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SERVICES
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MEDICARE PLAN PAYMENT GROUP

DATE: January 9, 2025

TO: All Part D Sponsors

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

SUBJECT: Additional Prescription Drug Event (PDE) Record Reporting Examples for the Implementation of the Inflation Reduction Act for Contract Year 2026

On April 15, 2025, the Centers for Medicare & Medicaid Services (CMS) published the Health Plan Management System (HPMS) memorandum “Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2026,” which provided PDE reporting example instructions consistent with the provisions of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) that became effective January 1, 2026 in the Part D program. Since the publication of that memorandum, CMS has received technical questions from Part D sponsors inquiring about specific PDE reporting scenarios that were not directly addressed in that document. Specifically, this new memorandum provides guidance related to reporting PDEs for selected drugs under the Medicare Drug Price Negotiation Program. The first example demonstrates how to report a selected drug for a covered insulin product that is subject to lesser of logic. The subsequent examples demonstrate how to report selected drug PDEs structured from a Direct Member Reimbursement (DMR) request.

The following PDE examples use contract year (CY) 2026 benefit parameters.

Please direct questions regarding this memo to PDE-Operations@cms.hhs.gov.

Example #1: Covered Insulin Product that is also a Selected Drug in the Initial Coverage Phase (ICP) of a Basic Plan or an Enhanced Alternative (EA) Plan with TrOOP-Eligible Costs above the Defined Standard (DS) Deductible Amount and Accounting for the Lesser of Logic (Applicable Drug)

This example demonstrates how to report a PDE for a beneficiary purchasing a \$129.00 covered insulin product (\$119.00 ingredient cost, \$10.00 dispensing fee) that is also a selected drug with a maximum fair price (MFP) of \$119.00. The plan’s ICP cost-sharing for this covered insulin product is the lesser of the \$30.00 copay under the plan or 25% coinsurance. When the claim

adjudication begins, the Total Gross Covered Drug Cost (TGCDC) Accumulator is \$1,380.00, and the True Out-of-Pocket (TrOOP) Accumulator is \$650.00. The beneficiary is in the ICP of the benefit (TrOOP Accumulator + Delta TrOOP¹ < \$2,100.00 for a covered insulin product); the ICP is the beginning and ending benefit phase.

The beneficiary pays the lesser of the covered insulin product copay amount under the plan² (\$30.00), an amount equal to 25% of the negotiated price (\$129.00 * 0.25 = \$32.25), or an amount equal to 25% of the maximum fair price (\$119.00 * 0.25 = \$29.75), which is \$29.75.³ In the ICP, the Selected Drug Subsidy is 10% of the total drug cost (\$129.00 * 0.10 = \$12.90), the Patient Pay Amount is \$29.75, and the plan pays the remaining \$86.35 and reports this amount in the Covered D Plan Paid Amount (CPP) field.

After the claim is processed, the TGCDC Accumulator increases by \$129.00, and the TrOOP Accumulator increases by \$29.75. The table below illustrates how the Part D sponsor would populate the PDE record.

| PDE Field | Value |
|--|----------|
| Drug Coverage Status Code | C |
| Ingredient Cost Paid | \$119.00 |
| Dispensing Fee Paid | \$10.00 |
| Total Amount Attributed to Sales Tax | \$0.00 |
| Vaccine Administration Fee or Additional Dispensing Fee | \$0.00 |
| Gross Drug Cost Below Out-of-Pocket Threshold (GDCB) | \$129.00 |
| Gross Drug Cost Above Out-of-Pocket Threshold (GDCA) | \$0.00 |
| Patient Pay Amount | \$29.75 |
| Other TrOOP Amount | \$0.00 |
| Low Income Cost Sharing Subsidy Amount (LICS) | \$0.00 |
| Patient Liability Reduction Due to Other Payer Amount (PLRO) | \$0.00 |

¹ Delta TrOOP is defined as total TrOOP-eligible costs that are accrued on the individual PDE being reported, excluding the TrOOP Accumulator value, and represents the change in TrOOP from the preceding PDE.

² Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 90 FR 15792,15804 (April 15, 2025) (See the response to comment where CMS clarifies that if a Part D sponsor places a covered insulin product on a formulary tier with a copayment or coinsurance that is lower than the statutory maximum cost-sharing amount (that is, the lesser of \$35, 25 percent of the negotiated price, or 25 percent of the MFP), the Part D sponsor will need to use the copayment or coinsurance amount specified for the tier when determining the enrollee's cost-sharing amount.)

³ Under section 1860D-2 of the Social Security Act, as amended by section 11406 of the IRA, beginning in CY 2026, the applicable copayment amount for a covered insulin product is the lesser of \$35, an amount equal to 25 percent of the maximum fair price established for the covered insulin product under the Medicare Drug Price Negotiation Program if the covered insulin product is a selected drug, or an amount equal to 25 percent of the negotiated price of the covered insulin product under the Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug (MA-PD) plan. Section 1860D-2(b)(9)(D)(ii) of the Social Security Act; 42 C.F.R. § 423.100 (*defining Covered insulin product applicable cost-sharing amount*).

| | |
|---|------------|
| Covered D Plan Paid Amount (CPP) | \$86.35 |
| Non Covered Plan Paid Amount (NPP) | \$0.00 |
| Selected Drug Subsidy | \$12.90 |
| Reported Manufacturer Discount | \$0.00 |
| Total Gross Covered Drug Cost (TGCDC) Accumulator | \$1,380.00 |
| True Out-of-Pocket (TrOOP) Accumulator | \$650.00 |
| Beginning Benefit Phase | N |
| Ending Benefit Phase | N |

Example #2: Actuarially Equivalent (AE) Plan – ICP (Selected Drug) for an In-Network DMR Claim

This example demonstrates how to report a PDE for a beneficiary in an AE plan where the beneficiary has submitted a DMR request to their Part D plan for a Part D selected drug and the plan has approved coverage. The beneficiary paid \$970.00 at the point-of-sale (POS) to the dispensing entity for this selected drug. The maximum fair price established under the Medicare Drug Price Negotiation Program for this drug is \$295.00. The Part D plan has determined from the DMR that the dispensing entity is an in-network provider, the negotiated price for this drug is \$300.00 (\$295.00 ingredient cost, \$5.00 dispensing fee), and the beneficiary copay is \$75.00. The Part D plan uses the negotiated price⁴ when reporting the PDE to CMS.⁵

At the time of processing, the TGCDC Accumulator is \$800.00, and the TrOOP Accumulator is \$710.00. The beneficiary is in the ICP of the benefit (TrOOP Accumulator \geq \$615.00 and TrOOP Accumulator + Delta TrOOP < \$2,100.00); the ICP is the beginning and ending benefit phase. In the ICP, the Selected Drug Subsidy is 10% of the total drug cost (\$300.00 * 0.10 = \$30.00), the Patient Pay Amount is \$75.00, and the remaining drug cost of \$195.00 (\$300.00 - \$30.00 - \$75.00) is reported in the CPP field. The Non-Standard Format Code field is populated with “B”.

After the claim is processed, the TGCDC Accumulator increases by \$300.00, and the TrOOP Accumulator increases by \$75.00. The table below illustrates how the Part D sponsor would populate the PDE record.

| PDE Field | Value |
|---------------------------|--------------|
| Drug Coverage Status Code | C |
| Non-Standard Format Code | B |

⁴ Under section 1860D-2(d)(1)(D) of the Social Security Act, as amended by section 11001 of the IRA, the negotiated price for each selected drug must not exceed the maximum fair price plus any dispensing fees for such drug.

⁵ For additional policy information regarding DMRs and access to the MFP for selected drugs, to include appropriate reimbursement to the beneficiary, see section 80.1 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (September 30, 2025).

| | |
|--|----------|
| Pricing Exception Code | <SPACE> |
| Ingredient Cost Paid | \$295.00 |
| Dispensing Fee Paid | \$5.00 |
| Total Amount Attributed to Sales Tax | \$0.00 |
| Vaccine Administration Fee or Additional Dispensing Fee | \$0.00 |
| Gross Drug Cost Below Out-of-Pocket Threshold (GDCB) | \$300.00 |
| Gross Drug Cost Above Out-of-Pocket Threshold (GDCA) | \$0.00 |
| Patient Pay Amount | \$75.00 |
| Other TrOOP Amount | \$0.00 |
| Low Income Cost Sharing Subsidy Amount (LICS) | \$0.00 |
| Patient Liability Reduction Due to Other Payer Amount (PLRO) | \$0.00 |
| Covered D Plan Paid Amount (CPP) | \$195.00 |
| Non Covered Plan Paid Amount (NPP) | \$0.00 |
| Selected Drug Subsidy | \$30.00 |
| Reported Manufacturer Discount | \$0.00 |
| Total Gross Covered Drug Cost (TGCD) Accumulator | \$800.00 |
| True Out-of-Pocket (TrOOP) Accumulator | \$710.00 |
| Beginning Benefit Phase | N |
| Ending Benefit Phase | N |

Example #3: AE Plan – ICP (Selected Drug) for an Out-of-Network DMR Claim

This example demonstrates how to report a PDE for a beneficiary in an AE plan where the beneficiary has submitted a DMR request to their Part D plan for a Part D selected drug and the plan has approved coverage. The beneficiary paid \$970.00 at the POS to the dispensing entity for this selected drug. The maximum fair price established under the Medicare Drug Price Negotiation Program for this drug is \$295.00. The Part D plan has determined from the DMR that the dispensing entity is an out-of-network provider, the customary dispensing fee⁶ for this selected drug is \$5.00, and the beneficiary copay is \$75.00. The Part D plan uses the maximum fair price when reporting the PDE to CMS and may add the customary dispensing fee for this selected drug.⁷ The Part D plan chooses to add the customary dispensing fee, which is \$5.00, when submitting this PDE to CMS.

⁶ Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (September 30, 2025) (In response to the comments requesting more information on how a plan should process DMR requests if it does not know the associated dispensing fees, CMS notes that in instances where the plan does not know the dispensing fee charged by the pharmacy and paid by the enrollee for the out-of-network claim, it may reimburse the enrollee based on the MFP and the plan's customary dispensing fee, if any, paid on an out-of-network point-of-sale electronic claim. CMS recommends that plans populate PDE records for these claims with the MFP and the dispensing fee paid, if any.)

⁷ For additional policy information regarding DMRs and access to the MFP for selected drugs, to include appropriate reimbursement to the beneficiary, see section 80.1 of the Medicare Drug Price Negotiation Program:

At the time of processing, the TGCDC Accumulator is \$800.00, and the TrOOP Accumulator is \$710.00. The beneficiary is in the ICP of the benefit (TrOOP Accumulator \geq \$615.00 and TrOOP Accumulator + Delta TrOOP $<$ \$2,100.00); the ICP is the beginning and ending benefit phase. In the ICP, the Selected Drug Subsidy is 10% of the total drug cost (\$300.00 * 0.10 = \$30.00), the Patient Pay Amount is \$75.00, and the remaining drug cost of \$195.00 (\$300.00 - \$30.00 - \$75.00) is reported in the CPP field. The Non-Standard Format Code field is populated with “B” and the Pricing Exception Code field is populated with “O”.

After the claim is processed, the TGCDC Accumulator increases by \$300.00, and the TrOOP Accumulator increases by \$75.00. The table below illustrates how the Part D sponsor would populate the PDE record.

| PDE Field | Value |
|--|--------------|
| Drug Coverage Status Code | C |
| Non-Standard Format Code | B |
| Pricing Exception Code | O |
| Ingredient Cost Paid | \$295.00 |
| Dispensing Fee Paid | \$5.00 |
| Total Amount Attributed to Sales Tax | \$0.00 |
| Vaccine Administration Fee or Additional Dispensing Fee | \$0.00 |
| Gross Drug Cost Below Out-of-Pocket Threshold (GDCB) | \$300.00 |
| Gross Drug Cost Above Out-of-Pocket Threshold (GDCA) | \$0.00 |
| Patient Pay Amount | \$75.00 |
| Other TrOOP Amount | \$0.00 |
| Low Income Cost Sharing Subsidy Amount (LICS) | \$0.00 |
| Patient Liability Reduction Due to Other Payer Amount (PLRO) | \$0.00 |
| Covered D Plan Paid Amount (CPP) | \$195.00 |
| Non Covered Plan Paid Amount (NPP) | \$0.00 |
| Selected Drug Subsidy | \$30.00 |
| Reported Manufacturer Discount | \$0.00 |
| Total Gross Covered Drug Cost (TGCDC) Accumulator | \$800.00 |
| True Out-of-Pocket (TrOOP) Accumulator | \$710.00 |
| Beginning Benefit Phase | N |
| Ending Benefit Phase | N |