Published on *The National Law Review* https://natlawreview.com

# CMS Proposes Changes to Part D Regulations: Pharmacy Price Concessions

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The next post in our series analyzing the recently proposed Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs rule (Proposed Rule) focuses on a regulation impacting Part D sponsors and their reporting of pharmacy price concessions. According to CMS, the proposed change—which would require the "negotiated price" of a covered Plan D drug to be the lowest possible payment made to a pharmacy by a Plan D sponsor—is expected to (i) reduce out-of-pocket costs for plan beneficiaries at the pharmacy counter, (ii) create greater drug price transparency, (iii) stabilize the operating environment for pharmacies, and (iv) improve market competition.

## Background

As CMS notes in the Proposed Rule, often following a Part D beneficiary's purchase of a covered drug at the pharmacy counter (otherwise known as the "point-of-sale"), the Part D sponsor administering the beneficiary's plan will receive compensation—either directly or via an intermediary (e.g., pharmacy benefit manager)—that lowers the final net amount the sponsor will pay to the pharmacy that sold the covered drug. This type of post point-of-sale compensation (called Direct and Indirect Remuneration or DIR) can be made in a variety of forms, including as a manufacturer rebate, administrative fee, or—as discussed in this post—a pharmacy price concession.

Most simply put, pharmacy price concessions are a type of financial agreement negotiated directly between pharmacies and Part D sponsors that require a pharmacy to pay a sponsor a certain amount post point-of-sale because of the pharmacy's failure to meet certain performance measures (i.e., having "poor performance"). These price concessions are distinguishable from pharmacy incentive payments, in which the sponsor pays a pharmacy post point-of-sale for meeting certain performance measures or having "high performance."

## Proposed Change to "Negotiated Price"

Plan D sponsors are required under Medicare Part D to report the "negotiated prices" (currently defined in the regulations in the plural form) for covered drugs to CMS, which are then factored into CMS's calculations to determine how much a plan beneficiary will pay at the pharmacy counter (i.e., the beneficiary's cost-sharing amount). Under the current regulations, "negotiated prices" is defined as the price paid to a pharmacy at the point-of-sale for a covered drug dispensed to a plan beneficiary, net of all rebates, dispensing fees, pharmacy incentive payments and pharmacy price concessions—but with an exception that allows the exclusion of pharmacy price concessions and incentive payments that cannot reasonably be determined at the point-of-sale (the reasonably determined exception).

As we previously noted in our 2018 and 2019 blog posts discussing CMS's initial consideration of this proposed change, current regulations generally give Part D sponsors significant discretion when deciding whether to reflect the various pharmacy price concessions they or their intermediaries receive in the negotiated prices they report to CMS.  Accordingly, if a Plan D sponsor opts to include pharmacy price concessions in the negotiated prices it reports to CMS, some amount of the price concession is apportioned to directly reduce plan beneficiaries' costs at the pharmacy counter. However, if a Plan D sponsor does not include pharmacy price concessions in the negotiated prices, and instead applies such concessions after the point-of-sale (i.e., as DIR), the price concession does not reduce a plan beneficiary's cost at the pharmacy counter (though it may ultimately help reduce a beneficiary's plan premium for a later year). Instead, as CMS notes in the Proposed Rule, the price concession generally accrues to the benefit of the plan (and in certain limited circumstances, to the government).

CMS notes that, although the reasonably determined exception was intended to be narrow, review of past data indicates that the exception has been applied more broadly than initially envisioned, in large part because of the significant growth in pharmacy price concessions.  According to DIR data provided in support of the Proposed Rule, pharmacy price concessions grew more than 107,400% between 2010 and 2020, totaling about $8.9 million in 2010, to $9.5 billion in 2020.

Because CMS believes that the current definition of "negotiated prices" has not furthered its intended goals of meaningful price transparency, consistent application of pharmacy payment concessions and prevention of cost-shifting to beneficiaries and taxpayers, CMS is proposing to replace "negotiated prices" with a newly defined "negotiated price" (in the singular).  The new definition would require Part D sponsors to report to CMS the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with a Part D sponsor or its intermediary (i.e., the total amount a pharmacy would receive for a covered drug if it received the poorest performance marks under its pharmacy price concession arrangement with the sponsor and had to pay back the maximum amount owed to the sponsor for its failure to perform).  In effect, the new definition would eliminate the reasonably determined exception, and require Part D sponsors to take all price concessions into account when reporting a negotiated price to CMS.

CMS anticipates that adopting the proposed "negotiated price" definition will reduce beneficiary cost-sharing at the pharmacy counter, lead to more accurate comparability of drug prices, provide financial transparency to pharmacies from the outset, and facilitate a more competitive market (given that beneficiaries will be able to better compare plans' cost-sharing and premiums).

Comments in response to the Proposed Rule are due by March 7, 2022 and may be submitted here.

National Law Review, Volume XII, Number 24

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price-concessions