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DISCOUNT DISRUPTION: PBM REBATE PROTECTION MAY BE REMOVED, NEW SAFE HARBORS COMBAT INCREASING DRUG COSTS

On January 31, 2019, the Department of Health and Human Services Office of Inspector General ("OIG") issued a proposed rule that, if finalized, would eliminate Anti-Kickback Statute ("AKS") safe harbor protection for prescription drug rebates paid by manufacturers to pharmacy benefit managers ("PBMs"), Medicare Part D plans and Medicaid managed care organizations ("Proposed Rule"). OIG proposes to: i) amend the AKS Discount Safe Harbor to exclude such reductions in price; and ii) create two new safe harbors intended to protect point-of-sale discounts and certain fixed fee arrangements between PBMs and drug manufacturers.

If finalized, the Proposed Rule could serve to increase patient insurance costs in the short term, though the goal is to eventually foster reduced drug prices, enhance pricing transparency and encourage point-of-sale discount benefits for patients.

PROPOSED AKS SAFE HARBOR REVISIONS – DETAILED DISCUSSION

The Proposed Rule revises the Discount Safe Harbor[1] to explicitly exclude rebates offered by drug manufacturers to PBMs, Medicare Part D plans and Medicaid managed care plans from its definition of an allowable "discount" in price. These rebates, which are heavily relied upon in the pharmacy benefit industry, presently receive safe harbor protection and are therefore permissible under the AKS.

The Proposed Rule also introduces two new safe harbors that are intended to encourage a move away from the current rebate system and incentivize upfront discounts for patients at the pharmacy point-of-sale.

One proposed safe harbor would protect price reductions offered to patients at the pharmacy point-of-sale under the rationale that encouraging drug manufacturers to provide discounts directly to the consumer will lower prescription drug prices and out-of-pocket costs, including percentage-based copays. OIG described that point-of-sale reductions in price pose less risk to Federal Health Care Program beneficiaries, Medicare Part D and Medicaid managed care organizations. This safe harbor aims to encourage the passing through of rebates that constitute a certain percentage of a drug's list price directly to the consumer. OIG has proposed that these price reductions would need to be set in advance at the time of the initial purchase, generally could not involve rebates and must be completely reflected in the price the pharmacy charges to the beneficiary at the point-of-sale. OIG has specifically solicited comments regarding how this safe harbor would apply during periods of 100 percent beneficiary cost sharing.

The other proposed safe harbor would permit a fixed fee model between PBMs and drug manufacturers. This safe harbor would allow fixed fees consistent with fair market value to be paid by pharmaceutical companies to PBMs for bona fide services provided to the manufacturer – not to a health plan – if certain criteria are satisfied. The Proposed Rule considers "pharmacy benefit management services" to be services 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. However, OIG has intentionally not included a definition for these services as they could evolve over time. OIG has specifically solicited comments on this approach and whether other services should be considered as a part of the safe harbor.

IMPACT ANALYSIS

According to the fact sheet accompanying the Proposed Rule, OIG's objective is to restructure the Discount Safe Harbor in a manner that counteracts the rebate system's "perverse incentives" that drive list price increases. These list prices are often used as an indirect basis for drug reimbursement as well as patient out-of-pocket costs.

HHS projects that the replacement of safe harbor protection for "opaque rebates" with "transparent discounts" will result in lower Medicare Part D beneficiary spending as a whole because the reduced out-of-pocket costs are expected to largely outweigh the potential premium increases. HHS further notes that this Proposed Rule derives from HHS's regulatory authority with respect to rebates in connection with Federal Health Care Programs and that Congress regulates commercial insurance. Therefore, while the Proposed Rule does not directly impact commercial insurance drug rebates, an indirect effect may materialize. In the short term, at least, we anticipate that PBMs and plans may try to make up for any lost revenues by increasing premiums and patient co-pay obligations.

TIMELINE

The current proposal targets January 1, 2020 for the amendments to the Anti-Kickback Statute to take effect. The new safe harbors would become effective 60 days after the final rule's publication in the Federal Register. HHS will initiate the 60-day public comment period on February 6, 2019 to seek feedback on the Proposed Rule's potential impact. If you would like to submit a comment, comments on the Proposed Rule must be received by HHS no later than **5:00 PM** on **April 7, 2019**.

PRACTICAL TAKEAWAYS

HHS projects that the replacement of safe harbor protection for traditional rebates with the proposed discounts will result in lower Medicare Part D beneficiary spending as a whole because the reduced out-of-pocket costs are expected to largely outweigh the potential premium increases. HHS further notes that this Proposed Rule derives from HHS's regulatory authority with respect to rebates in connection with Federal Health Care Programs and that Congress regulates commercial insurance. Therefore, while the Proposed Rule does not directly impact commercial insurance drug rebates, an indirect effect may materialize. In the short term, at least, we anticipate that PBMs and plans may try to make up for any lost revenues by increasing premiums and patient co-pay obligations.

Hall Render is closely monitoring the developments of this Proposed Rule and will publish additional information as it becomes available. Interested in submitting a comment or learning more? Hall Render has a group of attorneys who can assist with your questions. Let's get started.

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[1] 42 C.F.R. § 1001.952(h).