

## **NCPA's General Analysis for Members Regarding the Proposed Rebate Rule**

On February 6, 2019, The Department of Health and Human Services Office of Inspector General (“HHS” and “OIG”) published a proposed rule titled, *Fraud and Abuse; 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* (the “Proposed Rebate Rule”).<sup>1</sup> The Proposed Rebate Rule seeks to exclude rebates paid by manufacturers to plans under Medicare Part D and Medicaid MCOs from the discount safe harbor<sup>2</sup> and creates a new safe harbor for point-of-sale price reductions from manufacturers to plans.<sup>3</sup> By moving manufacturer rebates to the point of sale, this proposal intends to reduce list prices and lower patients’ out-of-pocket drug costs.<sup>4</sup>

This proposal, however, will have far-reaching implications on the entire supply chain, including how and when pharmacies are reimbursed for dispensing product under the Medicare Part D and Medicaid managed care programs. Thus, NCPA has prepared this summary to outline the Proposed Rebate Rule.

Changing the pharmacy payment model is a top priority for NCPA and the Proposed Rebate Rule is an important component of changing the model. To this end, NCPA is analyzing the proposal and working with members and industry partners on our response to HHS.

### ***What are the main points of the proposal?***

The Anti-Kickback Statute (“AKS”) provides for criminal penalties for those who knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under any federal healthcare program.<sup>5</sup> Pursuant to legal authority, Congress and HHS have designated certain safe harbors for activities that might otherwise violate the AKS. The rebates currently paid by manufacturers to plans under Medicare Part D and Medicaid MCOs is a practice that falls under what is known as the discount safe harbor.<sup>6</sup>

This Proposed Rebate Rule seeks to end the safe harbor protections for rebates paid by manufacturers to PBMs but would create a new safe harbor that would allow manufacturers to offer

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<sup>1</sup> 84 Fed. Reg. 2340 (Feb. 6, 2019).

<sup>2</sup> 42 C.F.R. § 1001.952(h).

<sup>3</sup> 84 Fed. Reg. 2340, 2343. The Proposed Rule also creates a new safe harbor to protect certain fixed fee arrangements between PBMs and drug manufacturers.

<sup>4</sup> *Id.* at 2344.

<sup>5</sup> 42 U.S.C. § 1320a-7b(b). Such action is considered a felony that is punishable by fines of up to \$100,000 and imprisonment for up to 10 years.

<sup>6</sup> 42 C.F.R. § 1001.952(h).

discounts to Part D plans and Medicaid MCOs in exchange for formulary placement so long as those discounts are applied at the point of sale. Once applied, these point-of-sale reductions would effectively base a patient's out-of-pocket payments on the "net price" of a drug (the proposal states "net price" is industry jargon to mean the difference between the list price of a drug and the rebate amount).<sup>7</sup> This net price becomes the benchmark for patients' out-of-pocket spending as well as pharmacy reimbursement. Then, a pharmacy's reimbursement would be subject to certain chargebacks from the manufacturer to the pharmacy, either directly or indirectly, to make the pharmacy whole.

Thus, under the new safe harbor a manufacturer can offer a reduction in price on a prescription pharmaceutical product to a Part D sponsor, Medicaid MCO, or PBM only if the following conditions are met<sup>8</sup>:

1. The reduction in price would have to be set in advance with the plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM.
2. The reduction in price could not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks. A chargeback is a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment the pharmacy receives for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Part D sponsor, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.

Example: When a pharmacy dispenses a drug to a beneficiary that is reimbursed by a particular Part D plan or Medicaid MCO, the total payment to the pharmacy will be at least equal to the price agreed upon between the manufacturer for that drug and the Part D plan of Medicaid MCO, or a PBM acting under contract with either.

3. The reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale.

Example: If the discounted rate is set in advance, at the time of dispensing the pharmacy would have the necessary information to appropriately charge a beneficiary who owes coinsurance, even if the manufacturer ultimately tenders the dispensing pharmacy a payment through a chargeback to reflect this negotiated price with the payor.

***If this proposal is finalized, when would the changes go into effect?***

The Proposed Rebate Rule states the proposal to end the safe harbor for rebates will go into effect as early as January 1, 2020. The creation of the new safe harbor for point-of-sale price reductions is slated to go into place 60 days after the publication of the final rule.<sup>9</sup>

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<sup>7</sup> 84 Fed. Reg. 2340, 2352.

<sup>8</sup> Id. at 2349.

<sup>9</sup> Id. at 2348.