release, the administration has enthusiastically touted the proposed rule as "historic" and having "the potential to be the most sweeping change to how Americans' drugs are priced at the pharmacy counter, ever." Notwithstanding the hype, the actual substance of the rule raises questions about the likely impact of the reform on beneficiary and program costs and on drug prices in general. As OIG itself acknowledges, "it is difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response."[1] Indeed, stakeholders considering the impact of the proposed rule are likely to ask at least two overarching questions:

- Will it actually lead to lower drug prices for federal plans and beneficiaries?
- Will the proposed rule's elimination of PBM rebates carry over into the private insurance market?

Although it seems possible that the proposed changes will reduce drug prices, the effect of the proposed rule may be uneven. After much discussion of various potential scenarios and requesting comments on a substantial number of topics including whether the point-of-sale safe harbor would incentivize manufacturer point-of-sale discounts, OIG ultimately concludes that with regard to Medicare Part D, the actuarial analyses seem to suggest that "total beneficiary cost sharing would decrease and premiums would increase, and that the decrease in total beneficiary cost-sharing would offset the total increase in premiums across all beneficiaries." The analyses also indicate, however, that "more beneficiaries would pay more for premiums than they would save in cost sharing, suggesting that out-of-pocket impacts are likely to vary by individual and the greatest benefit of these transfers accrues to sicker beneficiaries (e.g., those with more drug spending and/or those using high-cost drugs)." In other words, OIG acknowledges that although sicker patients might do better under the proposed rule, overall costs will increase for most Part D beneficiaries and for the Medicare program. The effect on the Medicaid program is similarly uncertain, with OIG soliciting comments on whether the reduction in rebate revenue could cause Medicaid MCOs to submit higher-cost bids for Medicaid MCO contracts. OIG also failed to acknowledge certain existing safeguards against potential improper rebate influence, such as Medicare rules regarding Part D plan formulary coverage and so-called direct and indirect remuneration (DIR) reports that provide transparency into manufacturer rebates.

There is also good reason to doubt a significant impact on the private insurance market. The anti-kickback statute and its safe harbor rules do not apply to private health plans in the employer-sponsored and individually purchased insurance markets. In an apparent effort to encourage the elimination of rebates for private health plans, OIG emphasizes in the proposed rule that it would be a potential violation of the anti-kickback statute for private health plan rebates to be used as an inducement for federal program business (by, for example, conditioning, whether explicitly or implicitly, a private plan rebate on a product's favorable formulary placement across all plans, including Part D plans). Manufacturers and PBMs have long recognized this compliance risk and

[1] The proposed rule is accompanied by three economic analyses by the Centers for Medicare & Medicaid Services Office of the Actuary (OACT) and the actuarial firms Milliman and Wakely Consulting Group that differed significantly in their assumptions about how stakeholders would respond to the proposed rule and their resulting estimates. For example, the OACT and Milliman projections regarding increases in government spending range from US$1.1 billion to US$13.4 billion in 2020. Projections for changes for 2020-2029 range from a decrease of US$78.8 billion to an increase of US$196.1 billion.

the need for separately negotiating private plan and Part D pricing arrangements. So, this warning from OIG seems unlikely to cause PBMs and private plans to suddenly forgo rebates that they have argued serve to reduce employer costs and insurer premiums. Instead, congressional action would seem to be needed to extend the proposed rule's elimination of rebates to private health plans. Although legislative action on health care continues to be a challenging prospect, the recent adoption of an all-payer anti-kickback provision for certain opioid abuse treatment services has shown that Congress can move quickly when there is bipartisan agreement, and Secretary Azar has indicated publicly that the administration will push Congress to extend the proposed rebate policy changes to commercial plans.

Despite the uncertain impact, the proposed rule still contemplates the most significant changes to the anti-kickback safe harbors in a generation, and no doubt would fundamentally change the way drug manufacturers interact with PBMs, Part D plans, and Medicaid MCOs. For that reason, the proposed rule merits careful study and planning for a different world of Part D pricing.

Comments due April 8

The proposed rule is subject to a 60-day public comment period that closes on April 8, 2019. OIG seeks input on virtually all aspects of the proposed rule, but there are a number of issues that seem especially worthy of comment:

- In particular, OIG states that it "does not intend for this proposal to have any effect on existing protections for value-based pricing arrangements between manufacturers and plan sponsors under Medicare Part D or Medicaid MCOs." Yet, in the absence of a specific safe harbor or waiver for a value-based arrangement, it's unclear how outcomes-based pricing arrangements could be structured without the use of rebates and be applied to the price paid by patients at the pharmacy, as required by the new safe harbor rules.
- Whether the increased transparency resulting from the proposed rule (including the potential ability of pharmacies to "reverse engineer" manufacturers' discount structures) could have a negative effect on pricing and competition.
- How the proposed rule might be modified to encourage point-of-sale price reductions.
- Whether January 1, 2020 gives manufacturers, plans, and PBMs sufficient time to restructure their existing arrangements to accommodate the new rules.
- The role that copay discount cards might be able to play in achieving the administration's goal of reducing patient out-of-pocket costs.
- The proposed rule's impact on prior OIG guidance that administrative fees to PBMs may be protected under the GPO safe harbor to the anti-kickback statute.

Hogan Lovells to host a client briefing

Given the importance of this proposed rule to the pharmaceutical industry, we will be hosting a webinar for firm clients on **February 22 at noon EST / 9 a.m. PST**. Further details and sign-up instructions will be forthcoming soon.

In the meantime, if you have questions about this proposed rule or are interested in submitting comments, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

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