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Cutting Out the "Middleman"? HHS Resurrects Anti-Rebate Rule for Medicare Part D

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On November 20, 2020 the Department of Health and Human Services ("HHS") and the HHS Office of Inspector General ("OIG") issued a final rule ("Final Rule") that the agencies contend will help to lower prescription drug prices by changing the structure for drug payments and pharmacy benefit manager ("PBM") services in connection with certain federal health care programs. Specifically, if it survives anticipated court challenges, the Final Rule will modify the federal health care program's Anti-Kickback Statute ("AKS") safe harbors in three key ways:[1]

- First, it will remove safe harbor protection under the AKS for rebates that a pharmaceutical manufacturer provides to Medicare Part D plan sponsors (either directly or indirectly through the PBMs[2] with which they contract). In apparent recognition of how disruptive this change will be to current business models, the Final Rule postpones the effective date for this change until January 1, 2022.

- Second, it will create a new safe harbor to protect certain price reductions given by pharmaceutical manufacturers that are passed through to beneficiaries at the point-of-sale. This new safe harbor will become available on January 29, 2021.

- Third, it will create a new safe harbor, also effective as of January 29, 2021, that protects certain fixed fees paid by manufacturers to PBMs for PBM services.

Although the two new safe harbors seem unlikely to generate much opposition, the amendments to the discount safe harbor for Medicare Part D may be subject to legal challenge on procedural and substantive grounds.[3]

This Alert summarizes key elements of the Final Rule and discusses potential legal challenges. Notably, this Final Rule is one of five rules – four final rules and one proposed rule[4] – directly addressing or otherwise impacting drug pricing released by the Trump administration in the last two-and-a-half months. For additional Ropes & Gray analysis of the other final rules, please see our prior Alerts on Canadian Drug Importation Programs, International Drug Pricing, and Transparency in Coverage.

The agency's stated rationale for the discount safe harbor amendments under the Final Rule is as follows: when PBMs, on behalf of Part D plans, negotiate rebates – commonly, based on formulary placement and utilization management criteria – that pricing and discounting structure (i) incentivizes drug manufacturers to maintain a high list price, and (ii) disadvantages beneficiaries, who commonly pay coinsurance on the basis of a drug price that does not reflect the full universe of rebates.[5] The Final Rule's discount safe harbor amendments only apply to Medicare Part D, despite the fact that the January 2019 proposed rule ("Proposed Rule") would have extended these changes to Medicaid managed care organizations ("Medicaid MCOs") as well. Nevertheless, HHS expects that the changes will serve as a catalyst for manufacturers to lower list prices generally, which will have spillover effects to the commercial market.[6] Notwithstanding these stated policy objectives, there is skepticism regarding whether these revisions to the AKS safe harbors ultimately can drive such broad, market-wide drug pricing changes.[7]

1. Amendment to the Discount Safe Harbor for Part D.

Currently, the AKS discount safe harbor set forth at 42 C.F.R. § 1001.952(h) enables a pharmaceutical manufacturer to provide rebates to health plans and PBMs so long as the rebate is disclosed to the buyer, and the buyer takes certain actions to disclose the rebate to HHS on its annual cost report. The Final Rule narrows the discount safe harbor by

carving out reductions in price or other remuneration that a pharmaceutical manufacturer provides to Medicare Part D sponsors, either directly or indirectly through a PBM.

Notably, the Final Rule's amendments to the discount safe harbor only affect discounts offered to Medicare Part D plans (including discounts offered to PBMs in connection with those plans). As noted above, the safe harbor revisions will not apply to Medicaid MCOs. The Proposed Rule included Medicaid MCOs in the change to the discount safe harbor, but the proposal drew significant objections centered around concerns that such a change, if finalized, would increase Medicaid costs for the federal government and states without providing cost-relief to Medicaid beneficiaries (who typically have nominal cost-sharing obligations). The agency acknowledged these objections and declined to include Medicaid MCOs in the discount safe harbor amendments under the Final Rule. Additionally, this amendment under the Final Rule does not apply to rebates negotiated in connection with other government health programs, including Medicare Part B fee for service, the Department of Veteran Affairs, or the TRICARE program administered by the Department of Defense.

This removal of safe harbor protection may be subject to legal challenge. In this regard, the Final Rule has a somewhat complex procedural history, which may make it vulnerable to legal challenge. HHS released the Proposed Rule on prescription drug safe harbors on January 31, 2019.[8] The Proposed Rule almost immediately drew significant scrutiny, including for the manner in which it was projected to increase government spending. The White House later released a statement through a spokesperson that "[b]ased on careful analysis and thorough consideration, the President has decided to withdraw the rebate rule."[9] Notwithstanding that public statement, HHS asserted in its concurrently released Final Rule fact sheet that it never withdrew the Proposed Rule because it never finalized such withdrawal through publication of a notice of withdrawal in the Federal Register.[10] Thus, the Final Rule may be subject to challenge on procedural grounds.

2. New Safe Harbors.

The Final Rule also creates new safe harbors to the AKS as follows.

a. Point of Sale Drug Price Reductions. The Final Rule creates a new safe harbor for prescription drug price reductions offered to Medicare Part D plan sponsors, Medicaid MCOs, and PBMs acting on behalf of Medicare Part D plans and Medicaid MCOs. Specifically, a pharmaceutical manufacturer may offer a rebate to a Medicare Part D plan sponsor, Medicaid MCO, or PBM acting on behalf of either entity, so long as three criteria are satisfied:

> i. Advance Agreement. The price reduction from the manufacturer to the Medicare Part D plan sponsor, Medicaid MCO, or PBM must be set forth in writing, in advance of the first purchase of the product at a reduced price by the plan sponsor or Medicaid MCO on behalf of the beneficiary;
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> ii. No Rebates. The reduction in price may not involve a rebate, unless the full value of the rebate is provided by the manufacturer to the dispensing pharmacy, directly or indirectly, through a point-of-sale chargeback[11] or a series of point-of-sale chargebacks, or where required by law; and
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> iii. Real-Time Reduction. The cost-sharing obligation of the beneficiary must reflect the reduction in price at the time the drug is dispensed.

HHS clarified in its commentary that reductions in price offered to Part D plan sponsors or Medicaid MCOs that are contingent on the formulary placement of a drug can qualify for protection under the new point-of-sale drug price reduction safe harbor so long as the reduction in price is not contingent on the provision of services to the manufacturer, such as marketing or switching, and so long as the three safe harbor conditions are otherwise satisfied.

b. PBM Service Fees. The PBM service fee safe harbor protects fixed fees that a manufacturer pays to a PBM in exchange for services provided by the PBM to the manufacturer in relation to the benefit management services the PBM provides to health plans (including federal health care plans other than those offered under Medicare Part D).[12] To qualify for the safe harbor, the fees must satisfy four conditions:

i. Written Agreement. The fees must be set forth in a written, signed agreement that sets forth all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans, and the compensation for each such service. Such services must be "legitimate" and distinct from the services and functions that the PBM provides to health plan customers;

ii. No Illegal Promotion. The services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law;

iii. Compensation Requirements. The compensation paid to the PBM for the services provided must be (i) be consistent with fair market value, (ii) fixed, and not based on a percentage of sales, and (iii) calculated such that it does not take into account the volume or value of referrals or business generated between the parties (or between the manufacturer and the PBM's health plan customers) for which payment may be made under a federal health care program; and

iv. Annual Written Disclosures. The PBM must disclose to each of its health plan customers the services it provides to each of its manufacturer clients as such services relate to the PBM's arrangements with the health plan. The disclosure must be made in writing at least annually, and also must be made to HHS upon request. HHS also may request fee information for the services the PBM provides to manufacturers.

3. Other Notes.

a. Chargeback Administration. HHS expects that manufacturers will have sufficient documentation to demonstrate that any chargebacks were administered in an amount equal to the agreed-upon point-of-sale reduction in price. HHS did not mandate or prohibit any type of entity from serving as a chargeback administrator, enabling PBMs, wholesalers, and other entities to step in as chargeback administrators. However, HHS did clarify that point-of-sale chargeback administration fees and other similar service fees will not be covered under the point-of-sale reduction in price safe harbor (but may qualify for another safe harbor). As such, pharmaceutical manufacturers should contemplate whether they may be able to satisfy the personal services safe harbor when structuring arrangements with chargeback administrators.

b. GPO Safe Harbor. The Final Rule does not impact another safe harbor – the group purchasing organization ("GPO") safe harbor – which continues to provide a safe harbor for pharmaceutical manufacturers to pay GPOs certain volume-based administrative fees so long as certain criteria, mostly related to transparency, are met. HHS addressed the GPO safe harbor in the Final Rule, noting that PBMs are not prohibited from qualifying for GPO safe harbor protection. We anticipate that PBMs may endeavor to restructure, or form complementary GPO entities, in an attempt to be eligible to qualify for the GPO safe harbor, which, in effect, would allow the continuation of many existing rebate approaches. Notwithstanding the Department's Preamble observations, we note that there may be at least technical questions about whether the PBM function constitutes acting as a "purchasing agent for a group of . . . entities . . . who are furnishing services for which payment may be made" under a federal health care program, as the GPO safe harbor requires.

If you have any questions about the Final Rule, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

1. 85 Fed. Reg. 76666 (Nov. 30, 2020), *available at* https://www.govinfo.gov/content/pkg/FR-2020-11-30/pdf/2020-25841.pdf.
2. Notably, HHS relies on a very broad definition of PBM (any entity that provides pharmacy benefits management on behalf of a health benefits plan that manages prescription drug coverage), rejecting many commenters' request that the definition be constructed with more precision out of concern that PBMs may take advantage of the safe harbor inappropriately.
3. Robert King, HHS finalizes rules to nix Part D rebate safe harbor, tie Part B prices to foreign countries, Fierce Healthcare (Nov. 20, 2020), https://www.fiercehealthcare.com/payer/hhs-to-finalize-rule-to-nix-part-d-rebate-safe-harbor-propose-tying-part-b-prices-to-foreign.
4. HHS Proposed Rule: Implementation of Executive Order 13937, "Executive Order on Access to Affordable Life-Saving Medications," https://www.federalregister.gov/documents/2020/09/28/2020-21358/implementation-of-executive-order-13937-executive-order-on-access-to-affordable-life-saving.
5. Press Release, HHS, Fact Sheet: Trump Administration Finalizes Proposal to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Nov.20, 2020), https://www.hhs.gov/about/news/2020/11/20/fact-sheet-trump-administration-finalizes-proposal-to-lower-drug-costs.html.
6. In a press release published concurrently with the issuance of the Final Rule, Secretary Azar noted that in his view – informed by his three decades of personal experience and the fifteen-year history of the Medicare Part D Program – the Final Rule would not lead to any "increase in federal spending, patient out-of-pocket costs, or premiums for Part D beneficiaries." However, the Congressional Budget Office thought differently as of May 2019, issuing a report in response to the Proposed Rule that estimated implementing the Proposed Rule would increase Medicare spending by approximately $170 billion dollars over 2020-2029, and Medicaid spending by about $7 billion.
7. Les Masterson, Hospitals, payers decry HHS proposal to change safe harbor for drug rebates, Healthcaredive (April 9, 2019), https://www.healthcaredive.com/news/hospitals-payers-decry-hhs-proposal-to-change-safe-harbor-for-drug-rebates/552313/.
8. *HHS Proposed Rule on Prescription Drug Safe Harbors*, Ropes & Gray (Feb. 11, 2019), https://www.ropesgray.com/en/newsroom/alerts/2019/02/HHS-Proposed-Rule-Prescription-Drug-Safe-Harbors.
9. Peter Sullivan, White House withdraws controversial rule to eliminate drug rebates, The Hill (Jul. 11, 2019), https://thehill.com/policy/healthcare/452561-white-house-withdraws-controversial-rule-to-eliminate-drug-rebates.
10. Press Release, HHS, Fact Sheet: Trump Administration Finalizes Proposal to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Nov. 20, 2020), https://www.hhs.gov/about/news/2020/11/20/fact-sheet-trump-administration-finalizes-proposal-to-lower-drug-costs.html.
11. A point-of-sale chargeback is a payment by a manufacturer made directly or indirectly to a dispensing pharmacy that is equal to the reduction in price agreed upon in writing between the manufacturer and the Medicare Part D plan sponsor, Medicaid MCO, or PBM.
12. HHS clarified that it would not specify the services to be protected under the safe harbor so as to avoid imposing a static list of services. The focus of the safe harbor, however, is to protect payment for the services provided to the manufacturer for the benefit of the manufacturer, while ensuring that PBMs, as the agents of health plans, are obligated to disclose any such arrangements with manufacturers.