Two Separate and Distinct Policies to Reform Medicare Part D DIR: Pharmacy DIR and Manufacturer Rebates

Direct and indirect remuneration ("DIR") in Medicare Part D is primarily comprised of two separate and distinct categories: 1) pharmacy price concessions (often referred to as "pharmacy DIR fees"); and 2) manufacturer rebates (often referred to as "rebates"). Over the past several years, policymakers have sought to reform both categories through distinct and separate proposals as outlined below.

Pharmacy Price Concessions/Pharmacy DIR Fees

Pharmacy price concessions/pharmacy DIR fees are a subset of total direct and indirect remuneration (DIR) in Medicare Part D. These fees are negotiated between a pharmacy and a PBM/plan and are currently assessed against pharmacies on a retroactive basis, meaning they are not included in the negotiated price at point of sale. Pharmacy price concessions can include fees to participate in a preferred network and/or fees based on performance measures, among others.[1]

On Nov. 30, 2018, the Centers for Medicare and Medicaid Services published the proposed rule, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS-4180-P,*[2] which featured critical policy changes to the application of pharmacy price concessions/pharmacy DIR. Of note, the proposed rule sought to:

- Implement a definition of "negotiated price" to include all pharmacy price concessions be assessed at the point of sale;
- Exclude from the "negotiated price" definition any positive contingent price concessions that could flow to a pharmacy that could be assessed after the point of sale; and
- Consider standardization of pharmacy performance metrics utilized in the Part D program.

Per CMS, patients win when pharmacy price concessions/pharmacy DIR is included in the negotiated price and assessed at the point of sale because "[b]eneficiary cost-sharing is generally calculated as a percentage of the negotiated price. When pharmacy price concessions are not reflected in the negotiated price at the point of sale . . . beneficiary cost-sharing increases, covering a larger share of the actual cost of a drug."[3]

This May, however, CMS did not finalize this proposal despite recognizing that there were over 4,000 comments that addressed the proposed change. However, the policy changes in the

[1] Pharmacy price concessions are the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates. CMS states, "[t]he data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017." *Id.* at 62174.
[2] 83 Fed. Reg. 62152 (proposed Nov. 30, 2018).
[3] *Id.* at 62176.

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aforementioned proposed rule are largely reflected in the *Phair Pricing Act,* introduced by Senator John Kennedy (R-La.) as S. 640 in the Senate and Representatives Doug Collins (R-Ga.) and Vicente Gonzales (D-Texas) as H.R. 1034 in the House.

Manufacturer Rebates

In contrast, manufacturer rebates are a different category of DIR in Medicare Part D. Manufacturer rebates are negotiated between PBMs and manufacturers. 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").[4]

The 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 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).[5] 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. The Proposed Rebate Rule is currently at OMB.

Pharmacy price concessions/pharmacy DIR must be addressed before or in conjunction with changes to the assessment of manufacturer rebates

NCPA has consistently argued that pharmacy price concessions/pharmacy DIR must be addressed before or in conjunction with any changes made to manufacturer rebates in Medicare Part D. This is because rebates are not the only types of remuneration that can lead to inflated drug prices and higher out-of-pocket costs for patients.

Further, NCPA is concerned that if manufacturer rebates are only addressed and policies regarding pharmacy price concessions/pharmacy DIR remain the status quo, PBMs may use the loss of revenue from rebates to levy larger and more aggressive pharmacy price concessions against pharmacies.

[4] 84 Fed. Reg. 2340 (Feb. 6, 2019).
[5] 84 Fed. Reg. 2340, 2352.

CMS has well-established data that demonstrates PBMs usage of retroactive pharmacy price concessions is growing rapidly.[6] If the level of manufacturer rebates being paid to plans/PBMs for formulary placement and market share are reduced under the new contractual arrangements implemented under a final HHS/OIG rule, plans/PBMs may be under pressure to provide alternative avenues to keep plan liability closer to its current levels. One way to achieve this would be to contract aggressively for increased pharmacy DIR. Increased pharmacy DIR would lead to lower pharmacy revenue, which could make it difficult for small pharmacies to continue to participate in or gain network access.[7]

In fact, a Milliman analysis in the Proposed Rebate Rule outlined the potential for this occurrence. In Scenario 7, Milliman assumes "PBMs and plans will more aggressively contract for pharmacy rebates in the absence of manufacturer rebates. Pharmacy rebates would still have strong value through their treatment as DIR and there may be opportunities to offset the increases to member premium by negotiating for increased pharmacy rebates."[8]

Thus, NCPA contends that pharmacy price concessions/pharmacy DIR must be addressed before or in conjunction with changes to the assessment of manufacturer rebates to avoid squeezing small business community pharmacies out of business.

[6] 83 Fed. Reg. 62,152, 62,174. In fact, CMS has projected that the average growth of pharmacy price concessions will be approximately 10% per year going forward. *Id.* at 62191.

[7] Milliman, *Impact of Potential Changes to the Treatment of Manufacturer Rebates* (2019), *available at* https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf.

[8] *Id.* at 14-15.