NCPA Member Summary of the CY 2023 Part D Final Rule

On April 29, 2022, the Centers for Medicare & Medicaid Services (CMS) issued its Medicare Part D final rule for contract year 2023. For CMS' press release and fact sheet, click here and here.

This final rule will revise the Medicare Advantage (MA) (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations to implement changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and most importantly for NCPA members, pharmacy price concessions aka direct and indirect remuneration (DIR) fees. **The final rule is effective on June 28, 2022, except for the price concession changes, which are effective Jan. 1, 2024.**

NCPA advocacy at work for you!

NCPA has advocated tirelessly for many years for Medicare Part D pharmacy DIR fee reform. While this final rule is not perfect, it is a huge step forward to bring much needed transparency to Part D drug pricing and pharmacy reimbursement. NCPA will continue the fight against anticompetitive plan sponsor/PBM activity that harms both Part D beneficiaries and small business pharmacies. This final rule is the latest chapter of NCPA and member pharmacies advocating for Part D changes that will make pharmacy reimbursement more transparent and predictable.

Key wins that NCPA secured

- ✓ **Negotiated price redefined.** CMS is applying a new definition of "negotiated price" to include all pharmacy price concessions at the point of sale. This will close the "reasonably determined" loophole from the previous definition in a 2014 final rule that led to the 107,400 percent rise in pharmacy DIR fees since 2010. NCPA has fought for years in front of Congress, multiple administrations, and the courts for such a change. This new definition will provide greater transparency of pharmacy reimbursement and should improve predictability of per-claim revenue.

- ✓ **Coverage gap loophole closed.** CMS closed the coverage gap loophole from the proposed rule. NCPA fought hard to make sure that the new definition of negotiated price would apply throughout all phases of the benefit and CMS agreed. A continued coverage gap loophole would have created a bifurcated system.

- ✓ **CMS sympathetic to pharmacist cash flow concerns.** CMS addressed NCPA's cash flow concerns. NCPA continually stressed the need for CMS to acknowledge that with implementation of this rule small business pharmacies will be cash strapped due to point-of-sale payment decreasing while also paying prior year DIR fees. NCPA urged CMS to require PBMs to offer payment plans to pharmacies and CMS strongly encourages alternate payment arrangements to avoid closures and harm to access.

Background

- **What is DIR?** DIR includes rebates from manufacturers, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, **pharmacy price concessions**, drug costs related to risk-sharing settlements, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan by the plan sponsor.
- To date, very few price concessions have been included in the negotiated price at the point of sale. All pharmacy and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year.
- **In 2020, pharmacy price concessions accounted for about 4.8 percent of total Part D gross drug costs ($9.5 billion), up from 0.01 percent ($8.9 million) in 2010.**

Why do plan sponsors/PBMs like DIR?

- Simply put, DIR:
  - Increases plan revenues;
  - Shifts costs to high-utilizing beneficiaries (higher cost-sharing) and the government (higher reinsurance and low-income cost-sharing subsidies);
  - Reduces plan costs; and
  - Obscures the true costs of prescription drugs for consumers and the government.
- **This rule will end the ability of plans/PBMs to reap these benefits from pharmacy DIR fees!**

Why is CMS redefining negotiated price?

- CMS believes the following:
  - Adopting the new definition of "negotiated price" is an important first step toward 1) improving the affordability of drugs for most beneficiaries who do not receive the low-income subsidy, and 2) improving price transparency.
  - **The new definition of "negotiated price" (modified to be applied across all phases of the Part D benefit, including the coverage gap phase) will save beneficiaries $26.5 billion between 2024 and 2032,** which accounts for both cost-sharing savings and minimal expected premium increases.
  - Variation in the treatment of pharmacy price concessions by Part D sponsors may have a negative effect on competition under the Medicare Part D program.
  - The new definition prevents cost-shifting to beneficiaries and taxpayers.

The Good!

In the final rule, beginning in 2024, CMS:

Finalized a new definition of "negotiated price."

- All pharmacy DIR fees from network pharmacies must be reflected in the negotiated price at the point of sale and reported to CMS on a Prescription Drug Event (PDE) record, even when such price concessions are contingent upon performance by the pharmacy.
- "Negotiated price" now equals the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account pharmacy price concessions.
- "Negotiated price" must include all pharmacy price concessions and any dispensing fees and exclude additional contingent amounts (such as incentive fees) if these amounts increase prices.
- The payment rate ultimately received by the pharmacy may be higher than the negotiated price.

Closed the coverage gap loophole.

- Pharmacy price concessions will now be applied to the negotiated price across all phases of the Part D benefit, including the coverage gap phase.

Addressed pharmacy cash flow concerns.

- CMS claims it does not have the authority to mandate payment plans between Part D plan sponsors and pharmacies. However, it encourages Part D sponsors to consider options such as payment plans or alternate payment arrangements to minimize impacts to vulnerable pharmacies and patients they serve. This is in response to NCPA concerns that pharmacy reimbursement is likely to decrease at the point of sale with implementation of the rule, while pharmacies are still paying DIR fees from the prior year.
- CMS acknowledges the possibility that changes in cash flow may cause some already-struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks.
- CMS will be particularly attuned to plan compliance with pharmacy access standards to ensure that all Medicare Part D beneficiaries have adequate access to pharmacies.

Addressed pharmacy administrative service fees again.

- When pharmacy administrative service fees, such as "network access fees," "administrative fees," "technical fees," and "service fees," take the form of deductions from payments to pharmacies, they represent charges that offset the sponsor's or its PBM's operating costs under Part D. If the sponsor or its PBM wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid.
- If the sponsor or its PBM deducts the above costs from payments to pharmacies, such costs are price concessions and must be reflected in the negotiated price.

Defined pharmacy "price concession" for the first time.

- "Price concession" includes any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor.
- This definition includes but is not limited to discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in-kind.
- For pharmacy price concessions that are not at the claim level, Part D sponsors would have to determine a methodology to attribute such concessions to the claim level to remain in compliance with the definition of negotiated price. Currently, it is unclear how that methodology will be formulated and NCPA will monitor closely.
- The negotiated price must include pharmacy price concessions and does not require inclusion of non-pharmacy price concessions, such as manufacturer rebates. To the extent a non-pharmacy price concession is applied to the negotiated price, it would reduce the negotiated price. However, it would not reduce the amount that is the lowest possible reimbursement the pharmacy could receive as reimbursement for a covered Part D drug under the contract between the pharmacy and the Part D sponsor or the PBM.

Discussed reasonable pharmacy reimbursement.

- CMS recognized commenters, including NCPA, who requested safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement.
- Specifically, NCPA's suggested safeguards included: 1) ensuring that the negotiated price at a minimum covers the pharmacy's costs of purchasing and dispensing covered items and providing covered services, and 2) establishing a flat dispensing fee or an alternative model such as a pharmacy reimbursement model based on a public drug pricing benchmark like national average drug acquisition costs plus a fair dispensing fee in line with those in state Medicaid fee-for-service programs.
- CMS agreed to consider these suggestions for future rulemaking.

The not-so-good

CMS delayed implementation of the changes to pharmacy price concessions until Jan. 1, 2024.

Why is CMS delaying changes it originally proposed going into effect Jan. 1, 2023?

- CMS asserted that concerns related to contracting and operational timelines that could disrupt successful implementation were sufficiently compelling to warrant making this policy applicable beginning on Jan. 1, 2024.

CMS did not mandate the amount paid to the pharmacy or the timing of payments and adjustments.

- Passing through all pharmacy price concessions to the point of sale only directly impacts the price that is used to determine patient cost-sharing.

- Contracts between plan sponsors or their PBMs and pharmacies can continue to provide for performance-based payment adjustments.
- **The final rule did not govern payment arrangements or eliminate post-point-of-sale price concessions, but pharmacies should know the concessions up front.**
- Sponsors must still comply with prompt payment requirements, but they continue to have discretion over the timeframes for settling payment incentives and penalties.

Why didn't CMS address the amount ultimately paid to the pharmacy or the timing of payments and adjustments?

- CMS referenced the Medicare law that prohibits CMS from instituting a price structure for the reimbursement of Part D drugs.
- CMS also stated the final rule does not violate the non-interference clause because it does not implicate or impose requirements on plan-pharmacy interactions, such as contracting, negotiations, payments rates, incentive arrangements, quality goals or targets, performance-based payments, or performance-based contracting. Sponsors and pharmacies remain free to negotiate any such arrangements they wish.

CMS did not address pharmacy performance metrics.

- CMS does not eliminate or restrict the use of any performance-based pharmacy payment arrangements.
- The new definition of negotiated price does not mandate how sponsors contract with, incentivize, or pay pharmacies in their network.
- Sponsors remain free to offer performance-based payment arrangements.
- Applying all pharmacy price concessions to the negotiated price will provide pharmacies with more information on the reimbursement they will receive if they fail to meet performance metrics.
- CMS encourages fair and equitable value-based arrangements, including those focused on social determinants of health.
- CMS does encourage the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency, and fairness.
- CMS has stated its awareness that the Pharmacy Quality Alliance is working to build consensus on pharmacy-level measures across pharmacies, plans, PBMs, and other stakeholders.

CMS did not address the impact of the rule on small business pharmacies.

- NCPA requested CMS provide an analysis on the impact of the rule on small business pharmacies. CMS responded that it does not have sufficient data to determine impacts by type of pharmacy, as the pharmacy price concessions are not reported in connection to a particular pharmacy or type of pharmacy.
- CMS did not amend its impact analysis from the proposed rule that CMS assumes that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow and maintains the further assumption that these business decisions will result in a slight increase in pharmacy payments of 0.2 percent of Part D gross drug cost.

The unknown

How will pharmacies know their lowest possible reimbursement?

- CMS disagreed with those who say there is no mechanism under the current NCPDP data format for Part D sponsors to provide information on a drug's negotiated price to pharmacies.
- CMS has identified two approaches that could accomplish the goal of transmitting a drug's negotiated price data between plan sponsors and pharmacies using the data format available today.
    - Both approaches can be reflected within the current standard, and historically this is how coordination of benefits occurred prior to availability of specific pricing fields.
- Any amount paid by the pharmacy to the plan post-point-of-sale could be reported at the claim level on the 835 and will be reported in the Estimated Rebate at the Point-of-Sale field on the PDE as some plans are doing today. This would allow the information to be transparent from the point-of-sale transaction to the PDE.
- ***It will be especially important for NCPA to remain engaged in NCPDP and for members to remain in active dialogue with their contracting entities as the industry prepares for implementation of this final rule for CY2024.***

Miscellaneous

Limited access to preferred cost-sharing pharmacies disclaimer in Medicare Communications and Marketing Guidelines.

- CMS is finalizing additional guidance and standards from the Medicare Communications and Marketing Guidelines that were not part of the January 2021 final rule related to limited access to preferred cost-sharing pharmacies. The disclaimer provides information to Medicare Part D beneficiaries that only have access to preferred cost-sharing through a limited number of pharmacies. Specifically, the disclaimer alerts these beneficiaries that the preferred costs may not be available at the pharmacy they use and provides information on how to access the list of pharmacies offering prescription drugs as a preferred cost in the beneficiary's area.

Greater transparency in medical loss ratio (MLR) reporting.

- CMS is finalizing its proposal to reinstate the detailed MLR reporting requirements that were in effect for contract years 2014–2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount. CMS is also finalizing the collection of additional details regarding plan expenditures to allow CMS to better assess the accuracy of MLR submissions, the value of services being provided to enrollees, and the impacts of recent rule changes.