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CMS Issues Final Rule Redefining Medicare Part D "Negotiated Price" As Pharmacy's Lowest Possible Reimbursement

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On April 29, 2022, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule revising the way Medicare determines the "negotiated price" (i.e., the price upon which beneficiary cost-sharing is based at the pharmacy counter) under Medicare Part D.[1] The final rule (the "2022 Final Rule") revises the definition of "negotiated price" to mean the lowest possible reimbursement a network pharmacy will receive in total for a covered Part D drug.[2] The 2022 Final Rule adopts this new definition of "negotiated price" across Part D, including the Coverage Gap Discount Program. As previewed and discussed at greater length in our January 18, 2022 alert discussing the proposed rule ("2022 Proposed Rule"),[3] the 2022 Final Rule could likely have several effects on the Medicare Part D market, including enhancing predictability of cash flow for pharmacies, reducing out-of-pocket prescription drug costs for certain Medicare Part D enrollees at the pharmacy counter, leading Part D plan sponsors to raise premiums even as they compete for beneficiaries, and reducing manufacturers' coverage gap discount payments as fewer beneficiaries enter the coverage gap phase. The revised definition of "negotiated price" becomes effective on January 1, 2024.

Regulatory History

CMS promulgated its first definition of "negotiated prices" in a 2005 rule, defining "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."[4]

CMS revised this definition in 2009[5] and again in 2014, with the latter revision expressly excluding contingent pharmacy price concessions that could not be reasonably determined at the point of sale (the "reasonably determined" exception).[6] CMS solicited stakeholder feedback in 2017 through a request for information in the Federal Register on whether to remove the "reasonably determined" exception from the definition of "negotiated prices."[7] In 2018, CMS proposed a rule (the "2018 Proposed Rule") that would have eliminated the "reasonably determined" exception,[8] but the agency did not finalize that proposed rule. CMS stated that it wished to continue studying this issue and left the original definition in place.[9]

CMS once again proposed eliminating the "reasonably determined" exception in the 2022 Proposed Rule, prompting significant interest and comments from stakeholders. Specifically, CMS received 6,179 comments on the 2022 Proposed Rule from "MA health plans, Part D sponsors, beneficiaries, MA enrollee and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, States, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, Members of Congress, and other vendor and professional organizations."[10] In the 2022 Final Rule, CMS indicates that the majority of comments it received supported this policy change, citing lower beneficiary spending for prescription drugs and increased price transparency.[11] However, according to CMS, some commenters argued that the policy "would harm competition among pharmacies, leading to higher program costs" as plan sponsors would no longer be able to "apply pharmacy price concessions as DIR to reduce plan premiums."[12] Other commenters, CMS states, asserted that this policy change would lead to higher premiums and increased government costs, thereby undermining the goal of reducing overall drug prices.[13]

In the 2022 Proposed Rule and in an earlier proposed rule, CMS considered but declined to propose changes to the definition of negotiated price in the coverage gap phase of the Part D benefit. "Negotiated price" within the coverage gap

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determines manufacturer liability for discounts.[14] Prior to the 2022 Final Rule, the "negotiated price" of applicable drugs in the coverage gap had been defined as the amount the Part D sponsor and the network dispensing pharmacy determined that "a network entity will receive, in total, for a covered Part D drug, reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect renumeration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale, and net of any dispensing fee or vaccine administration fee for the applicable drug."[15]

In the 2018 Proposed Rule, CMS stated it was "considering whether to require sponsors to include pharmacy price concessions in the negotiated price in the coverage gap" and requested comments on this issue.[16] The 2022 Proposed Rule explained that CMS had received comments in support of applying the same definition of "negotiated price" to all phases of the Part D benefit, including the coverage gap.[17] However, in the 2022 Proposed Rule, CMS declined to propose adopting the same definition for purposes of the Coverage Gap Discount Program, stating that "allowing plans flexibility with respect to the treatment of pharmacy price concessions for applicable drugs in the coverage gap will moderate increases in beneficiary premiums and government costs."[18] CMS stated that the two definitions of "negotiated price" differed because, for drugs under the coverage gap, "plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale, and beneficiary, plan, and manufacturer liability in the coverage gap would be calculated using this alternate negotiated price."[19] For more information on the regulatory history of the definition of "negotiated prices," please see our earlier alert.

Final Rule

In the 2022 Final Rule, CMS adopts its proposed definition of "negotiated price." Specifically, effective January 1, 2024, the definition of "negotiated price" at 42 CFR § 423.100 will be amended to eliminate the "reasonably determined" exception, and instead, will be defined as "the lowest possible reimbursement [a] network [pharmacy or dispensing provider] will receive, in total, for a [covered Part D] drug."[20] This new definition will include all pharmacy price concessions received by the plan sponsor.[21] CMS explains that it decided on an effective date of January 1, 2024, to provide Part D plan sponsors and PBMs adequate time to negotiate contracts and implement necessary system changes.[22]

In the 2022 Final Rule, CMS also adopts its proposed addition of the definition of "price concession" to § 423.100, defining "price concession" as including "any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor."[23]

The 2022 Final Rule also revises the definition of "negotiated price" for the Coverage Gap Discount Program at § 423.2305 to be consistent with the new definition at § 423.100.[24] CMS states that it implemented this revision in response to comments on the 2018 Proposed Rule and the 2022 Proposed Rule suggesting a single definition of "negotiated price" would minimize the beneficiary confusion, administrative burden and costs, and implementation challenges posed by having two different definitions of "negotiated price."[25]

Potential Implications

The 2022 Final Rule may significantly affect the stakeholders in Medicare Part D, including plan sponsors, pharmacies, and beneficiaries. On the whole, CMS expects that pharmacies, manufacturers and certain beneficiaries would benefit from the rule, while Part D sponsors would not. In the 2022 Final Rule, CMS revises its estimates of the financial impact of the regulatory changes from those in the 2022 Proposed Rule for these various stakeholders. CMS states that this revision is largely due to the application of the new definition of "negotiated price" to all phases of the Part D benefit.[26]

Beneficiaries: CMS explains that some beneficiaries are likely to benefit from the Final Rule changes because beneficiary cost-sharing is based on the negotiated price. If negotiated prices of drugs are lowered, then beneficiaries are expected to have lower cost-sharing at the pharmacy counter.[27] However, CMS believes that beneficiaries who do not

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have significant pharmacy drug spending may see increased premium costs as Part D plan sponsors pass pharmacy price concessions through to beneficiaries.[28] CMS estimates that, on the whole, the changes to the negotiated price definition will save beneficiaries $26.5 billion,[29] as compared with an estimated $21.3 billion under the 2022 Proposed Rule.[30]

Pharmacies: Although including pharmacy price concessions in negotiated prices is likely to result in lower payments to pharmacies at the point of sale, CMS expects the change will provide pharmacies greater predictability in their cash flow and thus their operations.[31] CMS also expects a modest indirect increase in payments to pharmacies (i.e., 0.2 percent of Part D gross drug cost) because pharmacies will likely 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.[32]

Part D Sponsors: CMS expects that Part D sponsors may increase beneficiary premiums due to their lower overall DIR fees; they may face increased competition for beneficiaries to the extent they raise premiums.[33] CMS also estimates a one-time administrative cost of approximately $1.4 million for Part D sponsors to implement necessary software updates related to CMS data reporting.[34]

Manufacturers: CMS estimates that manufacturers will save $16.8 billion in Coverage Gap Discount Program discounts under the Final Rule,[35] as compared to an estimated $14.6 billion in savings under the 2022 Proposed Rule.[36] CMS states that this estimated change is due to the application of the revised definition to all phases of the Part D benefit, including the coverage gap, "reducing aggregate manufacturer gap discount payments as fewer beneficiaries" enter the coverage gap phase.[37]

Government: CMS estimates that the revised definitions will cost the government $46.8 billion over the 2024-2032 time period,[38] as compared with the estimated cost of $40 billion under the 2022 Proposed Rule.[39] The primary costs to the Government are from an anticipated increase in Medicare funding of plan premiums and low-income premium payments (with a moderated effect from anticipated decreases in Medicare's reinsurance and low-income cost-sharing payments).[40]

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Ropes & Gray will continue to monitor developments in this area. If you have any questions, please do not hesitate to contact the authors or your usual Ropes & Gray advisor.

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1. The 2022 final rule is entitled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency."
2. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, *available at* https://public-inspection.federalregister.gov/2022-09375.pdf.
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. 70 Fed. Reg. 4,194, 4,534 (Jan. 28, 2005).
5. 74 Fed. Reg. 1,494, 1,505 (Jan. 12, 2009).
6. 79 Fed. Reg. 29,844, 29,879 (May 23, 2014).
7. 82 Fed. Reg. 56,336, 56,419 (Nov. 28, 2017).
8. 83 Fed. Reg. 62,152, 62,177 (Nov. 30, 2018).
9. *Id.* at 62,179.
10. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, *available at* https://public-inspection.federalregister.gov/2022-09375.pdf.

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11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.*
16. 83 Fed. Reg. 62,152, 62,179 (Nov. 30, 2018).
17. 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.
18. *Id.*
19. *Id.*
20. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, *available at* https://public-inspection.federalregister.gov/2022-09375.pdf.
21. *Id.*
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.*
26. *Id.*
27. *Id.*
28. *Id.*
29. *Id.*
30. 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.
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32. *Id.*
33. *Id.*
34. *Id.*
35. *Id.*
36. 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.
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38. *Id.*
39. 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.
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