Implications of Policy Reforms on Pharmacy DIR in Part D

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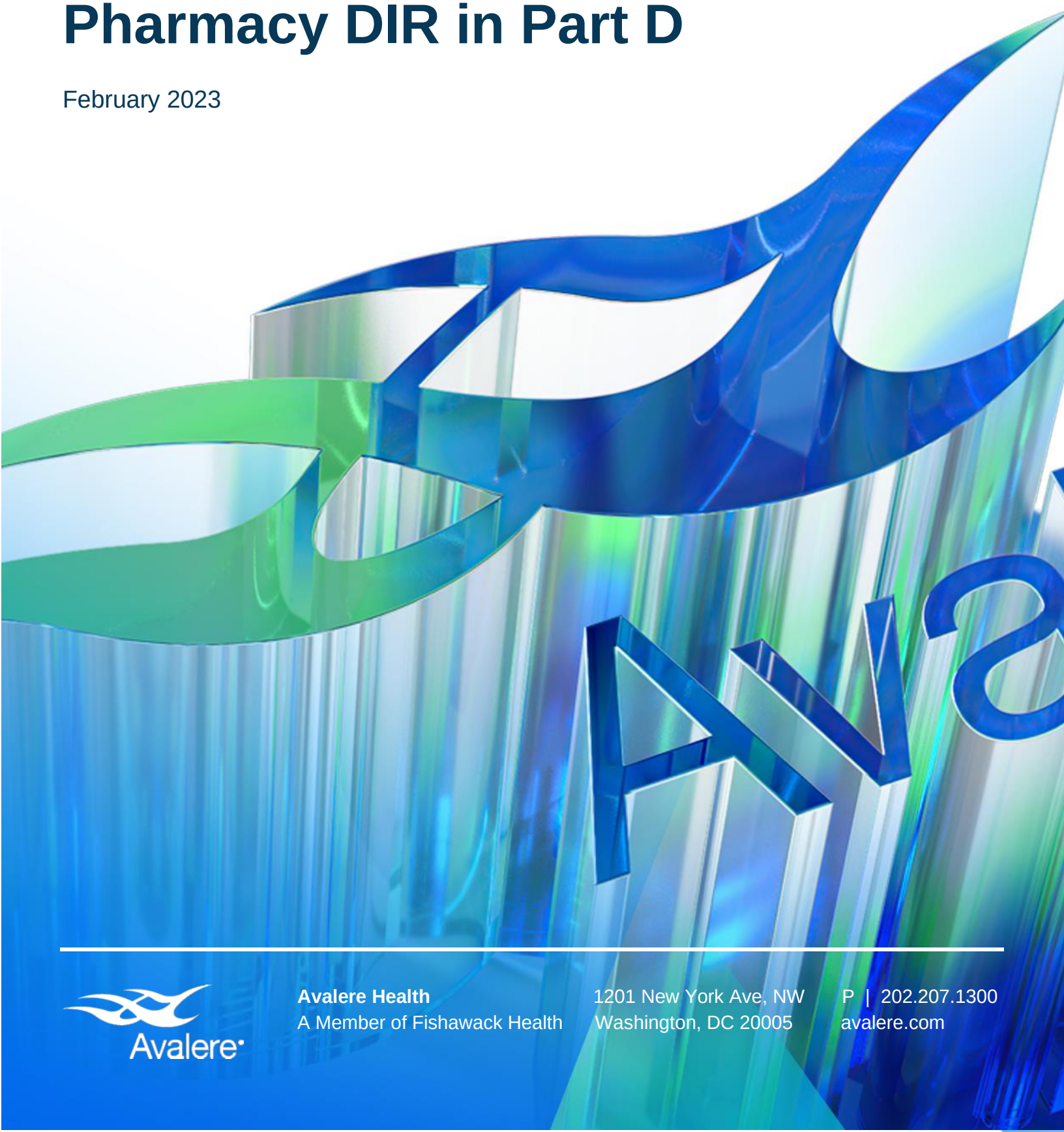

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Introduction

Use of Direct and Indirect Remuneration (DIR) in Part D has gained attention from policymakers in recent years. In this issue brief, Avalere illustrates current Part D plan incentives related to DIR, provides an overview of pharmacy DIR, and reviews how the Calendar Year (CY) 2023 Medicare Advantage (MA) and Part D rule from CMS may change pharmacy DIR incentives.

Background

In the Medicare Part D program, multiple stakeholders – including the plan and its contracted pharmacy benefit manager (PBM), manufacturer, and pharmacy – determine the payment amount for prescription drugs.[1] When a beneficiary fills a prescription at the pharmacy, the Part D plan pays the pharmacy for the drug based on a contracted rate, known as the Part D negotiated price. This rate is contracted as result of contract negotiations between pharmacies or pharmacy services administrative organizations (PSAOs) with plans and PBMs that determine what the reimbursement amount will be to a pharmacy.[2] Beneficiary cost sharing at the point-of-sale (POS) is based on the Part D negotiated price, the enrollee's plan benefit design which establishes the coinsurance percentage or flat copayment amount, and where the enrollee currently falls in the Part D benefit structure (e.g., the deductible versus the catastrophic portion of the benefit).

Part D plans frequently obtain price concessions, such as rebates, as well as other discounts These discounts are part of DIR, which generally refers to any payment adjustments that occur *after* the point of sale (i.e., after a beneficiary fills a script at the pharmacy) that changes the final cost of a drug to a Part D plan.[3] While DIR encompasses many forms of discounts and price concessions such as administrative fees above fair market value, price concessions for administrative services, and risk-sharing settlements, the two largest categories of DIR include:

1) **Manufacturer DIR** (e.g., manufacturer rebates), which is primarily paid to Part D plans by drug manufacturers for formulary placement, and
2) **Pharmacy DIR**, which generally refers to all discounts, subsidies, or rebates that a pharmacy pays to a Part D sponsor (i.e., negative payment adjustments known as

[1] Part D plans contract with pharmacy benefit managers (PBMs) to manage drug benefits, including for aspects related to pharmacy network contracting, formulary negotiations with manufacturers and formulary development, and claims adjudication. Throughout this paper, Avalere references Part D plans which is assumed to mean Part D plans and their contracted PBMs.

[2] Smaller, independent pharmacies may use third-party entities called pharmacy services administrative organizations (PSAOs), which provide a variety of administrative services to pharmacies, including evaluating and executing contracts with Part D plans. It is estimated that PSAOs contract with approximately 80% of independent pharmacies and provide a range of services which may include certain support services associated with Part D network contract management.

[3] 42 CFR § 423.308

pharmacy price concessions) or that a Part D sponsor pays to the pharmacy (i.e., positive adjustments known as pharmacy incentive payments).[4]

DIR is integral to the Part D bidding and payment structure. When plans submit their annual prospective bids (i.e., the estimate of plan costs for providing basic Part D benefits for a given plan year) to the federal government, they include projected DIR. If DIR results in payments from the Part D plan to the pharmacy, that could increase costs to the plan. Conversely, when there are payments by the pharmacy to the Part D plan after the POS, these payments reduce the plan's expected costs, which allows them to lower premiums for enrollees. Because DIR is applied after the beneficiary fills a prescription, DIR changes the final cost of the drug to the plan but does not change the Part D negotiated price. DIR does not lower cost sharing at the pharmacy counter for beneficiaries because beneficiary cost sharing is based the negotiated price. This tradeoff between cost sharing and premiums is a critical part of the policy debate surrounding DIR, as plans have generally opted for lower premiums instead of reduced cost sharing that could be achieved if the price concessions were applied at the POS in the negotiated price. Although overall Part D spending has grown over the years, average Part D premiums have remained stable since the start of the program, in part due to growth in DIR. According to the Medicare Trustees, DIR grew from 11.7% of total Part D expenditures in 2006 to 27.0% of total Part D expenditures in 2020.[5]

The DIR associated with rebates that manufacturers pay Part D plans is the largest category of DIR in terms of dollar volume.[6] As a result, manufacturer DIR has received significant attention from stakeholders due to concerns about the growth of high-rebate, high-list price arrangements and their impact on increasing beneficiary out-of-pocket (OOP) costs, as enrollee cost sharing at the POS reflects the price before DIR is applied.[7] However, CMS has also cited the substantial growth in pharmacy DIR in recent years, increasing from $1.7B in 2015 to $9.5B in 2020.[8]

The growth in pharmacy DIR is thought to be driven in large part by increases in the use of performance-based payment arrangements over the past decade. The contracts that pharmacies and PSAOs negotiate with plans and PBMs have increasingly included a variety of contingent payment amounts that are tied to performance by the pharmacy on a set of quality metrics (e.g., medication adherence, generic drug dispensing rates, etc.) as well as pricing benchmarks (e.g., maximum allowable cost lists that caps reimbursement rates for multi-source medications). Any payment adjustments to a pharmacy's initial payment (e.g., contingent amounts based on a pharmacy's performance against quality metrics) that happen after the POS are considered pharmacy DIR. For example, plans and PBMs may include performance-based payments as part of their initiatives to improve their Medicare Star Ratings. For 2023, 5 of the 40 Star Rating

[4] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.
[5] Medicare Trustees. 2022 Annual Report. Available here.
[6] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.
[7] 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. Available here.
[8] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.

measures are tied to pharmacy activities: medication adherence measures (one each for diabetes, hypertension, and cholesterol), medication therapy management, and use of statins for enrollees with diabetes.

As a result of the substantial volume of manufacturer DIR, growth of pharmacy DIR, and impact of DIR on beneficiary cost sharing, the Department of Health and Human Services (HHS) developed rules addressing some forms of DIR, including a rule finalized in 2020 to eliminate manufacturer rebates and require manufacturer price concessions to be reflected at POS,[9,10] as well as the CY 2023 MA and Part D rule finalized in May 2022, which focuses on pharmacy DIR. The CY 2023 rule requires Part D plans and PBMs to reflect pharmacy price concessions in the negotiated price and in the price paid by beneficiaries at the POS beginning in 2024.[11] CMS estimates that the change will increase plan premiums by $13.8 billion over 10 years, as pharmacy price concessions will no longer count as DIR, thus increasing plan net costs, bids, and premiums. However, because pharmacy price concessions will be reflected at the POS, CMS estimates that the rule will decrease beneficiary cost sharing by $40.3 billion over 10 years.[12]

Pharmacy DIR can be positive or negative – in some cases a pharmacy may receive additional payment from the Part D plan or its PBM, which is considered "negative" DIR to a plan or PBM (i.e., increases costs for the Part D plan). However, more frequently, pharmacies are required to make payments to the Part D plan after the POS, which is positive DIR for a plan (i.e., decreases costs for the Part D plan). According to CMS, in aggregate, price concessions paid by pharmacies are "far greater" than amounts paid to pharmacies for positive incentive payments.[13] Since retrospective payment adjustments between Part D plans and pharmacies typically reduce the net payment amount to the pharmacy, the Part D negotiated price is higher than the final amount paid by the Part D plan or its PBM. Price concessions can be owed by pharmacies to plans months after a claim is processed at the POS. Because these payments are often based on pharmacy performance against certain metrics (e.g., generic dispensing rates, medication adherence), pharmacy groups have asserted that final payment amounts to pharmacies are not transparent and predictable, creating cash flow and other financial challenges.[14,15] Pharmacies have therefore advocated for reforms, such as those finalized in the CY 2023 MA and Part D rule, to pharmacy DIR.[16,17]

[9] 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. Available here.
[10] The Inflation Reduction Act Delayed implementation of the 2020 rebate rule to January 1, 2032.
[11] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.
[12] Ibid.
[13] Ibid.
[14] National Association of Chain Drug Stores (NACDs). "DIR Fees." Available here.
[15] National Community Pharmacists Association (NCPA). "Frequently Asked Questions (FAQs) About Pharmacy "DIR" Fees." Available here.
[16] National Community Pharmacists Association (NCPA). "Pharmacy DIR Fees and NCPA Advocacy Efforts." Available here.
[17] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.

Part D Plan Incentives for Pharmacy DIR

The federal government subsidizes Part D plans to provide drug benefits for enrollees. Plan subsidies from the government are based on expected drug costs that reflect predicted utilization and drug prices with adjustments to reflect DIR. Because member cost sharing in the deductible and for any drug with coinsurance is based on the Part D negotiated price, which does not reflect DIR, member cost sharing is higher than it would be if the price concession were applied to the POS price at the pharmacy counter.

Positive DIR is advantageous for plans because it lowers plan costs more than if reductions in price were applied at the POS; this in turn lowers member premiums. There are two main, interrelated dynamics that work together to lower plan costs and premiums: 1) the current Part D benefit design, in which plan liability is limited to a set percentage, and 2) how the federal government applies DIR when reconciling Part D plan payments.

Under the current standard Part D benefit design, plans are responsible for a majority (75%) of costs in the initial coverage phase of the benefit and have more limited financial liability in the later phases of the benefit where they are responsible for 5% of costs in the coverage gap and 15% of costs in the catastrophic phase (Exhibit 1).

Exhibit 1. Standard 2023 Part D Benefit for Non-Low-Income Subsidy (LIS) Enrollee

Benefit Phase	Total Drug Spending	Benefit Sharing
Deductible	Below $505	Beneficiary: 100%
Initial Coverage	$505 to $4,659	Beneficiary: 25% Plan: 75%
Coverage Gap	$4,660 to $11,206	Beneficiary: 25% Plan 5% Manufacturer 70%
Catastrophic Coverage	Above $11,206	Beneficiary: 5% Plan: 15% Medicare: 80%

A portion of the DIR received by Part D plans is shared with the government based on the portion of a plan's spending that falls in the catastrophic phase of the benefit. As shown in Exhibit 1, the government pays 80% of costs once a member is in the catastrophic phase of the benefit. Assuming that, on average, about one-third of a plan's total costs are in the catastrophic phase of the benefit, the plan would receive 73.3% of the rebates (1 minus the product of one-third multiplied by 80%), with the government receiving the other 26.7%.[18] Given how script volumes

[17] CMS. "Prescription Drug Event Participant Guide." Available here.

are distributed across the phases of the Part D benefit, plan liability across the Part D benefit is about 29% before the application of DIR.

Based on how DIR is shared with the government and the current benefit structure, positive DIR results in a lower net cost to a plan than if the full value of the discount were applied at the POS (Exhibit 2). For example, consider two cases, one where the drug cost is $100 with $10 of positive DIR and another where the drug cost is $100 with a $10 price concession applied at the POS. The plan's net liability is $4.43 lower with the use of DIR after POS compared to a case with DIR applied at POS.

Exhibit 2. Impact of Price Concession Application at POS on Plan Liability Under Current Part D Benefit Design

	$100 Drug with $10 DIR	$100 Drug with $10 POS Price Concession
Negotiated Price	$100	$100 - $10 = $90
Plan DIR	$10	$0
Net Plan Retained DIR[19]	73.3% * $10 = **$7.33**	N/A
Net Cost to Plan[20]	($100 * 29%) - $7.33 = **$21.67**	$90 * 29% = **$26.10**

Overview of Recent Policy Proposals for Pharmacy DIR

In 2014, CMS originally proposed a rule to include all pharmacy price concessions in Part D negotiated prices. However, in the final rule, CMS stated, based in part on stakeholder feedback, that pharmacy price concessions established on contingent amounts that cannot "reasonably be determined" at the POS should not be included in the negotiated price, and should instead be reported as DIR.[21] Under this "reasonably determined" exception, CMS notes that negotiated

[19] Assumes that plan retained DIR is equal to 73.3% (assumes 1/3 of plan costs fall above catastrophic; therefore, plan retained DIR is equal to 1 minus the product of one-third multiplied by 80%)
[20] Assumes that average plan liability across benefit is approximately 29%.
[21] Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.

prices today typically do not reflect any performance-based pharmacy price concessions.[22] As a result, this clarification may have contributed to the substantial increase in performance-based payment arrangements and pharmacy price concessions in recent years. The pharmacy stakeholder community has pointed to the operational and financial challenges associated with the often-complex contract terms involving performance-based and other retrospectively determined payments, which they assert make final payment amounts unpredictable and administratively burdensome to manage.[23,24]

Under the new definition of negotiated price finalized in the CY 2023 MA and Part D rule that will be effective beginning in 2024, as requested by pharmacy stakeholders, CMS is eliminating this exception for contingent pharmacy price concessions. Specifically, the negotiated price will be defined as the lowest possible reimbursement amount a pharmacy could receive net of the maximum negative adjustment (i.e., net of all pharmacy price concessions) across all phases of the benefit. As a result, any adjustments applied after the point of sale would no longer be considered pharmacy DIR and any adjustments that increase payment relative to the lowest possible cost will be considered negative DIR. Pharmacy groups have expressed support for these changes, noting that they would increase transparency of pharmacy payment amounts.[25,26]

Implications of CY 2023 MA and Part D Rule on Pharmacy DIR

Revising the definition of negotiated price to reflect the lowest possible reimbursement amount has direct impact on pharmacy DIR. In the CY 2023 MA and Part D rule, CMS notes that the change to the definition of the Part D negotiated price does not impact the ability for plans to include retroactive performance-based payment adjustments in Part D plan contracts with pharmacies.[27] However, because any POS adjustments would have to be positive (since the negotiated price is defined as the lowest possible reimbursement), these adjustment would be considered negative DIR and would therefore increase plan net costs and premiums.

Exhibit 3 demonstrates how positive retrospective payment adjustments (i.e., any bonus payments to pharmacies above the lowest possible reimbursement) under the new definition of negotiated price would increase net costs for a Part D plan. The example in Exhibit 3 shows an instance where, under the new definition of negotiated price, the lowest possible reimbursement for a drug would be $90 (the new negotiated price), with an average performing pharmacy earning a $5 positive payment adjustment and the highest performing pharmacy earning a $10 payment adjustment. As shown in the exhibit below, net plan liability increases by $26.10 in the low

[22] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Final Rule. Available here.
[23] National Community Pharmacists Association. 2022 Independent Community Pharmacy Legislative Priorities. Available here.
[24] National Association of Chain Drug Stores (NACDS). "DIR Fees." Available here.
[25] National Association of Chain Drug Stores (NACDS). Comments on Contract Year 2023 Proposed Rule. Available here.
[26] National Community Pharmacists Association (NCPA). "NCPA Member Summary of the CY 2023 Part D Final Rule." Available here.
[27] National Community Pharmacists Association (NCPA). "NCPA Member Summary of the CY 2023 Part D Final Rule." Available here.

performing pharmacy with no bonus to $33.43 for the highest performing pharmacy with a $10 bonus, a more than $7 increase.

Exhibit 3. Impact of Pharmacy Bonus Payment on Net Plan Costs Under Current Part D Benefit Structure and New 2024 Pharmacy Price Concession Rules

	Low Performing Pharmacy	Average Performing Pharmacy	Highest Performing Pharmacy
Negotiated Price	**$90**	**$90**	**$90**
Pharmacy Bonus	**$0**	**$5**	**$10**
Final Price Paid to Pharmacy	**$90**	**$95**	**$110**
Plan DIR	**$0**	**-$5**	**-$10**
Net Plan Retained DIR[28]	**$0**	73.3% * (-$5) = **-$3.67**	73.3% * (-$10) = **-$7.33**
Net Drug Cost to Plan[29]	29% * $90 = **$26.10**	(29% * $90) - (-$7.33) = **$29.77**	(29% * $90) - (-$7.33) = **$33.43**

Under current rules, plan costs for a $100 drug with a $10 price concession applied as DIR would be $21.67 (Exhibit 2) compared to $26.10 under the new rules that would apply the $10 pharmacy price concession at the POS (Exhibit 3). Because of the impact of positive POS payment adjustments on net costs (and therefore upward movement on member premiums) as shown in Exhibit 3, plans are less likely to include post-POS adjustments in their contract terms with pharmacies under the new pharmacy price concession rules beginning in 2024.

Conclusion

DIR plays a key role in Part D payment under the current benefit structure. However, the changes to pharmacy DIR finalized as part of the CY 2023 MA and Part D rule are likely to lead to adjustments in pharmacy contracting. Under Part D benefit redesign in the Inflation Reduction Act (IRA), changes in the benefit design will also shift plan incentives for positive DIR. However, due to the requirement to reflect pharmacy price concessions in the Part D negotiated price under the CY 2023 rule, pharmacy DIR will only result in increased costs to plans (i.e., negative DIR) and

[28] Assumes that plan retained DIR is equal to 73.3% (assumes 1/3 of plan costs fall above catastrophic; therefore, plan retained DIR is equal to 1 minus the product of one-third multiplied by 80%)
[29] Assumes that average plan liability across benefit is approximately 29%.

will therefore be disadvantageous to Part D plans even under the new Part D benefit structure. In response to the changes to pharmacy DIR in the CY 2023 rule and under the IRA (e.g., Part D benefit redesign), Part D plans may implement broader changes to their formulary and benefit designs as they seek to mitigate premium impacts associated with these policy changes.

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