DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Poulsyand

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CENTER FOR MEDICARE

DATE: November 6, 2023

TO: All Part D Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: Application of Pharmacy Price Concessions to the Negotiated Price at the Point of

Sale Beginning January 1, 2024

The Centers for Medicare & Medicaid Services (CMS) is issuing this memorandum to highlight upcoming requirements regarding pharmacy price concessions effective January 1, 2024. We also remind Part D plan sponsors and/or their pharmacy benefit managers (PBMs) that CMS strongly encourages them to make necessary cash flow arrangements with network pharmacies in preparation for these upcoming changes.

The pharmacy price concessions provision finalized in the Contract Year 2023 final rule (CMS-4192-F) takes effect January 1, 2024 and requires the application of all pharmacy price concessions to the negotiated price at the point of sale (POS). Through 2023, Part D plan sponsors are required to apply pharmacy price concessions to the negotiated price if they can reasonably be determined at the POS. As finalized in the Contract Year 2023 final rule, beginning January 1, 2024, the negotiated price must reflect the lowest possible reimbursement a network pharmacy will receive for a drug and include all pharmacy price concessions according to the new definitions of "negotiated price" and "price concession" at § 423.100 and § 423.2305. This guidance is applicable in all phases of the Part D benefit, including the coverage gap.

Commenters on the Contract Year 2023 proposed rule (CMS-4192-P) noted concerns regarding the potential impact on pharmacy cash flow during the first quarter of the first year of implementation of the provision. Commenters explained that pharmacies' direct and indirect remuneration (DIR) fees for the prior year would be due to Part D plan sponsors and/or their PBMs concurrently with when pharmacies expect to receive lower reimbursements at the POS under the new provision. These commenters, noting that these potential cash flow concerns could cause vulnerable pharmacies to close, requested that CMS require Part D plan sponsors and/or their PBMs to establish payment plans with pharmacies during the transition period and urged CMS to emphasize that prompt payment requirements will continue to be enforced.

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¹ See final rule titled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-F) (87 FR 27704) at: https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf.

In the Contract Year 2023 final rule, CMS acknowledged potential cash flow concerns for pharmacies upon implementation, but noted that we do not have the authority to mandate payment plans between Part D plan sponsors and pharmacies due to the non-interference clause at section 1860D-11(i) of the Social Security Act, which prohibits CMS from requiring a particular price structure for the reimbursement of covered Part D drugs. Consequently, CMS finalized the provision with a one-year delay, setting the effective date as January 1, 2024 instead of the proposed date of January 1, 2023. As we stated in the final rule, this delay gives all parties sufficient time to implement the policy, including granting Part D plan sponsors and pharmacies adequate time to establish payment plans or make other arrangements to address any potential cash flow concerns ahead of the January 1, 2024 effective date.

CMS is aware that stakeholders continue to have concerns regarding pharmacy cash flow and contracting challenges ahead of the 2024 implementation date. We are continuing to strongly encourage Part D plan sponsors to provide payment plans or alternate payment arrangements to pharmacies in advance of the January 1, 2024 effective date. If such an arrangement is offered, Part D sponsors and their PBMs should provide pharmacies with a straightforward means of requesting it. CMS also reminds Part D plan sponsors that as the pharmacy price concessions provision takes effect on January 1, 2024, the prompt payment requirements at § 423.520 will continue to apply, and CMS will closely monitor plan compliance with pharmacy access standards at § 423.120 to ensure that all Medicare Part D beneficiaries continue to have access to pharmacies and medications.

In addition, as discussed in the June 2, 2023 HPMS memo "Reminder of Regulatory Requirements for Pharmacy Price Concessions," we have previously received questions about arrangements whereby pharmacies may contribute to a pool of money, where the contribution is not related to the number of prescriptions filled, or other such arrangements that reduce pharmacy payments. As we stated in the June memo, if the payment to a Part D pharmacy may be reduced by up to a certain amount, the maximum possible reduction in payment must be treated as a pharmacy price concession and reflected in the negotiated price available at the POS and reported to CMS on a prescription drug event (PDE) record. This is the case regardless of whether the maximum possible reduction in payment is calculated on a per claim basis. For pharmacy price concessions that are not assessed at the claim level, Part D sponsors must determine a methodology to attribute such concessions to the claim level to remain in compliance with the new definition of negotiated price. As such, CMS stated in the June 2, 2023 memo that the pharmacy price concessions provision is applicable to the arrangements described. The pharmacy's contribution to the plan's pool, even when not assessed on a per claim basis, is considered a price concession that must be applied at the POS to reduce the negotiated price. Further, if a pharmacy receives a post-POS payment from the plan for good performance, then that payment amount must be reported as a negative DIR amount.

The pharmacy price concessions provision is expected to lower total beneficiary out-of-pocket costs, provide meaningful price transparency, better reflect pharmacy payment arrangements, and enable CMS to assess the payment practices of Part D plan sponsors and PBMs with respect to pharmacies under the Medicare program. To ensure compliance with the pharmacy price concessions provision effective January 1, 2024, CMS encourages Part D plan sponsors to

review requirements in the Contract Year 2023 final rule (CMS-4192-F) and additional clarifications on the provision provided in the October 13, 2022 HPMS memo, "Reporting Estimated Remuneration Applied to the Point-of-Sale Price" and in the June 2, 2023 HPMS memo "Reminder of Regulatory Requirements for Pharmacy Price Concessions."