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TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

FROM: Vanessa S. Duran, Director
Medicare Drug Benefit and C & D Data Group

Jennifer R. Shapiro, Director
Medicare Plan Payment Group

SUBJECT: Additional Guidance on the Impact of Supplemental Payments on Manufacturer Discount Program Calculations and True Out-of-Pocket (TrOOP) Cost Accumulation

This memorandum includes additional guidance related to how supplemental payments by non-Part D payers affect manufacturer discounts under the Manufacturer Discount Program and True Out-of-Pocket (TrOOP) costs in certain scenarios. This guidance is effective beginning Contract Year (CY) 2025.

Calculating Manufacturer Discounts When Straddle Claims Are Adjusted by Supplemental Payments That Reduce TrOOP

CMS has received questions regarding how a manufacturer discount is calculated and reported on a prescription drug event (PDE) when a Part D sponsor adjudicates a claim for an applicable drug¹ with a total TrOOP amount that moves the beneficiary from one benefit phase to another, but then receives an Information Reporting (N) transaction² indicating a non-Part D, non-TrOOP eligible supplemental payment has been made. The supplemental payment reduces the total TrOOP represented on the PDE to below the defined standard deductible amount or the out-of-pocket (OOP) threshold, at the pharmacy as a coordination of benefits (COB) transaction. It is worth noting that the Inflation Reduction Act of 2022 made changes to section 1860D-2(b)(4)(C) of the Social Security Act that increase the number of non-Part D supplemental payer

¹ See sections 40.1 and 130 of the Medicare Part D Manufacturer Discount Program Final Guidance at <https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf>.

² See sections 30.4.4 and 30.4.5 of Chapter 14 of the Prescription Drug Benefit Manual at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-14-2018.pdf>.

types that are TrOOP eligible, so there should be fewer supplemental payers that are non-TrOOP eligible beginning in 2025, and the scenario discussed here should not be common.

As specified in § 423.120 and 45 CFR Part 162, Part D plans must utilize the National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards for adjudication of pharmacy claims. The standard allows for real time, point-of-sale claims processing which the Part D plan summarizes on the PDE record and submits to CMS. If a Part D sponsor adjudicates the claim in accordance with the beneficiary's Part D benefit and subsequently receives an N transaction, indicating that a non-Part D, non-TrOOP eligible payer has reduced the beneficiary's liability for the claim, the Part D sponsor must account for the reduction in TrOOP on the subsequent PDE. This approach is consistent with how Coverage Gap Phase to Catastrophic Phase straddle claims (the only benefit phase transition prior to January 1, 2025 where the beneficiary transitions to the next benefit phase based exclusively on TrOOP) with dates of service prior to January 1, 2025 are currently handled under the Coverage Gap Discount Program (see HPMS memorandum "May 2014 Updates to the Drug Data Processing System" issued on April 11, 2014).

CMS will provide PDE examples at a later time.

TrOOP Cost Accounting When Supplemental Payer Patient Pay Amount is Greater than Part D Cost Sharing

There are multiple COB methods supported by the NCPDP Telecommunication standard which health insurers may require for pharmacy claims processing as determined by business needs and contractual agreements (e.g., COB claims based on Other Payer Amount Paid [OPAP] or Other Payer Patient Responsibility Amount [OPRA]). Depending on the COB method utilized, in some cases where the beneficiary has supplemental coverage to Part D, the final patient pay amount on a pharmacy claim may be higher than the patient pay amount had the claim been processed by the Part D plan alone (i.e., without any supplemental coverage).

Consistent with section 1860D-2(b)(4)(C)(i) of the Social Security Act, the beneficiary patient pay amount *in excess of* the Part D cost sharing should *not* be applied towards TrOOP accumulators and should *not* be reflected in the Patient Pay Amount field on PDEs submitted to CMS. This is consistent with the guidance issued to Part D sponsors in the Medicare Prescription Payment Plan Final Part Two Guidance,³ which indicates that in these cases the Part D sponsor may only include the Medicare Prescription Payment Plan participant's original Part D cost sharing in the Medicare Prescription Payment Plan. Further, this avoids potential scenarios where Part D plans submit PDEs with supplemental patient pay amounts that exceed Part D statutory limits.

This policy does not apply to Employer Group Waiver Plan (EGWP) supplemental coverage where an EGWP enrollee's OOP costs are in excess of the Part D defined standard cost sharing

³ See comment/response on page 45 and section 50.1 of the Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments at <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-two-guidance.pdf>.

since EGWPs are Part D plans. Part D enrollee OOP costs for EGWP supplemental benefits will count towards TrOOP consistent with the Final CY 2025 Part D Redesign Program Instructions.⁴

Please email PartD_COB@cms.hhs.gov with questions regarding this memorandum or PDE-Operations@cms.hhs.gov with questions about PDE reporting.

⁴ See comment/response on pages 5-6 and section 30 of the Final CY 2025 Part D Redesign Program Instructions at <https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf>.