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CENTER FOR MEDICARE & MEDICAID INNOVATION

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To: Medicare Part D Prescription Drug Plan Sponsors Participating in the Contract Year (CY) 2023 Part D Senior Savings (PDSS) Model

From: Laura T. McWright, Deputy Director, Seamless Care Models Group, Center for Medicare and Medicaid Innovation

Subject: Additional CY 2023 PDSS Model Guidance Related to Inflation Reduction Act (IRA) Changes to Part D Coverage of Insulin

This memorandum provides Part D sponsors participating in the PDSS Model in CY 2023 with additional clarifying guidance, specific to the Model, for implementing section 11406 (Appropriate Cost Sharing for Covered Insulin Products under Medicare Part D) of the Inflation Reduction Act (IRA, P.L. 117-169). This guidance is specific to CY 2023 PDSS Model. This memorandum also presents the operational approach that the Centers for Medicare & Medicaid Services (CMS) will take when implementing section 11406 of the IRA in the Part D program for Part D plans that are also participating in the PDSS Model and includes Prescription Drug Event (PDE) reporting instructions specifically for PDSS-participating plans to implement the appropriate cost-sharing obligations for covered insulin products.

In addition to the obligations stated in the September 26, 2022 HPMS memorandum titled, "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin," PDSS-participating plans must continue to provide Model-Specific Supplemental Benefits for Plan-Selected Model Drugs in accordance with the CY 2023 addendum to their Part D contract for participation in PDSS ("CY 2023 PDSS Addendum"), inclusive of the requirements in PDSS Model guidance and their submitted and approved bids for CY 2023.

The following table provides an overview of the interaction between a PDSS-participating plan's obligations under the PDSS Model and its obligations under the IRA for coverage of insulin products when the PDSS Model does not apply. The temporary retrospective subsidy under section 1860D-15(h) of the Social Security Act (the Act) as added by the IRA may be available to reimburse PDSS-participating plans for costs incurred in applying the IRA's $35 cap on cost sharing for a one-month supply of a covered insulin product to: covered insulin products that are not Plan-Selected Model Drugs, Plan-Selected Model Drugs for which the plan does not provide supplemental benefits in the catastrophic phase, and covered insulin products provided to low-income subsidy eligible (LIS-eligible) beneficiaries.

Plan Coverage/Benefit	PDSS Model Requirements	IRA Requirements
Eligible Beneficiaries	Non-LIS beneficiaries	LIS beneficiaries
Part D Benefit Phase Coverage for Plan-Selected Model Drugs	First three phases of the Part D benefit only. (Deductible, Initial Coverage Limit, and Coverage Gap phases of the Part D benefit)	Catastrophic Phase
Plan-Selected Model Drugs	Plan-Selected Model Drugs. Identified in Part D sponsor's Approved Proposal for which Part D sponsor offers Model-Specific Supplemental Benefits.	Drugs that are not Plan-Selected Model Drugs but are covered insulin products on the Part D plan's formulary. Deductible does not apply for covered insulin products and coverage is available in all other phases of the Part D benefit.
Formulary Exceptions	Must provide formulary exceptions where applicable at the approved cost-sharing for the designated formulary exceptions tier(s). Not required to offer Model cost sharing for non-formulary insulins approved through the formulary exceptions process.	Required to provide covered insulin products treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal, or covered under the transition process in accordance with § 423.120(b)(3) at cost-sharing of $35 or less for a one-month supply.
Extended Day Supplies	Extended day supplies and associated cost sharing as submitted and approved in the PDSS section of the approved 2023 plan benefit package (PBP).	Required to cover extended day supplies (two-month and/or three-month supplies) consistent with the approved Part D bid. Cost-sharing must not exceed $70 for up to a two-month supply or $105 for up to a three-month supply.

Out-of-Network (OON)	OON cost sharing as submitted and approved in the PDSS section of the 2023 PBP.	Cost sharing for all covered insulin products (including Plan-Selected Model Drugs) must not exceed $35 for a one-month supply of a covered insulin product when provided by an OON provider in accordance with §423.124(a) and (c). Consequently, although Part D sponsors, including those participating in the PDSS Model, may charge an enrollee for the differential between the OON price and the plan allowance, in no event may a Part D sponsor require an enrollee to pay cost sharing (inclusive of any OON differential) that exceeds the statutory limit of $35 for a one-month supply of a covered insulin product.

CY 2023 PDSS Plan Bids, including PDSS Supplemental Files

PDSS Model participants should not submit requests to update, based on IRA requirements, the PDSS cost sharing or Plan Selected Model Drugs in the bids that have already been submitted and approved to be offered under the PDSS Model for CY 2023 or their PDSS supplemental file. Any changes to the PDSS supplemental file should be submitted only if they are in accordance with Article 3, Section F (Notice of Changes) of the CY 2023 PDSS Addendum.

Coverage Gap Discounts

PDSS-participating plans will continue to determine coverage gap discounts for Plan-Selected Model Drugs in accordance with previously published guidance for enhanced alternative plans participating in the PDSS Model.

Please refer to the September 26, 2022 HPMS memorandum titled, "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin," for guidance on determination of coverage gap discounts for covered insulin products that are not Plan-Selected Model Drugs provided to applicable beneficiaries enrolled in PDSS plans.

Prescription Drug Event (PDE) Data

In addition to the PDE calculation and reporting guidance in the September 26, 2022 HPMS memorandum titled, "PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023,"[1,2] PDSS-participating plans must also ensure their PDE calculations and reporting properly account for Plan-Selected Model Drugs dispensed to Model-eligible beneficiaries.

When a covered insulin product that is a Plan-Selected Model Drug is dispensed to a Model-eligible beneficiary, PDSS-participating sponsors shall continue to follow existing PDSS guidance[3] regarding PDE calculation and reporting, with the amendments described in this memorandum.

We are updating Example #2 from the September 24, 2021 HPMS memorandum, "CORRECTION - Part D Senior Savings Model Prescription Drug Event (PDE) Reporting Guidance (Part 2)"[4] to reflect the cost-sharing cap on insulin products added by the IRA in the Catastrophic Phase. We have increased the drug cost for the drug in the example so that we can illustrate what occurs in the scenario where the sum of the coinsurance in the Catastrophic Phase and the copay in the Coverage Gap would exceed $35. The updates to this example are provided in **bolded red text** below to clarify how reporting should account for the IRA's beneficiary cost-sharing reduction in the Catastrophic Phase. The Part D Model Indicator is also noted in **bolded red text**, as this PDE field was unavailable when Example #2 was originally provided.

Example #2: PDE for a Plan-Selected Model Drug that straddles copay to coinsurance benefit phases (Coverage Gap to Catastrophic), the drug cost remaining in the Coverage Gap is below the Model-Specific Supplemental copay, and the Inflation Reduction Act Subsidy Amount (IRASA) applies in the Catastrophic Phase
This example demonstrates how to report a PDE for an **$800.00** Plan-Selected Model Drug on tier 3, having a **$795.00** ingredient cost and a $5.00 dispensing fee. The EA plan has a $35 copay for tier 3 drugs until the Catastrophic Phase (this is also the **Model-Specific Supplemental** copay) and does not have supplemental benefits in the Catastrophic Phase.

Step 1 - Determine costs that fall within the Coverage Gap:
When the claim adjudication begins, the TGCDC Accumulator is **$13,950.00**, the TrOOP Accumulator is **$7,380.00**, the beginning benefit phase is the Coverage Gap, and remaining

[1] As stated in the September 26, 2022 HPMS memorandum, the guidance provided in that memo applies to all non-Model covered insulin products provided to all beneficiaries enrolled in PDSS plans, all covered insulin products provided to LIS-eligible beneficiaries enrolled in PDSS plans, all covered insulin products provided to all beneficiaries enrolled in PDSS plans in the catastrophic phase, and ACIP-recommended vaccines covered by PDSS plans.
[2] This memorandum is available here.
[3] PDSS PDE guidance is available in the additional information section of the PDSS Model website here.
[4] This memorandum is available here.

TrOOP is $20.00. To determine the drug cost in the Coverage Gap, the remaining TrOOP amount is divided by 1 minus the covered plan cost-sharing in the Coverage Gap or 0.95. The total drug cost in the Coverage Gap is $21.05. This amount excludes the dispensing fee, which falls completely in the Catastrophic Phase.

Step 2 – Determine the discount eligible cost:
Because this is a Plan-Selected Model Drug, the discount eligible cost is equal to the ingredient cost falling in the Coverage Gap, which is $21.05. The dispensing fee falls entirely in the Catastrophic Phase.

Step 3 - Calculate the Gap Discount:
The gap discount is 70% of the $21.05 discount eligible cost or $14.74.

Step 4 - Determine beneficiary cost-sharing and calculate IRASA:
The beneficiary has a $35 copay for tier 3 drugs in the Coverage Gap and does not have supplemental coverage in the Catastrophic Phase. Because there is only $5.26 of remaining TrOOP in the Coverage Gap ($20.00 - $14.74), the beneficiary pays a capped copay of $5.26 in the Coverage Gap instead of $35.00. In the Catastrophic Phase, **prior to the application of the requirements of section 1860D-2(b)(9) of the Act, as added by section 11406 of the IRA**, the beneficiary would have been responsible for the greater of 5% of drug costs falling in the Catastrophic Phase (**$778.95** * 0.05 = **$38.95**) or **$10.35 in CY 2023**. In this case, the beneficiary **would have paid** a total of **$44.21** (**$38.95** + $5.26). **Although PDSS Model benefits do not apply in the Catastrophic Phase, the PDSS Model Plan must still apply the beneficiary cost-sharing maximum of $35.00 as required under the IRA. Therefore, the beneficiary cost-sharing in the Catastrophic Phase is reduced to $29.74 ($35.00 - $5.26).**

The IRASA is calculated by subtracting the IRA-reduced beneficiary cost sharing from the original beneficiary cost sharing under the plan's 2023 benefit design consistent with the plan's 2023 bid ($38.95 - $29.74 = $9.21). This amount is reported in the Other TrOOP Amount field, and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

Step 5 - Calculate CPP, NPP, and PLRO amounts:
For Plan-Selected Model Drugs, supplemental benefits that fall in the Coverage Gap are reported as PLRO and supplemental benefits that fall in the Catastrophic Phase are reported as NPP.

Coverage Gap: To determine the portion of this amount that is CPP, we consider this claim in light of the Defined Standard benefit where CPP is 5% of ingredient cost and sales tax in the gap plus 75% of dispensing fee in the gap. Because the amount of the claim falling in the Catastrophic Phase exceeds the dispensing fee on the claim, there is no plan liability for this fee in the Coverage Gap. CPP equals $1.05 ($21.05 * .05). PLRO is determined by taking the cost falling within the Coverage Gap and subtracting the beneficiary cost-sharing, reported gap discount, and CPP. PLRO is $21.05 - ($5.26 + $14.74 + $1.05) = $0.00.

Catastrophic Phase: CPP is the lesser of 95% of the drug cost in the Catastrophic Phase or drug cost in the Catastrophic Phase minus **$10.35 in CY 2023**. In this case, CPP in the Catastrophic Phase is **$740.00** ((**$778.95** * 0.95 = **$740.00**) < (**$778.95** - **$10.35** = **$768.60**)). NPP is determined by taking the cost falling within the Catastrophic Phase and subtracting the beneficiary cost-sharing, CPP, **and IRASA**. NPP is **$778.95** - (**$29.74** + **$740.00** + **$9.21**) = $0.00.

The Model Plan will populate the Part D Model Indicator with an "07" value for this PDE record.

PDE Field	Value
TGCDC Accumulator	**$13,950.00**
TrOOP Accumulator	**$7,380.00**
Tier	3
GDCB	$21.05
GDCA	**$778.95**
Ingredient Cost	**$795.00**
Dispensing Fee	$5.00
Beginning Benefit Phase	G
Ending Benefit Phase	C
Patient Pay	**$35.00**
CPP	**$741.05**
NPP	$0.00
PLRO	$0.00
Reported Gap Discount	$14.74
Part D Model Indicator	**07**
Other TrOOP Amount Indicator	**S**
Other TrOOP Amount	**$9.21**

PDSS-participating sponsors should also be aware that the IRA's beneficiary cost-sharing reduction requirement applies for LIS-eligible beneficiaries. Examples #6 and #7 from the April 27, 2021 HPMS memorandum, "Part D Senior Savings Model – Prescription Drug Event (PDE) Reporting Guidance,"[5] detail how PDSS plans should adjudicate the benefit and report costs for Plan Selected Model Drugs for LIS-eligible beneficiaries. PDSS plans should adjudicate the benefit and report costs in accordance with these examples prior to CY 2023. Beginning in CY 2023, PDSS-participating sponsors should adjudicate the benefit and report costs for all covered insulin products (including Plan Selected Model Drugs) for LIS-eligible beneficiaries in accordance with the examples for LIS-eligible beneficiaries in the September 26, 2022 HPMS memorandum, "PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023."

Medicare Plan Finder (MPF)

[5] This memorandum is available here.

The CY 2023 MPF will reflect Part D sponsors' insulin benefits and cost sharing as submitted in their 2023 bid and formulary submissions, including PDSS Model benefits/coverage. For CY 2023 Open Enrollment, CMS is updating MPF to include a new insulin drug footnote and other help features to explain the benefit changes resulting from the IRA.

Please refer to the September 12, 2022 HPMS memorandum titled, "Updates to PDSS Model Communications and Marketing Guidelines for Contract Year 2023" for guidance on PDSS-specific Model requirements.

Special Enrollment Period

Since MPF will reflect Part D sponsors' insulin benefits and cost sharing as submitted in their CY 2023 bids, CMS is granting a Special Enrollment Period (SEP) for Exceptional Circumstances to allow beneficiaries to add, drop, or change their Part D coverage if they find a better option after the 2022 Annual Enrollment Period (AEP). This SEP will be available for all beneficiaries who use a covered insulin product and begins on December 8, 2022 and ends on December 31, 2023. Beneficiaries may use this SEP one time during this period. To utilize this SEP, beneficiaries must call 1-800-MEDICARE so a customer service representative can process the enrollment change. Consistent with current policy, when Part D enrollees change plans mid-year, their True Out-of-Pocket (TrOOP) costs carry over from one plan to the next.

Questions concerning this memorandum may be directed to PartDSavingsModel@cms.hhs.gov.