January 18, 2022

CMS Proposes Revised Definition of Medicare Part D Drug "Negotiated Prices": Rule Could Increase Predictability for Pharmacies and Lower Medicare Enrollee Drug Cost-Sharing but Increase Premiums

Attorneys
Margaux J. Hall
Stephanie A. Webster
Thomas N. Bulleit
Gregory F. Malloy
Chandler Gray

On January 6, 2022, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule entitled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (the "2022 Proposed Rule"). Of great significance to Medicare Part D plan sponsors, pharmacies, and beneficiaries, the 2022 Proposed Rule includes proposed changes to the way Medicare determines the "negotiated price" (*i.e.*, the price upon which beneficiary cost-sharing is based at the pharmacy counter), and consequently could affect Part D plan sponsors' reporting of costs to CMS. If finalized in its current form, the 2022 Proposed Rule could enhance predictability of cash flow for pharmacies, reduce out-of-pocket prescription drug costs for Medicare Part D enrollees, and lead Part D plan sponsors to raise premiums, thereby causing increased competition among Part D plan sponsors for beneficiaries. The 2022 Proposed Rule would take effect on January 1, 2023. Comments on the rule are due by March 7, 2022.

Background on "Negotiated Prices"

Medicare reimburses Part D plan sponsors for providing prescription drug benefits to Medicare enrollees. The Medicare Act requires plan sponsors to, among other things, "provide enrollees with access to negotiated prices used for payment for covered part D drugs."[1] Under the Medicare Act, "negotiated prices shall take into account negotiated price concessions" between Part D sponsors and pharmacies.[2] Under CMS policy, price concessions that are not included in the "negotiated prices" must be reported to CMS as Direct and Indirect Remuneration ("DIR") at the end of the coverage year.[3]

Under existing regulations, pharmacy price concessions negotiated by Part D plan sponsors must be included in the "negotiated prices" at the point of sale, *unless* the price concessions "cannot reasonably be determined at the point-of-sale."[4] This regulatory exception has left latitude for Part D sponsors and PBMs to negotiate pharmacy reimbursement terms featuring aggregate performance guarantees that, Part D sponsors and PBMs argue, cannot reasonably be determined at the point of sale. These price concessions therefore are not taken into account in the negotiated prices and, instead, are reported as DIR after the close of the plan year.

Because pharmacy performance metrics assessed after the point of sale commonly result in payment reconciliations that that are not reflected in the "negotiated prices," pharmacies often must repay the PBM or Part D sponsor sizeable amounts long after furnishing the drugs to beneficiaries. Since these repaid amounts are not reflected in the "negotiated prices," Medicare enrollees are negatively impacted as they typically pay higher out-of-pocket costs at the pharmacy counter. This occurs because patient cost-sharing at the pharmacy counter (*i.e.*, at the point of sale) is based on the higher "negotiated price," *not* based on the final, net price that a pharmacy ultimately may receive after end-of-plan-year pharmacy-PBM payment reconciliations have occurred.

This dynamic has been of great financial import for pharmacies as pharmacy price concessions have continued to grow in size. For pharmacies, it may be difficult to determine net remuneration for dispensed drugs until after a plan year has closed – creating business strain.

From the perspective of Part D plan sponsors, an increase in contingent pharmacy price concessions – and a consequent increase in DIR – has potentially favorable spill-over effects, such as lower future Part D plan premiums. Part D plan

sponsors – and the PBMs with which they contract and often are affiliated – have a strong business incentive to increase DIR in order to compete for Medicare enrollees with more favorable monthly premiums.

Repeated past efforts to change this system (discussed below) have not succeeded. However, the Biden Administration publicly committed to addressing this issue. In particular, in a December 14, 2021 letter to Congress, CMS Administrator Chiquita Brooks-LaSure explained that CMS was planning to write a rule to limit price concessions that PBMs retroactively charge pharmacies.[5] Brooks-LaSure stated, "CMS agrees that the significant growth in DIR amounts is troubling and is planning to use our administrative authority to issue proposed rulemaking addressing price concessions and DIR."[6]

Regulatory History

- 2005 Rule: In January 2005, CMS promulgated its first regulatory definition of "negotiated prices" as prices for covered Part D drugs that "(1) Are available to beneficiaries at the point of sale at network pharmacies; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Includes any dispensing fees."[7]

- 2009 Rule: In January 2009, CMS revised the first clause of the definition of "negotiated prices" to refer to the "total" negotiated amount that would be received by the network pharmacy.[8]

- 2014 Proposed Rule: CMS proposed changing the definition of "negotiated prices" to require that all price concessions from pharmacies be reflected in the price at the point of sale. Specifically, the agency proposed to redefine "negotiated prices" to mean prices for covered Part D drugs that "(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; and (2) are inclusive of all price concessions and any other fees charged to network pharmacies; and (3) include any dispensing fees; but (4) exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance; and (5) may not be rebated back to the Part D sponsor (or other intermediary contracting organization) in whole or in part."[9]

- 2014 Final Rule: CMS did not adopt the proposed definition of "negotiated prices" and instead adopted a definition that expressly excluded contingent pharmacy price concessions that could not be reasonably determined at the point of sale (negotiated prices are "inclusive of all price concessions from network pharmacies *except those contingent price concessions that cannot reasonably be determined at the point-of-sale*").[10] CMS claimed that this "reasonably determined" exception would be "narrow" in nature.[11]

- 2017 Request For Information ("RFI"): CMS solicited stakeholder feedback on the definition of "negotiated prices" through an RFI in the Federal Register.[12] In the RFI, CMS stated that its "reasonably determined" exception was not as narrow as the agency claimed it would be when adopted due to the "shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements."[13] As a result, the "reasonably determined" exception did not have the "intended effect on price transparency, consistency, and beneficiary costs."[14] Accordingly, CMS advised that it was "considering revising the definition of negotiated price … to remove the *reasonably determined* exception and to require that all price concessions from pharmacies be reflected in the negotiated price."[15] In order to effectively capture all pharmacy price concessions at the point of sale, the agency was considering "requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug."[16] The agency sought comments that would assist the agency in making such revisions.[17]

- 2018 Proposed Rule: CMS proposed a rule that would have eliminated the "reasonably determined" exception from the definition of "negotiated prices."[18]

- 2018 Final Rule: Pharmacies, health care providers, patient advocacy organizations, and a coalition of United States Senators voiced their support of the proposed change in definition, while Part D plan sponsors and PBMs strongly opposed the change. Ultimately, CMS declined to adopt this proposed definition of "negotiated prices" and instead maintained the "reasonably determined" exception.[19]

Specific Proposal

The 2022 Proposed Rule would eliminate the "reasonably determined" exception and require Part D plans, in reporting their "negotiated prices" for prescription drugs, to include an estimate of post point-of-sale price concessions.[20] The definition would be amended to state that "negotiated price" refers to "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 [i.e., the PBM]."[21] Like earlier proposals, the proposed rule would remove the "reasonably determined" exception, meaning that the negotiated prices would reflect all pharmacy price concessions negotiated by Part D sponsors and their PBMs, even when such price concessions are contingent upon performance by the pharmacy.[22] The new definition would exclude additional contingent payments, such as incentive fees, if these amounts raise the price of the drug.[23] The proposed rule also would change the defined term from the plural "negotiated prices" to the singular "negotiated price" to "make clear that a negotiated price can be set for each covered Part D drug, and the amount of pharmacy price concessions may differ on a drug-by-drug basis."[24]

To implement this change at the point of sale, the proposed rule states that CMS would use the existing reporting requirements of Part D sponsors and their PBMs.[25] Specifically, the proposed rule states that Part D sponsors and their PBMs would load drug pricing tables that show the lowest possible reimbursement for a drug into the claims processing systems that interface with contracted pharmacies.[26]

The proposed rule also would add a broad definition of "price concession" at 42 C.F.R. § 423. 100 that would include "all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors."[27] The term "price concession" was previously undefined in the Part D statute, regulations, and subregulatory guidance.[28]

Potential Implications

If finalized, the 2022 Proposed Rule could significantly affect Medicare Part D plan sponsors, PBMs, pharmacies, and beneficiaries. As discussed below, the potential effects of the rule are complex, but it is likely that pharmacies and certain beneficiaries would benefit from the rule, while Part D sponsors and PBMs would not.

- Beneficiaries: Some beneficiaries could benefit from the changes under the proposed rule, if finalized, because beneficiary cost-sharing for prescription drugs is based on their negotiated prices. If the negotiated prices of drugs are lowered, then the cost of Part D drugs to beneficiaries at the pharmacy counter also would be lowered. CMS believes that beneficiaries would see lower drug prices starting in 2023 and that beneficiary costs would decrease by $21.3 billion over 10 years.[29] However, CMS also states that beneficiaries likely would encounter higher premiums as Part D plan sponsors pass pharmacy price concessions through to beneficiaries at the point of sale, since Part D sponsors would have lower aggregate DIR.[30] Beneficiaries who do not have significant pharmacy drug spending likely would see higher premiums without a commensurate offset in the form of lower cost-sharing for drugs.[31]

- Pharmacies: The inclusion in negotiated prices of pharmacy price concessions at the point-of-sale could mean lower payments to pharmacies at the point of sale, but ultimately provide pharmacies greater predictability in their cash flow and, thus, their operations. CMS also expects a modest indirect effect on the level of payments to

pharmacies.[32] CMS estimates that pharmacies would seek to retain two percent of the existing pharmacy price concessions they negotiate with plan sponsors to compensate for pricing risk and cash flow differences.[33] It is unclear, though, whether this assumption is accurate.

- Part D Sponsors and PBMs: If the proposed rule were finalized, Part D sponsors could increase beneficiary premiums due to their lower overall DIR fees.[34] Plan D sponsors may then face increased competition for beneficiaries to the extent they raise premiums.[35] Premium increases could occur across the board for all Plan D sponsors, mitigating the adverse effects for any particular plan sponsor. Additionally, CMS estimates that there would be a one-time cost of $0.1 million to Plan D sponsors as they would need to update their claims processing systems to implement the proposed changes.[36]

- Government: If the proposed rule is adopted, the agency estimates $40 billion in Part D costs for the Government over 10 years.[37] These costs would be the result of a significant increase in funding by Medicare of plan premiums and low-income premium payments.[38] The increased cost to the Government would be somewhat balanced by the decreases in Medicare's reinsurance and low-income cost-sharing payments.[39] Medicare's reinsurance payments would decrease because beneficiaries would not exhaust the Part D benefit and enter the catastrophic phase as quickly. Further, Medicare's reinsurance payments would be based on lower negotiated prices. As drug prices decline at the point of sale, beneficiaries' cost-sharing obligations decline as well, lowering low-income cost-sharing payments by the Government.[40]

In sum, if CMS were to finalize the 2022 Proposed Rule in its current form, the agency's changes to the definition of "negotiated prices" could have notable effects on Medicare beneficiaries and pharmacies, as well as Part D plan sponsors, and PBMs, including reduced out-of-pocket prescription drug costs for Medicare Part D enrollees, lower payments at the point of sale but enhanced predictability of cash flow for pharmacies, and higher premiums by Part D plan sponsors yielding potentially increased competition for beneficiaries. Affected parties should consider submitting comments on the proposal by the deadline of March 7, 2022. If you have any questions, please do not hesitate to contact the authors or your usual Ropes & Gray advisor.

1. 42 U.S.C. § 1395w-102(d)(1)(A).
2. *Id.* § 1395w-102(d)(1)(B).
3. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, *available at* https://public-inspection.federalregister.gov/2022-00117.pdf.
4. 42 C.F.R. § 423. 100.
5. CMS Plans to Write Rule that Curtails PBM Pharmacy Fees, available at CMS https://insidehealthpolicy.com/inside-drug-pricing-daily-news/cms-plans-write-rule-curtails-pbm-pharmacy-fees.
6. *Id.*
7. 70 Fed. Reg. 4,194, 4,534 (Jan. 28, 2005).
8. [1] 74 Fed. Reg. 1,494, 1,505 (Jan. 12, 2009).
9. 79 Fed. Reg. 1,918, 1,974 (Jan. 10, 2014).
10. 79 Fed. Reg. 29,844, 29,879 (May 23, 2014).
11. *Id.* at 29,878.
12. 82 Fed. Reg. 56,336, 56,419 (Nov. 28, 2017).
13. *Id.* at 56,426.
14. *Id.*
15. *Id.*
16. *Id.* at 56,427.
17. *Id.* at 56,426.
18. 83 Fed. Reg. 62,152, 62,177 (Nov. 30, 2018).
19. 84 Fed. Reg. 23,832, 23,867 (May 23, 2019).
20. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, *available at* https://public-inspection.federalregister.gov/2022-00117.pdf.
21. *Id.*
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.*
26. *Id.*
27. *Id.*
28. *Id.*
29. *Id.*
30. *Id.*
31. *Id.*
32. *Id.*
33. *Id.*
34. *Id.*
35. *Id.*
36. *Id.*
37. *Id.*
38. *Id.*
39. *Id.*
40. *Id.*