

CMS PROPOSES RULE TO LOWER PART D DRUG COSTS FOR BENEFICIARIES

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The rising cost of prescription drugs in the United States, particularly for the Medicare population, has been a hot button issue for many years. At the same time, pharmacies have been challenging the Direct and Indirect Remuneration (DIR) fees imposed by pharmacy benefit managers (PBMs). DIR fees are sometimes based on whether a pharmacy meets certain performance standards, which are often a moving target and disparately impact specialty pharmacies that have less control or influence over the quality measures utilized by PBMs. Because these performance-based fees are assessed after the point-of-sale, the reimbursement reductions associated with the DIR fees do not benefit beneficiaries and make it difficult for pharmacies to predict their drug reimbursement amounts. Last week, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that aims to address both of these issues in part by requiring any potential cost savings realized from DIR fees to be passed through to beneficiaries at the point-of-sale.¹ This would help lower the cost sharing amounts for Medicare Part D beneficiaries and in turn offer pharmacies greater predictability in their (albeit lower) Part D reimbursement amounts.

The proposed rule comes after Part D sponsors have reported significant growth in DIR in recent years, which CMS links to increased use of performance-based pharmacy payment arrangements.² However, such performance-based adjustments that measure performance over a period of time are not typically factored into the price of the drug at the point-of-sale, given that the current definition of the “negotiated price” of drugs specifically excludes contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale.³

CMS is proposing to eliminate this language for contingent pharmacy price concessions and redefine the term as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor (that is, the amount the pharmacy would receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). CMS is also defining the term “price concession” for the first time 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.

To implement the proposed change at the point-of-sale, CMS notes that Part D sponsors and their PBMs would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. CMS believes the change will result in greater price transparency.

CMS also expects the changes would reduce beneficiary costs by about 2% or US\$21.3 billion over 10 years by requiring these pharmacy price concessions to be included in the negotiated price. In addition, CMS projects

savings to manufacturers of about US\$14.6 billion over 10 years due to an anticipated reduction in aggregate manufacturer gap discount payments.

If finalized, the proposed changes would take effect on 1 January 2023, and Part D sponsors would need to account for the changes in the bids that they submit for contract year 2023. Comments regarding the proposed rule must be submitted by 7 March 2022. Our Health Care practice and Public Policy and Law practice routinely assists stakeholders with legal advice regarding pharmacy, drug pricing, and 340B Program matters, including with the submission of public comments. We can advise and engage with Congress and the administration on these matters.

FOOTNOTES

¹ Press Release, Ctrs. for Medicare & Medicaid Servs., [CMS Takes Action to Lower Out of Pocket Medicare Part D Prescription Drug Costs](#) (Jan. 6, 2022).

² See Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 1,842 (Jan. 12, 2022).

³ See 42 C.F.R. § 43.100.

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