DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop WB-06-05 Baltimore, Maryland 21244-1850



#### CENTER FOR MEDICARE AND MEDICAID INNOVATION

- **TO:** Contract Year (CY) 2024 Medicare Advantage Organization (MAO) Participants of the Medicare Advantage (MA) Value-Based Insurance Design (VBID) Model
- **FROM:** Laura T. McWright, Deputy Director, Seamless Care Models Group, Center for Medicare and Medicaid Innovation

SUBJECT: VBID Model Prescription Drug Event (PDE) Reporting Guidance for CY 2024

The Centers for Medicare & Medicaid Services (CMS) has received technical questions from MAOs and other interested parties about the treatment of the VBID Model flexibility to provide targeted reductions in Part D cost sharing, specifically scenarios where a participating plan has waived the full Low-Income Subsidy (LIS) copay for all drugs for LIS category 1 and 2 beneficiaries in CY 2024. This memorandum provides guidance and specific PDE examples related to these technical questions as a follow-up to the December 1, 2022 VBID Model Guidance on Treatment of Reductions in Part D Cost-Sharing and June 1, 2022 VBID Prescription Drug Event (PDE) Reporting Guidance for Contract Year (CY) 2023.<sup>1</sup> The guidance in this memorandum is specific to CY 2024 of the VBID Model.

MAOs participating in the VBID Model in CY 2024 that have waived the full LIS copay for all drugs for LIS category 1 and 2 beneficiaries brought to our attention that these enrollees cannot transition from the Coverage Gap Phase into the Catastrophic Phase. CMS has determined this to be a result of the Inflation Reduction Act (IRA) changes that eliminated beneficiary cost sharing in the Catastrophic Phase in 2024, subsequently resulting in the elimination of low-income cost sharing subsidy (LICS) in the Catastrophic Phase. Because the VBID Model benefit is not True Out-of-Pocket Cost (TrOOP) eligible and is applied after the total LICS on a claim is calculated, beneficiaries that would have accumulated TrOOP exceeding the annual out-of-pocket (OOP) threshold in CY 2023 on a straddle claim are unable to accumulate sufficient TrOOP to satisfy the OOP threshold in CY 2024 for the same straddle claim. Notably, this issue only occurs in CY 2024 because, starting with CY 2025, the VBID Model's buydown of the LIS copay will count towards TrOOP.

For CY 2024 only, so that the application of the Model benefit does not prevent beneficiaries from entering the Catastrophic Phase, we interpret the existing Part D waiver under the Model as authorizing CMS to modify how the LICS amount is determined on Coverage Gap to Catastrophic straddle claims. We believe this will result in participating MAOs' actual liability for the cost-sharing reductions for targeted LIS enrollees offered as a Model Benefit aligning

<sup>&</sup>lt;sup>1</sup> VBID Model participating Part D sponsors are required to comply with CMS guidance regarding PDE reporting, as noted in the applicable year's Contract Amendment Addendum.

more closely with the projected value of the cost-sharing reductions that these participating MAOs included as administrative costs in the Part D portion of their bids. Therefore, for CY 2024 only, CMS is applying a reporting adjustment under the VBID Model (hereinafter referred to as the "VBID reporting adjustment"), which adjusts the drug cost in the Coverage Gap Phase so that the calculation of LICS will result in an amount that is sufficient to satisfy the annual OOP threshold. This VBID reporting adjustment permits enrollees to transition from the Coverage Gap Phase into the Catastrophic Phase.

With this VBID reporting adjustment, participating MAOs should not have beneficiaries who remain in the Coverage Gap Phase indefinitely as a result of applying the VBID Model Benefit. In addition, claims should not continually be reported as Coverage Gap Phase to Catastrophic Phase straddle claims upon the application of the VBID Model Benefit after all other PDE fields have been calculated. In this memorandum, CMS is providing PDE reporting examples with specific instructions for determining whether a claim is eligible for this VBID reporting adjustment and the reporting requirements for relevant VBID Model claims.

MAOs participating in the CY 2024 VBID Model should take careful note of the additional step in the below examples for determining drug costs that fall in the Coverage Gap Phase. This additional step accounts for the 2024 IRA changes and the VBID Model Benefits not counting toward TrOOP in CY 2024.

CMS will conduct additional monitoring and oversight as needed to ensure that relevant VBID Model claims are appropriately adjusted by MAOs participating in the VBID Model, in accordance with the following examples.

In order to appropriately process VBID-eligible PDEs, CMS requires VBID-eligible PDEs with a date of service (DOS) on or after January 1, 2023 to be submitted with a value of "01" in the Part D Model Indicator field.<sup>2</sup>

The following examples use CY 2024 Part D benefit parameters.

# Example 1: Defined Standard plan, Coverage Gap to Catastrophic Phase for an LIS Beneficiary with a VBID Reporting Adjustment Applied

This example demonstrates how to report a VBID-eligible PDE for a \$100.00 covered Part D brand drug (\$100.00 ingredient cost/\$0.00 dispensing fee) that straddles the Coverage Gap Phase and the Catastrophic Phase of a Defined Standard (DS) plan for an LIS category 1 beneficiary. When the claim adjudication begins, the Total Gross Covered Drug Cost (TGCDC) Accumulator is \$12,750.00, and the TrOOP Accumulator is \$7,980.00. The plan's VBID Model benefit waives the LIS copay on all Part D claims for LIS category 1 and 2 beneficiaries.

<sup>&</sup>lt;sup>2</sup> See HPMS memorandum, Updates to the Drug Data Processing System (DDPS), October 13, 2022 (available at <u>https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-wk-2-october-10-14</u>).

In the reporting steps below, the first step determines whether a VBID reporting adjustment is applied and describes how to calculate it. Only after this calculation is made is the non-LIS beneficiary cost sharing amount determined, and subsequently all other fields calculated.

# Step 1 – Determine the VBID reporting adjustment and, subsequently, costs that fall in the Coverage Gap Phase:

Because the VBID Model benefit waives the full LIS copay on all Part D claims for LIS category 1 and 2 beneficiaries, this PDE is potentially eligible for a VBID reporting adjustment. To determine the VBID reporting adjustment to Coverage Gap Phase drug costs, the remaining TrOOP amount is compared to the total drug cost minus the LIS copayment. In this example, the remaining TrOOP amount is \$20.00 (\$8,000.00 - \$7,980.00) and the total drug cost minus the LIS copayment is \$88.80 (\$100.00 - \$11.20). When the remaining TrOOP amount is less than the total drug cost minus the LIS copayment to the remaining TrOOP amount, a VBID reporting adjustment is made by adding the LIS copayment to the remaining TrOOP amount, and this amount is determined to be the portion of the total drug cost in the Coverage Gap Phase. This VBID reporting adjustment modifies the drug cost in the Coverage Gap Phase so that the calculation of LICS will result in an amount that is sufficient to satisfy the annual OOP threshold. In this example, the claim has satisfied the requirements for the VBID reporting adjustment, so the total drug cost in the Coverage Gap Phase is \$31.20 (\$20.00 + \$11.20).

#### Step 2 – Calculate the *non-VBID*, non-LIS beneficiary cost sharing:

In the Coverage Gap Phase, for purposes of determining the LICS amount only, the non-LIS cost-sharing for covered Part D drugs is determined as 100% of Gross Covered Drug Cost in the Coverage Gap Phase, without taking into account any plan limits on beneficiary cost-sharing (including cost-sharing limits required by the IRA), Coverage Gap discount, or generic coinsurance. Therefore, in this example, the non-LIS cost-sharing is \$31.20 (\$31.20 \* 1.00 = \$31.20) in the Coverage Gap Phase and \$0.00 in the Catastrophic Phase, where there is a 0% coinsurance, equaling a total of \$31.20 from across the two phases.

#### Step 3 – Determine the *non-VBID*, LIS beneficiary cost sharing:

According to 2024 Part D benefit parameters, a category 1 LIS beneficiary pays \$11.20 for a brand drug in the Coverage Gap Phase and \$0.00 in the Catastrophic Phase.

#### Step 4 – Compare <u>non-VBID</u>/non-LIS and <u>non-VBID</u>/LIS beneficiary cost sharing:

The non-LIS beneficiary cost sharing amount, as calculated in Step 2, is \$31.20. The LIS beneficiary cost sharing amount, as determined in Step 3, is \$11.20. According to the "lesser of" test, the LIS beneficiary is responsible for whichever amount is less. In this example, the LIS beneficiary cost sharing amount is less than the non-LIS beneficiary cost sharing amount. Therefore, the plan will use the LIS beneficiary cost sharing amount of \$11.20 to calculate the LICS amount in Step 5.

#### **Step 5 – Apply LICS formula:**

The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. As determined in Step 4, the LIS beneficiary cost sharing used in the LICS formula is equal to the LIS beneficiary cost sharing that was calculated in Step 3 because of the "lesser of" test. The LICS amount is therefore \$20.00 (\$31.20 - \$11.20).

#### Step 6 – Calculate Covered D Plan Paid (CPP) Amount:

Under the Defined Standard benefit, the plan covers the drug costs not covered by the beneficiary or the LICS amount. The total amount of the plan-covered drug costs is reported on the PDE record as the CPP amount. In this example, the CPP amount is \$68.80 (\$100.00 - \$11.20 - \$20.00).

**Step 7 – Calculate Patient Liability Reduction due to Other Payer (PLRO) & Patient Pay:** Patient Pay is determined by applying the VBID Model benefit (i.e., \$0.00 beneficiary cost sharing). In this example, PLRO is the VBID Model benefit amount paid by the plan in lieu of the beneficiary cost sharing as determined in Step 4. PLRO is \$11.20 (\$11.20 - \$0.00).

The plan populates the Part D Model Indicator with "01". The table below illustrates how the plan would populate the PDE record.

PDE Field	Value
Drug Coverage Status Code	С
Part D Model Indicator	01
Ingredient Cost Paid	\$100.00
Dispensing Fee Paid	\$0.00
Total Amount Attributed to Sales Tax	\$0.00
Vaccine Administration Fee or Additional Dispensing Fee	\$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	\$31.20
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	\$68.80
Patient Pay Amount	\$0.00
Other TrOOP Amount	\$0.00
Low Income Cost Sharing Subsidy Amount (LICS)	\$20.00
Patient Liability Reduction Due to Other Payer Amount (PLRO)	\$11.20
Covered D Plan Paid Amount (CPP)	\$68.80
Non Covered Plan Paid Amount (NPP)	\$0.00
Reported Manufacturer Discount	\$0.00
Total Gross Covered Drug Cost Accumulator	\$12,750.00
True Out-of-Pocket Accumulator	\$7,980.00
Beginning Benefit Phase	G
Ending Benefit Phase	C

## Example 2: Defined Standard plan, Coverage Gap Claim for an LIS Beneficiary with a VBID Model Benefit where the VBID Reporting Adjustment is not Applied

This example demonstrates how to report a VBID-eligible PDE for a \$100.00 covered Part D brand drug (\$100.00 ingredient cost/\$0.00 dispensing fee) in the Coverage Gap Phase of a DS plan for an LIS category 1 beneficiary. When the claim adjudication begins, the TGCDC Accumulator is \$12,750.00, and the TrOOP Accumulator is \$7,910.00. The plan's VBID Model benefit waives the LIS copay on all Part D claims for LIS category 1 and 2 beneficiaries.

In the reporting steps below, the first step determines whether a VBID reporting adjustment is applied and describes how to calculate it. Only after this calculation is made is the non-LIS beneficiary cost sharing amount determined, and subsequently all other fields calculated.

## Step 1 – Determine the VBID reporting adjustment and, subsequently, costs that fall in the Coverage Gap Phase:

Because the VBID Model benefit waives the full LIS copay on all Part D claims for LIS category 1 and 2 beneficiaries, this PDE is potentially eligible for a VBID reporting adjustment. To determine the VBID reporting adjustment to Coverage Gap Phase drug costs, the remaining TrOOP amount is compared to the total drug cost minus the LIS copayment. In this example, the remaining TrOOP amount is \$90.00 (\$8,000.00 - \$7,910.00) and the total drug cost minus the LIS copayment is \$88.80 (\$100.00 - \$11.20). When the remaining TrOOP amount is less than the total drug cost minus the LIS copayment to the remaining TrOOP amount, a VBID reporting adjustment is made by adding the LIS copayment to the remaining TrOOP amount, and this amount is determined to be the total drug cost that falls in the Coverage Gap. This VBID reporting adjustment modifies the drug cost in the Coverage Gap Phase so that the calculation of LICS will result in an amount that is sufficient to satisfy the annual OOP threshold. In this example, the remaining TrOOP amount is not less than the total drug cost minus the LIS copayment. Therefore, the total drug cost falls in the Coverage Gap Phase, meaning this VBID-eligible PDE does not straddle the Coverage Gap and Catastrophic phases. Thus, there is no VBID reporting adjustment, and the drug cost in the Coverage Gap Phase remains \$100.00.

#### Step 2 – Calculate the *non-VBID*, non-LIS beneficiary cost sharing:

In the Coverage Gap Phase, for purposes of determining the LICS amount only, the non-LIS cost-sharing for covered Part D drugs is determined as 100% of Gross Covered Drug Cost in the Coverage Gap Phase, without taking into account any plan limits on beneficiary cost-sharing (including cost-sharing limits required by the IRA), Coverage Gap discount, or generic coinsurance. Therefore, in this example, the non-LIS cost-sharing is \$100.00 (\$100.00 \* 1.00 = \$100.00) in the Coverage Gap Phase.

#### Step 3 – Determine the *non-VBID*, LIS beneficiary cost sharing:

According to 2024 Part D benefit parameters, a category 1 LIS beneficiary pays \$11.20 for a brand drug in the Coverage Gap Phase.

#### Step 4 – Compare <u>non-VBID</u>/non-LIS and <u>non-VBID</u>/LIS beneficiary cost sharing:

The non-LIS beneficiary cost sharing amount, as calculated in Step 2, is \$100.00. The LIS beneficiary cost sharing amount, as determined in Step 3, is \$11.20. According to the "lesser of" test, the LIS beneficiary is responsible for whichever amount is less. In this example, the LIS beneficiary cost sharing amount is less than the non-LIS beneficiary cost sharing amount. Therefore, the plan will use the LIS beneficiary cost sharing amount of \$11.20 to calculate the LICS amount in Step 5.

#### **Step 5 – Apply LICS formula:**

The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. As determined in Step 4, the LIS beneficiary cost sharing used in the LICS formula is equal to the LIS beneficiary cost sharing that was calculated in Step 3 because of the "lesser of" test. The LICS amount is therefore \$88.80 (\$100.00 - \$11.20).

#### Step 6 – Calculate CPP Amount:

Under the Defined Standard benefit, the plan covers the drug costs not covered by the beneficiary or the LICS amount. The total amount of the plan-covered drug costs is reported on the PDE record as the CPP amount. In this example, the CPP amount is \$0.00 (\$100.00 - \$11.20 - \$88.80).

#### Step 7 – Calculate PLRO & Patient Pay:

Patient Pay is determined by applying the VBID Model benefit (i.e., \$0.00 beneficiary cost sharing). In this example, PLRO is the VBID Model benefit amount paid by the plan in lieu of the beneficiary cost sharing as determined in Step 4. PLRO is \$11.20 (\$11.20 - \$0.00).

The plan populates the Part D Model Indicator with "01". The table below illustrates how the plan would populate the PDE record.

PDE Field	Value
Drug Coverage Status Code	С
Part D Model Indicator	01
Ingredient Cost Paid	\$100.00
Dispensing Fee Paid	\$0.00
Total Amount Attributed to Sales Tax	\$0.00
Vaccine Administration Fee or Additional Dispensing Fee	\$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	\$100.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	\$0.00
Patient Pay Amount	\$0.00
Other TrOOP Amount	\$0.00
Low Income Cost Sharing Subsidy Amount (LICS)	\$88.80
Patient Liability Reduction Due to Other Payer Amount (PLRO)	\$11.20
Covered D Plan Paid Amount (CPP)	\$0.00
Non Covered Plan Paid Amount (NPP)	\$0.00
Reported Manufacturer Discount	\$0.00
Total Gross Covered Drug Cost Accumulator	\$12,750.00
True Out-of-Pocket Accumulator	\$7,910.00
Beginning Benefit Phase	G
Ending Benefit Phase	G

# Example 3: Defined Standard plan, Coverage Gap Claim for an LIS Beneficiary with a VBID Model Benefit where the VBID Reporting Adjustment is not Applied and the LIS Copay exceeds the Drug Cost

This example demonstrates how to report a VBID-eligible PDE for a \$5.00 covered Part D brand drug (\$5.00 ingredient cost/\$0.00 dispensing fee) in the Coverage Gap Phase of a DS plan for an LIS category 1 beneficiary. When the claim adjudication begins, the TGCDC Accumulator is \$12,750.00, and the TrOOP Accumulator is \$7,996.00. The plan's VBID Model benefit waives the LIS copay on all Part D claims for LIS category 1 and 2 beneficiaries.

In the reporting steps below, the first step determines whether a VBID reporting adjustment is applied and describes how to calculate it. Only after this calculation is made is the non-LIS beneficiary cost sharing amount determined, and subsequently all other fields calculated.

## Step 1 – Determine the VBID reporting adjustment and, subsequently, costs that fall in the Coverage Gap Phase:

Because the VBID Model benefit waives the full LIS copay on all Part D claims for LIS category 1 and 2 beneficiaries, this PDE is potentially eligible for a VBID reporting adjustment. To determine the VBID reporting adjustment to Coverage Gap Phase drug costs, the remaining TrOOP amount is compared to the total drug cost minus the LIS copayment. In this example, the remaining TrOOP amount is \$4.00 (\$8,000.00 - \$7,996.00) and the total drug cost minus the LIS copayment is -\$6.20 (\$5.00 - \$11.20). When the remaining TrOOP amount is less than the total drug cost minus the LIS copayment to the remaining TrOOP amount, a VBID reporting adjustment is made by adding the LIS copayment to the remaining TrOOP amount, and this amount is determined to be the total drug cost that falls in the Coverage Gap. This VBID reporting adjustment modifies the drug cost in the Coverage Gap Phase so that the calculation of LICS will result in an amount that is sufficient to satisfy the annual OOP threshold. In this example, the remaining TrOOP amount is not less than the total drug cost minus the LIS copayment. Therefore, the total drug cost falls in the Coverage Gap Phase. There is no VBID reporting adjustment, and the drug cost in the Coverage Gap Phase so.

#### Step 2 – Calculate the *non-VBID*, non-LIS beneficiary cost sharing:

In the Coverage Gap Phase, for purposes of determining the LICS amount only, the non-LIS cost-sharing for covered Part D drugs is determined as 100% of Gross Covered Drug Cost in the Coverage Gap Phase, without taking into account any plan limits on beneficiary cost-sharing (including cost-sharing limits required by the IRA), Coverage Gap discount, or generic coinsurance. Therefore, in this example, the non-LIS cost-sharing is  $5.00 (5.00 \times 1.00 = 5.00)$  in the Coverage Gap Phase.

#### Step 3 – Determine the *non-VBID*, LIS beneficiary cost sharing:

According to 2024 Part D benefit parameters, a category 1 LIS beneficiary pays \$11.20 for a brand drug in the Coverage Gap Phase, but because this amount exceeds the total drug cost, the cost sharing for an LIS beneficiary would be equal to the total drug cost, which is \$5.00.

## Step 4 – Compare <u>non-VBID</u>/non-LIS and <u>non-VBID</u>/LIS beneficiary cost sharing:

The non-LIS beneficiary cost sharing amount, as calculated in Step 2, is \$5.00. The LIS beneficiary cost sharing amount, as determined in Step 3, is \$11.20. According to the "lesser of" test, the LIS beneficiary is responsible for whichever amount is less. In this example, the LIS beneficiary cost sharing amount is equal to the non-LIS beneficiary cost sharing amount, so the plan will use the cost sharing amount of \$5.00 to calculate the LICS amount in Step 5.

## Step 5 – Apply LICS formula:

The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. The LICS amount is \$0.00 (\$5.00 - \$5.00).

## Step 6 – Calculate CPP Amount:

Under the Defined Standard benefit, the plan covers the drug costs not covered by the beneficiary or the LICS amount. The total amount of the plan-covered drug costs is reported on

the PDE record as the CPP amount. In this example, the CPP amount is 0.00 (5.00 - 5.00 - 0.00).

#### Step 7 – Calculate PLRO & Patient Pay:

Patient Pay is determined by applying the VBID Model benefit (i.e., \$0.00 beneficiary cost sharing). In this example, PLRO is the VBID Model benefit amount paid by the plan in lieu of the beneficiary cost sharing as determined in Step 4. PLRO is \$5.00 (\$5.00 - \$0.00).

The plan populates the Part D Model Indicator with "01". The table below illustrates how the plan would populate the PDE record.

PDE Field	Value
Drug Coverage Status Code	С
Part D Model Indicator	01
Ingredient Cost Paid	\$5.00
Dispensing Fee Paid	\$0.00
Total Amount Attributed to Sales Tax	\$0.00
Vaccine Administration Fee or Additional Dispensing Fee	\$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	\$5.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	\$0.00
Patient Pay Amount	\$0.00
Other TrOOP Amount	\$0.00
Low Income Cost Sharing Subsidy Amount (LICS)	\$0.00
Patient Liability Reduction Due to Other Payer Amount (PLRO)	\$5.00
Covered D Plan Paid Amount (CPP)	\$0.00
Non Covered Plan Paid Amount (NPP)	\$0.00
Reported Manufacturer Discount	\$0.00
Total Gross Covered Drug Cost Accumulator	\$12,750.00
True Out-of-Pocket Accumulator	\$7,996.00
Beginning Benefit Phase	G
Ending Benefit Phase	G