FOLEY HOAG LLP

Summary of Final Rule: Removal of Safe Harbor Protection for Rebate Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection

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Ross Margulies
rmargulies@foleyhoag.com
202.261.7351

FOLEY HOAG LLP

OVERVIEW

On November 20, 2020 the Department of Health and Human Services Office of Inspector General ("OIG") released a Final Rule entitled "Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection" (hereinafter, the "Rebate Rule") that that amends the discount safe harbor regulation to eliminate protection for price concessions, including rebates, that are offered by pharmaceutical manufacturers to plan sponsors, or pharmacy benefit managers (PBMs) under contract with them, under the Medicare Part D program. The Rebate Rule was released in tandem with an Interim Final Rule implementing a new Most Favored Nation Model, announced at a drug pricing press conference by President Trump. In its press release on the Rebate Rule, HHS notes: "By removing the incentives that reward list price increases, patients who have out-of-pocket costs based on list price will save."

As set forth in the Final Rule, OIG proposes to create two new safe harbors effective 60 days after the publication of the final rule in the Federal Register (scheduled for November 30, 2020), the first of which would protect certain point-of-sale (POS) reductions in price offered by manufacturers, and the second that would protect certain PBM service fees. The current safe harbor protection for rebates would end later, on January 1, 2022 (in advance of the CY 2022 plan year), to allow Part D plans adequate time to "come into compliance and to minimize any disruption."

Major changes from Proposed Rule: Most notably, the rule delays the amendment to the discount safe harbor until January 1, 2022. In addition, while the Proposed Rule issued in 2019 had proposed to exclude protection for rebates paid to Medicaid managed care organizations (MCOs), the Final Rule only eliminates safe harbor protection under the discounts safe harbor for Part D plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDPs).

In short, the primary provisions in the Final Rule include:

- **Creation of a New Safe Harbor for POS Price Reductions**. Effective December 30, 2020, OIG is creating a new safe harbor to protect price reductions paid by manufacturers to PDPs, MA-PDs, and Medicaid MCOs, that are fully reflected at the POS. Rebates could be protected under this new safe harbor so long as: (1) the rebate is set in advance, in writing, by the time of the first purchase of the product at the reduced price; and (2) the full value of the price reduction is extended to the dispensing pharmacy in its entirety through a "point-of-sale-chargeback" or series of point-of-sale chargebacks to be reflected in the price paid by the beneficiary at the time of dispensing. The Final Rule clarifies that price reductions conditioned on formulary placement can qualify for protection under the new safe harbor.
- **Creation of a New Safe Harbor for PBM Services**. Also effective December 30, 2020, OIG is creating a new safe harbor to protect fair-market-value (FMV) service fees paid to PBMs by manufacturers. The service fee agreement must (1) be signed by the parties; (2) involve a FMV, fixed payment and a description of all of the services provided by the PBM pursuant to the agreement; (3) not take into account the value or volume of referral or business between the parties; and (4) not involve the counseling or promotion of a business arrangement or other

activity that violates state or Federal law. Furthermore, the services rendered must be disclosed in writing to health plans with which the PBM contracts on an annual basis, and be made available (along with fees paid for such services) to the Secretary upon request.

- **Amendment to the Discount Safe Harbor**. Effective January 1, 2022 and in advance of the CY 2022 Part D plan year, safe harbor protection will be eliminated for manufacturer rebates paid directly (or indirectly through a PBM) to Part D prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs). OIG clarifies that it intends the discount safe harbor to continue to protect rebates extended to other entities, including Medicaid MCOs, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other federal healthcare programs.

Below is a more detailed summary of the Final Rule.

BACKGROUND ON THE 2019 PROPOSED RULE

The Rebate Rule was first released in January 2019 as a notice of proposed rulemaking. During a 60-day public comment period following formal publication of the proposed rule in the Federal Register, the agency received nearly 20,000 comments, many in opposition. On July 10, 2019, the Office of Management and Budget (OMB) announced that HHS-OIG was "withdrawing" the proposed rule and listed the rule as a "Completed Action" on its website.[1]

On July 24, 2020, President Trump announced a series of four Executive Orders (EOs) focusing on drug pricing, including an EO directing HHS to complete its 2019 Rebate Rule rulemaking process. The July 2020 EO provided as a condition precedent to any finalization of the rebate policy the following requirement: "Prior to taking action under section 3 of this order [to issue rulemaking], the Secretary of Health and Human Services shall confirm — and make public such confirmation — that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[2] In 2019, CMS' Office of the Actuary estimated that the Rebate Rule would increase Federal spending for Medicare Part D by about $196 billion on net over the 2020-2029 period.

In the Final Rule, in lieu of a formal actuarial analysis, Secretary Azar released a statement confirming the Rebate Rule would meet the requirements of the EO, stating in part: "I confirm that in my view the Final Rule implementing the Executive Order is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[3]

[1] *See* https://www.reginfo.gov/public/do/eoDetails?rrid=129208. *See also* https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[2] *See* https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/.
[3] *See* https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html.

BACKGROUND ON THE DISCOUNT SAFE HARBOR

Finalized on January 29, 1991,[4] the regulatory discount safe harbor was created by the OIG under its regulatory authority to provide protection from the anti-kickback statute (AKS), which establishes a general prohibition on the knowing and willful remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs. In part, the discount safe harbor was intended to align and expound upon the statutory exception to the AKS that was created by Congress for "a discount or other reduction in price obtained by a provider of services or other entity…."[5]

Under its plain terms, the discount safe harbor currently protects "rebates", which the OIG defines as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale."[6]

In the 2019 Proposed Rule, OIG noted that the discount statutory exception and the regulatory discount safe harbor, and all revisions made to such safe harbor (including the explicit inclusion of rebates), occurred *before* promulgation of comprehensive regulations governing Medicaid managed care and before the enactment of the Medicare prescription drug benefit. Thus, the OIG suggested in the Proposed Rule that the prevailing rebate system may not be optimal under the existing regulatory environment for the purposes of reducing drug costs and beneficiary out-of-pocket costs. In the Final Rule, OIG reiterates its belief that the rule will create incentives for manufactures to lower their list prices, reduce the incentives for Part D plans to choose high-cost, highly rebates drugs, and lower beneficiary out-of-pocket spending.

FINAL RULE SUMMARY

Amendment the Discount Safe Harbor

In the Final Rule, OIG amends the discount safe harbor by eliminating safe harbor protection for manufacturer reductions in price on prescription pharmaceutical products to Medicare Part D and Medicare Advantage Plans, unless the price reduction is one required by law. The amendment would be effective January 1, 2022 for the CY 2022 plan year to allow Part D plans additional time to transition to a new discounting system (the CY 2021 plan year begins in less than 60 days). Even with this added times, given that Part D bids for CY 2022 are due in June 2021, we suspect efforts to come into compliance will need to begin immediately.

OIG proposes to interpret the term "plan sponsor under Medicare Part D" to include both the sponsors of a prescription drug plan (PDPs) as well as Medicare Advantage organizations offering prescription drug plans (MA-PDs).

[4] 56 Fed. Reg. 35952 (July 29, 1991).
[5] § 1128B(b)(3)(A).
[6] 42 C.F.R. § 1001.952(h)(4).

OIG also clarifies that its proposed amendment does not affect its longstanding interpretation of the discount safe harbor as it relates to the prohibition on offering price reductions to one payor, but not to Medicare Part D. Furthermore, the agency clarifies that it intends the discount safe harbor to continue to protect discounts on prescription drugs offered to other entities, including but not limited to, Medicaid managed care organizations (MCOs), wholesalers, hospitals, physicians, pharmacies, and third-party payors in other federal healthcare programs. OIG also states supplemental rebate agreements and existing value-based purchasing arrangements (including under Part D and Medicaid MCOs) should also not be affected by its proposal.

With respect to specific terms under its proposed amendment to the discount safe harbor, the OIG proposes the definitions below:

- Manufacturer – As defined under section 1927(k)(5).
- Wholesaler or Distributor – As defined in section 1927(k)(11).
- Pharmacy Benefit Manager or PBM – Any entity that provides pharmacy benefit management on behalf of a health benefit plan that manages prescription drug coverage.
- Prescription Pharmaceutical Product – As defined in section 1927(k)(2)(A), (B), and (C).
- Point-of-Sale Chargeback –A payment from a manufacturer directly or indirectly to a dispensing pharmacy that would be at least equal to the reduction in price agreed to by the manufacturer and the Part D Plan sponsor or Medicaid MCO.

In the Proposed Rule, OIG had proposed to remove safe harbor protection under the discount safe harbor to Medicaid managed care organization. It had also sought comment on whether the prescription drugs affected by its amendment should also apply to prescription drugs payable under other HHS programs, including Medicare Part B fee-for-service, a Medicaid managed care program operating under a section 1915(b) waiver, and a PACE plan including qualified prescription drug coverage. In the Final Rule, OIG declined to expand the prescription drugs impacted by the rule and removed its application to Medicaid MCOs.

Creation of Two New Safe Harbors

The Final Rule also creates two new safe harbors, both effective well in advance of the elimination of the discount safe harbor, in order to allow for a period of transition. The first safe harbor would protect point-of-sale price reductions (i.e., rebates that flow through directly to the price a consumer pays at the pharmacy counter). The second would protect fixed-fee service arrangements between pharmaceutical manufacturers and PBMs. According to the OIG, these new safe will be "beneficial and present a low risk of fraud and abuse if structured in accordance with the [new] safe harbor's conditions."

While the Final Rule keeps in place protection under the discount safe harbor for rebates provided to Medicaid MCOs, it also extends protection under the two new safe harbors to Medicaid MCOs (along with PDPs and MA-PDPs).

Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products Safe Harbor

The first new safe harbor, "Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products" (the "point-of-sale safe harbor"), will protect price reductions offered by manufacturers at the point-of-sale for products that are paid to PDPs, MA-PDPs, and Medicaid MCOs that meet specified criteria.

To be protected under the Anti-Kickback Statute, these payments must:

- **Be set in advance**. This means that the price reduction would set in advance, in writing, by the time of the first purchase of the product at the reduced price.
- **Not involve a rebate**. The discount in price cannot be structured as a rebate unless the full value of the reduction in price is passed through to the pharmacy in its entirety through a "point-of-sale chargeback" or series of point-of-sale chargebacks administered by a PBM, wholesaler, or other entity.
- **Fully transparent to the beneficiary**. The new safe harbor requires that the reduction in price be fully reflected in the price of the prescription drug at the time it is dispensed by the pharmacy.

This new safe harbor will be effective 60 days after the publication of the Final Rule in the Federal Register (December 30, 2020). OIG intends that it apply at all phases of the Part D benefit.

PBM Service Fees Safe Harbor

The second new safe harbor, entitled "PBM Service Fees" (the "PBM safe harbor'), will protect fixed fees that manufacturers pay to PBMs for services rendered to manufacturers that meet a set of specified criteria. As might be expected, these criteria center around services typically performed by PBMs for the manufacturer's benefit.

Importantly, the safe harbor will only protect payments for services that the PBM is providing for the manufacturer, not for the health plan. These services might include pharmacy contracting; setting reimbursement levels for network pharmacies; negotiating rebate arrangements; development and management of formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.

To be protected under the PBM safe harbor, the flat fee arrangement will need to meet the following conditions:

- **Be set in advance**. The signed, written agreement setting out the fixed fee arrangement must cover all of the services that the PBM provides to the manufacturer for the term of the agreement and must also specify the compensation for the services.
- **Based on fair market value**. The compensation arrangement must be based on fair market value in an arm's-length transaction, be a fixed payment (i.e., not a percentage-based

payment), and not take into account the volume or value of any referrals or business generated between the parties (or between the manufacturer and the PBM's health plan clients).

- **Be disclosed to health plans and the Secretary**. The PBM will be required to disclose in writing to each health plan with which it contracts the services that it rendered (but not the fees) to each pharmaceutical manufacturer that are related to the PBM's arrangement with that health plan. This information will also have to be made available, along with the fees paid for such services, to the Secretary upon request.

RESPONSE TO COMMENTS ON THE PROPOSED RULE

Compliance with EO Cost Savings Requirement: In accordance with the July 24, 2020 EO requiring the Secretary to confirm that the Rebate Rule will not increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs, Secretary Azar released a public statement in tandem with the Final Rule clarifying that: "in my view the Final Rule implementing the Executive Order is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." The "confirmation" statement details Secretary Azar's extensive experience with the Part D program as the basis for his findings. The final rule does not contain any new economic and/or actuarial analyses or estimates of the Rebate Rule, but does restate the findings included in the Proposed Rule.

Point-of-Sale Chargebacks: For purposes of complying with the new Point-of-Sale safe harbor, HHS had suggested in the Proposed Rule that any price concessions offered by a manufacturer must be fully reflected in the total payment to the pharmacy for the prescription drug and that such payments would likely occur through the use of "chargebacks" or a series of chargebacks. In the Final Rule, HHS renames the process "point-of-sale chargebacks" and clarifies that OIG is agnostic as to which entities administer this function (PBMs, wholesalers, etc.) OIG also modifies the definition of chargeback to clarify that a chargeback should equal to the reduction in price of the drug, as opposed to the discounted price of the drug, to avoid "gaming."

Formulary Placement: In the Proposed Rule OIG provided, in part, "[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price." In response, a number of commenters sought clarification as to the permissibility of price reductions conditioned on formulary placement under the new point-of-sale safe harbor. In the Final Rule, OIG clarifies: "reductions in price given to Part D plan sponsors or Medicaid MCOs that are conditioned on formulary placement of a particular drug can qualify for protection under the new safe harbor for point-of-sale reductions in price (and could have been protected for Part D plan sponsors under the discount safe harbor, and can continue to be protected under the discount safe harbor for Medicaid MCOs if all safe harbor conditions are met)."