NCPA Member Summary of Rebate Rule

High-level summary of relevant provisions for small business community and long-term care pharmacists contained in the final rule "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" more commonly known and describe as the "rebate rule" released by the U.S. Department of Health and Human Services, Office of Inspector General. The rule was published in the Federal Register on November 20th, 2020 and will take effect on January 1st, 2022.

HHS aims to transfer the benefits of rebates from the Pharmacy Benefit Managers (PBMs) to patients at the point of sale in Medicare Part D. The safe harbor only applies if a rebate is used. The Administration hopes by changing the safe harbors to ensure rebates flow to patients at the point of sale that drug prices and out of pocket patient costs will decline. Much of the operational details of the rule are still yet to be determined, as CMS is tasked with developing those rules –but the effective date of the rule remains January 1st, 2022.

Changes From Initial Proposal

There were three significant changes from the earlier proposed rule, on which NCPA provided comments, and the final rule published in the Federal Register:

- A change of the date of compliance to account for industry implementation from January 1st, 2020 to January 1st, 2022.
- A change in the definition of a chargeback, which is discussed in greater detail below.
- The exclusion of Medicaid MCOs from the change in the safe harbor protections. HHS OIG, acknowledging existing legal and regulatory requirements for MCOs and the flexible cost-sharing arrangements, decided the inclusion of MCOs in the final rule would have minimal impact on the amount a patient spends on a prescription at the point of sale.

Highlights

- The "rebate rule" has no direct impact on DIR fees as it was beyond the scope of the OIG. Any potential changes to pharmacy reimbursement because of this rule will be the result of contracting between the pharmacy and the PBM, per the rule. The rule contains language to make the pharmacy whole for its costs through a "chargeback" process.
- A chargeback is defined by HHS as "a payment from a manufacturer to a dispensing pharmacy that would be at least equal to the discounted price of the drug agreed to by the manufacturer and the Part D Plan sponsor or Medicaid MCO." HHS is implementing this to ensure the pharmacy is made whole for the cost of dispensing the drug at the point of sale. The rule leaves chargebacks to be handled by a "chargeback administrator" which could be a PBM or any other entity or third-party administrator, or even direct payments to the pharmacy from the manufacturer. HHS OIG left the rule intentionally vague to allow for the market to develop innovative programs.
- The underlying executive order which requested the Secretary of HHS to finalize the rebate rule required the Secretary to certify the rule will not raise premiums, increase out of pocket cost for patients, or increase federal spending. The Secretary made a public statement on his belief the rule would not do so. However, HHS' own actuaries published a study which said the rule would increase Medicare premiums for all seniors by 25%.
- Implementation of the rule will require knowledge of any rebates passed on from the manufacturer to the PBM and detailed price information at the point of sale. The rule is unclear on how that information will be presented or what will be required on behalf of pharmacy to be able to obtain that information. NCPA will work with NCPDP, which is developing the framework on fields and information presented at the point of sale, and CMS on the practical implementation of the rule. NCPA will also work with industry stakeholders to produce the best outcome for independent pharmacy.

HHS proposed the rebate rule in February of 2019 in which the Secretary set forth his concerns and issues with the current prescription drug model and the entire rebate system and its' effects on drug prices. On July 24, 2020, President Trump signed an executive order directing the Secretary to finalize the rule, which was never formally withdrawn, subject to a public proclamation which would not raise costs for patients, premiums, or federal spending. On November 20th, 2020, the Secretary publicly stated his approval of the "rebate rule" and the Office of Management and Budget published the final rule in the Federal Register. NCPA commented on the initial proposal and provided the Administration with the minimum requirements for NCPA's support. After HHS finalized and published the rule, NCPA and other national pharmacy organizations released a statement[1] expressing disappointment the agency did not do anything to address DIR fees.

Rebate Rule Basics

The final rule would transform the current system from a manufacturer to PBM rebate model to one where the change in the safe harbors make the rebate "flow" to the patient at the point of sale. HHS OIG updates the discount safe harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to PBMs and Part D plans from the safe harbor's definition of a "discount." It replaces that mechanism with a new safe harbor designed specifically for price reductions on pharmaceutical products, but only those that are reflected in the price charged to the patient at the pharmacy counter. In order to qualify for these newly established safe harbors, "the reduction in price does not involve a rebate, unless the full value of the price reduction is accomplished through chargebacks or is a rebate required by law", be set in advance of the purchase, and "the reduction in price is completely reflected in the price the pharmacy charges to the beneficiary at the point of sale."

This means the patient would be the main beneficiary of any rebates offered by the manufacturer and would remove financial incentives for formularies to encourage the use of heavily rebated brand name pharmaceuticals over generics. This is a stated goal of HHS in putting forth this policy.

Pharmacy Chargebacks

Additionally, the rule provides a payment mechanism to ensure the final point of sale dispensing pharmacy is made whole throw a "chargeback." HHS defines a "chargeback" as a "payment from a manufacturer to a dispensing pharmacy that would be at least equal to the discounted price of the drug agreed to by the manufacturer and the Part D Plan sponsor or Medicaid MCO" and further clarifies in the rule that the "chargeback should be equal to the reduction in price, not the discounted price of the drug, so we define a chargeback in the final rule as a payment equal to the reduction in price." Through this chargeback payment mechanism, HHS reiterates "as we stated in the Proposed Rule, we intend for the point-of-sale chargeback to make 'pharmacies whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment.'"

In comments to the proposed rule, NCPA encouraged HHS to adopt a better definition of chargeback to fully cover the cost of the pharmaceuticals to the pharmacy. In response, HHS did modify the definition to address those concerns by redefining chargebacks as "equal to the *reduction in* price" between the manufacturer and the Part D plan sponsor or Medicaid MCO, rather than "at least equal to the [discounted] price," as in the proposed rule. Unfortunately, the rule language did not address concerns about costs related to standing up the necessary changes to the system, increased transparency to the pharmacy, liability concerns, or several other issues related to independent pharmacy participation.

HHS anticipates PBMs or third-party administrators being the pass-through entities for chargebacks to pharmacies. However, HHS does not preclude direct payments to pharmacies in the chargeback arrangements stating, "while a chargeback may be paid directly to the pharmacy, the Medicaid MCO or Part D plan is the anticipated recipient of the reduction in price." However, the new safe harbor requires this reduction to be passed through to the patient at the point of sale.

[1] https://ncpa.org/newsroom/news-releases/2020/11/24/pharmacy-groups-say-new-rebate-rule-does-not-do-enough-support

HHS does not believe this rule will have an impact on existing agreements between plans and pharmacies on DIR fees as "we are not specifying the reimbursement terms of an agreement between a PBM or plan and a pharmacy for prescription pharmaceutical products in the final safe harbor." The rule explicitly states "the administration of pharmacy DIR fees is outside the scope of this rulemaking. Nothing in this final rule changes CMS's rules with respect to DIR." The HHS OIG only has authority to modify the rules derived from the Antikickback Statute.

However, HHS notes "nothing in this rule limits pharmacies' ability to inquire about missing chargeback payments or to enter into contracts that provide for appealing chargeback decisions, utilizing audit processes, and engaging in dispute resolution. We further note that community pharmacies would not necessarily be liable under the anti-kickback statute if other parties violate the anti-kickback statute. Whether a party is subject to liability under the anti-kickback statute depends **upon the actions and intent of that party** and not solely upon the actions and intent of other parties to an arrangement." (Bold added for emphasis)

There are a lot of details left up to contract negotiations between the different stakeholders. As HHS notes "the Part D program is a private sector-based program in which the participating entities negotiate with their partners to make what they believe are the most effective arrangements to participate in the Part D market."

As HHS notes "the final rule does not require fees, but only provides a safe harbor from liability under the anti-kickback statute for certain fees or other remuneration, under certain conditions. Whether pharmacy reimbursements are affected by price reductions agreed to between manufacturers and PBMs or plans for purposes of compliance under this rule will depend on the particulars of private contracting between the parties."

Vertical Integration of PBMs and Pharmacies

HHS OIG is concerned about possible gaming of the rebate system by funneling rebates through non-PBM entities to avoid passing the rebate along to the patient at the point of sale. HHS provides "we note, however, that arrangements in which PBMs funnel discounts through affiliated or commonly owned entities, or arrangements where it appears that a PBM is channeling kickbacks through a commonly owned entity or otherwise in order to evade this rule, are highly suspect. If a discount offered to a pharmacy is for the purpose of inducing a commonly owned entity, e.g., a PBM, to arrange for the purchase of a drug paid for by Federal health care programs, through formulary placement or otherwise, then the discount would not be protected by the discount safe harbor." Any purposeful circumvention of the requirements of the safe harbor would open that entity to potential liability for violating the AKS.

Next Steps

NCPA will continue working with all impacted stakeholders on implementation of the rebate rule. HHS OIG has left CMS to fill in many of the details and is intentionally vague with many of the new definitions and implementing procedures. NCPA will be active in advocating for the adoption of policies favorable to community pharmacy as CMS moves forward through their own rulemaking.

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