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CLIENT ALERT

CMS Proposes Major Change to Rules Governing Part D Plan Accounting

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The proposed technical changes for the 2023 Medicare Advantage and Part D contract year (87 Fed. Reg. 1842 (January 12, 2022)) include revisions to the definition of the term "negotiated prices" that CMS previously contemplated but had held off implementing. The proposed change could reduce cost-sharing paid by beneficiaries at the point of service and reduce the amount of DIR that Part D plan sponsors report to CMS.

Comments on the proposed rule must be submitted no later than March 7, 2022.

Picking up where it left off in 2018, CMS is proposing to delete the existing definition of "negotiated prices" at § 423.100 and to adopt a new definition for the term "negotiated price," (singular not plural), as "the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary." As summed up by CMS:

> [I]f a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that drug under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR as part of the annual report on DIR following the end of the year.

To implement the proposed change at the point of sale, Part D sponsors and their pharmacy benefit managers (PBMs) would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. The proposed changes would take effect on January 1, 2023, meaning, if finalized, Part D sponsors would need to account for the changes in the bids that they submit for contract year 2023.

CMS is also proposing to add a definition of "price concession," which is not currently defined, "to include all forms of discounts and direct or indirect subsidies or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors."

Background:

Under the existing definition at § 423.100, negotiated prices are used to determine a Part D member's cost-sharing liability, and must include all price concessions from network pharmacies that can reasonably be determined at the point-of-sale. CMS notes in the proposed rule that, to date, "very few price concessions have been included in the negotiated price at the point-of-sale." In particular, negotiated prices typically do not reflect any performance-based pharmacy price concessions because such amounts are considered by plans to be contingent upon performance measured over a period that extends beyond the point of

sale and thus cannot reasonably be determined at the point of sale. These amounts must still be reported to CMS as direct and indirect remuneration (DIR) received by the plan that affects the cost of drugs to the plan, and this reporting data are used in the calculation of final plan payments.

CMS reviewed DIR data and found that the percentage of price concessions that are attributable to pharmacy performance programs has grown significantly since 2012, and "now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates." DIR data also shows that "sponsors and PBMs have been recouping increasing sums from network pharmacies after the point-of-sale (pharmacy price concessions) for 'poor performance,' sums that are far greater than those paid to network pharmacies after the point-of-sale (pharmacy incentive payments) for 'high performance.'"

CMS first requested information on price concessions from pharmacies in the proposed MAPD technical changes for 2017 (82 FR 56419, Nov. 28, 2017) and then requested comments from stakeholders on changing the definition of negotiated price along the lines of what it is currently proposing, in the proposed MAPD technical changes for 2018 ((83 FR 62174, Nov. 30, 2018). CMS received over 4,000 comments on this potential policy approach, but did not change the policy or definitions in either of the two succeeding proposed technical changes. It is now proposing to change the definition of negotiated price for the 2023 plan cycle.

In CMS's view, the proposed rule will better reflect the price that plans actually receive from and end up paying pharmacies. If the price to the pharmacy ends up being higher than the "lowest" possible reimbursement, the plan will still have a mechanism for reporting that to CMS as drug costs. However, in CMS' view, requiring sponsors to use the lowest possible pharmacy performance when reporting the negotiated price would provide a "standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point-of-sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point-of-sale."

CMS acknowledges that there are sound competitive reasons that prompt plans to use price concessions to lower premiums rather than reduce cost-sharing, because beneficiaries are much likelier to compare – and select – plans based on plan level premiums than cost sharing practices. However, according to CMS, DIR amounts that exceed bid-projected figures are not always used to lower beneficiary premiums but can contribute to a plan's increased profitability. According to CMS, this can give sponsors "an incentive to opt for higher negotiated prices in exchange for higher DIR and, where price concessions are in the form of percentage-based fees, to prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies."

The trade-off between lower premiums to all beneficiaries and lower cost-sharing to beneficiaries that use expensive drugs was highlighted in the comments received by the Office of Inspector General when it proposed to exclude manufacturer rebates paid to plan sponsors from discount safe harbor protection. *See* Final Rule, 85 FR 76666 (Nov. 30, 2019), proposed at 84 FR 2340 (January 31, 2019). The Secretary is now prohibited from implementing this rule, which would have limited safe harbor status to manufacturer discounts passed through to beneficiaries at the point of service. *See* section 90006 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021). CMS states that in making a change to the definition of negotiated price that could lower beneficiary cost-sharing it is "following an incremental approach and only proposing policies related to pharmacy price concessions at this time."

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