# Common Prescription Drug Event (PDE) Reporting Edits and Solutions Computer Based Training (CBT) Text-Only Version

## 1. Introduction

### *1.1 Introduction*

Welcome to the Common Prescription Drug Event (PDE) Reporting Edits and Solutions Computer Based Training or CBT.

This CBT provides an overview of common PDE edits, illustrates the reporting challenges encountered by Part D sponsors through examples, and identifies recommended solutions.

This course should take approximately 60 minutes.

### *1.2 Keyboard Shortcuts*

Note the following keyboard commands are available throughout the CBT. Use p to pause the CBT, r to resume the CBT, k to review the keyboard shortcuts shown on this screen, o to move back to the previous slide, n to move to the next slide, and m to turn the audio Off. Please note, selecting m will only turn the audio off on the current slide. Audio will resume upon replaying the current slide, or progressing to the next slide.

### *1.3 Learning Objectives*

The learning objectives for this training are: identify benefit phase indicator reporting rules to prevent Edit 787, illustrate rules for reporting benefit phase indicators through scenarios and examples, recommend resolutions to rectify common PDE reporting errors associated with Edit 787, recommend resolutions to rectify biosimilar drugs (Edit 867), describe how biosimilar drugs differ from applicable and generic drugs, and demonstrate how to accurately populate a PDE record for a biosimilar drug in the Coverage Gap and Catastrophic phases.

### *1.4 Topics to Cover*

This course is broken into two sections: Edit 787 and Biosimilar drugs.

## 2. Edit 787 Overview

### *2.1 Edit 787 Overview*

One of the more frequent PDE edits is Edit 787. This edit is issued when the Beginning and Ending Benefit Phase combination does not match the True Out-of-Pocket or TrOOP Accumulator and/or the Total Gross Covered Drug Cost or TGCDC Accumulator values.

During PDE processing, various data elements are edited and compared field-to-field. When the fields do not match, Part D sponsors are notified with Edit 787 on their PDE Return File and other error reports.

Edit 787 is an informational edit. Informational edits either question data reported by the plan or provide additional information from CMS. In the case of Edit 787, the data reported is being

questioned and requires plan action to examine the PDE claim and ensure the accuracy of the data submitted. If data was submitted inappropriately, the Part D sponsor must submit adjustments to correct the data.

This Edit is effective for dates of service January 1, 2011 and forward. Edit 787 is bypassed for calendar year Employer Group Waiver Plans, also known as EGWPs, with dates of service prior to January 1, 2014 and bypassed for non-calendar year EGWPs for all dates of service.

As just mentioned, it is essential that the benefit phases and accumulator reported are accurate. Edit 787 is a trigger for Part D sponsors to ensure the accuracy of the submitted data as the gap discount calculation edits also depend on the accuracy of that reporting.

**Message to be Reported**

Beginning and Ending Benefit Phase combination does not match the True Out-of-Pocket Accumulator and/or Total Gross Covered Drug Cost Accumulator.

**Processing of PDE to Determine Edit 787**

The following data elements are edited during the processing of the PDE to determine Edit 787:

- Beginning Benefit Phase
- Ending Benefit Phase
- Total Gross Covered Drug Cost Accumulator
- TrOOP Accumulator
- Gross Drug Above OOP Threshold (GDCA)
- Gross Drug Cost Below OOP Threshold (GDCB)
- Patient Pay Amount, Other TrOOP Amount
- Reported Gap Discount
- Low Income Cost Sharing Subsidy Amount.

**Edit Type: Informational**

- Informational edits question data reported or provide additional information from CMS.
- Requires plan action

**Edit Application**

Applies to:

- Covered Drugs only. Drug Coverage Status Code = C
- Effective for Dates of Service (DOS) 1/1/2011 and forward.
- Bypassed for calendar year Employer Group Waiver Plans (EGWPs) DOS prior to 1/1/2014).
- Bypassed for non-calendar year EGWPs for all DOS.

## 3. Edit 787 - Example 1

### *3.1 Edit 787 Example #1 – Enhanced Alternative (EA) Plan, No Deductible*

Now that you have a general understanding of Edit 787, let's go through several examples of a submitted PDE record that received the edit. Each example explains a scenario, the PDE report,

resolution of the error, and prevention strategies. In the first example, we will explore an Enhanced Alternative, or EA, Plan with no deductible.

### *3.2 Scenario*

In 2016, a beneficiary in Sunhealth PBP, which is an EA plan, has no deductible. The year to date TGCDC accumulator is $75.00, with no accumulated TrOOP. The beneficiary purchases a covered generic drug that costs $10.00. An excerpt of the submitted PDE Record is illustrated below.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $10.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $75.00 |
| TrOOP Accumulator | $0.00 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $0.00 |
| CPP | $0.00 |
| NPP | $10.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | D |

### *3.3 Report*

When the Part D sponsor receives their PDE Return File, the Detail Record indicates INF for the Record ID indicating that the file includes informational edits. When the error portion of the file is reviewed, it includes an Edit 787.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $10.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $75.00 |
| TrOOP Accumulator | $0.00 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $0.00 |
| CPP | $0.00 |
| NPP | $10.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | D |
| Error 1 | 787 |

### *3.4 – 3.5 Resolution*

In this scenario, why was there an Edit 787 identified? Do the Benefit Phase Indicators match the plan-determined phase that is in effect when adjudication of the PDE begins?

At first impression, it would appear that they do. However, since this EA Plan waived the Deductible Phase, they should not be populating the Beginning and Ending Benefit Phase Indicators with "D" for deductible.

| Field | Value | Adjusted Value |
|---|---|---|
| Drug Coverage Status Code | C | |
| Adjustment/Deletion | | **A** |
| GDCB | $10.00 | |
| GDCA | $0.00 | |
| TGCDC Accumulator | $75.00 | |
| TrOOP Accumulator | $0.00 | |
| Beginning Benefit Phase | D | **N** |
| Patient Pay Amount | $0.00 | |
| CPP | $0.00 | |
| NPP | $10.00 | |
| Reported Gap Discount | $0.00 | |
| Ending Benefit Phase | D | **N** |
| | | |

Upon receiving Edit 787, the plan needs to take action. The plan would submit an Adjustment PDE with A in the Adjustment/Deletion Code field and change the Beginning and Ending Benefit Phase Indicators to N for the Initial Coverage Phase.

### *3.6 Prevention*

For this particular scenario, Edit 787 can be avoided by populating the Beginning and Ending Benefit Phase Indicators with "N" for Initial Coverage Phase, which corresponds with the EA plan's benefit structure, which included no deductible.

In general, when populating PDE records, always be sure to populate the Benefit Phase Indicators based on the plan type benefit structure in which the claim was adjudicated.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $10.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $75.00 |
| TrOOP Accumulator | $0.00 |
| Beginning Benefit Phase | N |
| Patient Pay Amount | $0.00 |
| CPP | $0.00 |
| NPP | $10.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | N |

Below is a crosswalk that provides guidance for reporting benefit phase indicators for each plan type benefit structure.

| Plan Type | Rule for Reporting Benefit Phase Indicators |
|---|---|
| Defined Standard (DS) | Report as DS |
| Actuarially Equivalent (AE) | Report as DS |
| Basic Alternative (BA) | Report as DS |
| Enhanced Alternative (EA) | Report as EA |
| Medicare-Medicaid Plan (MMP) | Report dollar fields as DS; Report Benefit Phase according to benefit structure |
| Employer Group Waiver Plan (EGWP) | Report as DS regardless of the benefit structure of the Other Health Insurance (OHI) benefit (As of 1/1/2014 CY)<br>*Source: 2014 PDE Guidance memo* |

# 4. Edit 787 - Example 2

## *4.1 Edit 787 Example #2 - EGWP Plan, Zero Deductible*

In example two, let's go through an example of an EGWP Plan with a zero deductible.

## *4.2 Scenario*

In 2016, a non-Low-Income Subsidy (LIS) beneficiary is enrolled in an EGWP plan and purchases a $100.00 drug, which includes $95.00 ingredient cost and $5.00 dispensing fee. Prior to this claim, the TGCDC Accumulator is $260.00 and the TrOOP Accumulator is $230.00. The claim falls within the Deductible Phase of the Defined Standard benefit. Under the Other Health Insurance Benefit, or OHI, the beneficiary does not have a deductible and has a $30.00 copay for this drug. An excerpt of the submitted PDE Record is illustrated below.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $260.00 |
| TrOOP Accumulator | $230.00 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $30.00 |
| CPP | $0.00 |
| NPP | $0.00 |
| PLRO | $70.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | N |

### *4.3 Report*

When the Part D sponsor receives their PDE Return File, the Detail Record indicates INF for the Record ID indicating that the file includes informational edits. When the error portion of the file is reviewed, it includes an Edit 787.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $260.00 |
| TrOOP Accumulator | $230.00 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $30.00 |
| CPP | $0.00 |
| NPP | $0.00 |
| PLRO | $70.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | N |
| Error 1 | 787 |

### *4.4 – 4.5 Resolution*

In this scenario, why was there an Edit 787 identified? Beginning in calendar year 2014, EGWP sponsors follow the rules that apply for Defined Standard Benefit plans, regardless of the benefit structure of the OHI benefit. If the OHI plan does not have a deductible or changes in the Initial Coverage Limit, for PDE reporting purposes, the sponsor reports the benefit phase parameters consistent with the Defined Standard Benefit parameters.

| Field | Value | Adjusted Value |
|---|---|---|
| Drug Coverage Status Code | C | |
| n/a | n/a | **A** |
| GDCB | $100.00 | |
| GDCA | $0.00 | |
| TGCDC Accumulator | $260.00 | |
| TrOOP Accumulator | $230.00 | |
| Beginning Benefit Phase | D | |
| Patient Pay Amount | $30.00 | |
| CPP | $0.00 | |
| NPP | $0.00 | |
| PLRO | $70.00 | |
| Reported Gap Discount | $0.00 | |
| Ending Benefit Phase | N | **D** |
| | | |

Upon receiving Edit 787, the plan needs to take action. According to the Defined Standard 2016 parameters, the Deductible Phase ends when the drug cost equals $360.00. With this claim the beneficiary has paid exactly $360.00; therefore, the beneficiary does not advance to the Initial Coverage Phase. The Ending Benefit Phase should be D for Deductible.

The plan would submit an Adjustment PDE with A in the Adjustment/Deletion Code field and change the Ending Benefit Phase Indicators to D for the Deductible Phase.

### *4.6 Prevention*

The PDE record populated correctly for this particular example. Because EGWP plans are required to populate the Beginning and Ending Benefit Phase Indicators according to the Defined Standard Benefit, regardless of changes to the Deductible or Initial Coverage Limit. The Ending Benefit Phase Indicator were updated to "D" for deductible according to the TGCDC and TrOOP Accumulator values.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $260.00 |
| TrOOP Accumulator | $230.00 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $30.00 |
| CPP | $0.00 |
| NPP | $0.00 |
| PLRO | $70.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | D |

## 5. Edit 787 - Example 3

### *5.1 Edit 787 Example #3 - Medicare-Medicaid Plans*

In example three, we will review a Medicare-Medicaid Plan (MMP) example for Edit 787.

### *5.2 Scenario*

In 2016, a Low Income Subsidy (LIS) Level 2 beneficiary enrolled in an MMP purchases a $100.00 covered brand drug. The MMP plan buys down the beneficiary's cost-sharing. Because the beneficiary is LI Level 2, there is no deductible. At the beginning of the claim, the TGCDC Accumulator is $200.00 and the TrOOP Accumulator is $196.40.

MMPs submit plan benefit packages in the Health Plan Management System (HPMS) as Enhanced Alternative (EA) plans to allow the system to generate plan descriptions that most closely reflect what the full-benefit dual eligible enrollee in an MMP experiences.

However, MMPs are Defined Standard (DS) plans, not EA plans, for purposes of PDE reporting of payment fields only. MMPs should report benefit phases based on benefit design as experienced by the Low Income (LI) beneficiary enrolled in the plan.

In this example, the MMP populated the entire PDE, including payment fields and benefit phase indicators, as in a Defined Standard plan. The Patient Pay Amount is initially determined to be $3.60, but the MMP plan buys down the beneficiary's cost-sharing so the Patient Pay Amount is $0.00 and the Non-Plan Paid Amount (NPP) is $3.60. The table below demonstrates the fields submitted on the PDE. As we will describe next, this is incorrect.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $200.00 |
| TrOOP Accumulator | $196.40 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $0.00 |
| CPP | $0.00 |
| NPP | $3.60 |
| LICS | $96.40 |
| PLRO | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | D |

## *5.3 Report*

When the Part D sponsor receives their PDE Return File, the Detail Record indicates INF for the Record ID indicating that the file includes informational edits. When the error portion of the file is reviewed, it includes an Edit 787.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $200.00 |
| TrOOP Accumulator | $196.40 |
| Beginning Benefit Phase | D |
| Patient Pay Amount | $0.00 |
| CPP | $0.00 |
| NPP | $3.60 |
| LICS | $96.40 |
| PLRO | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | D |
| Error 1 | 787 |

## *5.4 – 5.5 Resolution*

In this scenario, why was there an Edit 787 generated? Edit 787 was generated because the combination of Beginning and Ending Benefit Phase Indicators and Accumulators may not match the plan benefit design submitted by the plan in HPMS and the MMP should take a closer look at the claim to make sure the information is accurate and determine if an adjustment is needed. The MMP reported the Benefit Phase Indicators incorrectly on the PDE claim in this scenario. According to the accumulators, the beneficiary is in the Deductible Phase if populated according to a Defined Standard plan.

The MMP correctly populated the dollar fields on the PDE. The MMP buys down the beneficiary cost in the Deductible Phase so the patient pay amount is $0.00. The Low Income Subsidy (LICS) copay amount is paid by the plan and is reported as NPP.

The error was with the reporting of the Beginning and Ending Benefit Phase Indicators, which should be reported based on the benefit phase experienced by the LI enrollee in the MMP.

Therefore, the Beginning and Ending Benefit Phase Indicators should be reported as if the LIS 2 beneficiary was in the Initial Coverage Phase with an N.

| Field | Value | Adjusted Value |
|---|---|---|
| Drug Coverage Status Code | C | |
| Adjustment/Deletion Code | | **A** |
| GDCB | $100.00 | |
| GDCA | $0.00 | |
| TGCDC Accumulator | $200.00 | |
| TrOOP Accumulator | $196.40 | |
| Beginning Benefit Phase | D | **N** |
| Patient Pay Amount | $0.00 | |
| CPP | $0.00 | |
| NPP | $3.60 | |
| LICS | $96.40 | |
| PLRO | $0.00 | |
| Reported Gap Discount | $0.00 | |
| Ending Benefit Phase | D | **N** |
| | | |

Upon receiving Edit 787, the plan needs to take action. The plan would submit an Adjustment PDE with A in the Adjustment/Deletion Code field and change the Beginning and Ending Benefit Phase Indicators to N based on the phase for the plan design of the beneficiary enrolled in the MMP.

## *5.6Prevention*

Below is a correctly populated PDE Record for this scenario.

As the MMP did in this scenario, plans should populate the PDE record according to the Defined Standard benefit with regard to the payment fields. While the payment fields are reported based on the Defined Standard, the Beginning and Ending Benefit Indicators are reported based on the MMP benefit.

Remembering this reporting rule for MMPs will help prevent instances of Edit 787.

When calculating the non-LI cost-sharing amount, the full cost of the drug is used, which is $100.00 and the LICS copay amount is subtracted from this amount. Under the Defined Standard reporting of dollar fields, there is no Covered Plan Paid Amount (CPP).

The LIS maximum cost-sharing amount for a Level 2 beneficiary is $3.60 in 2016. Since the MMP buys down the patient pay amount, the copay is reported in the NPP Amount.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $200.00 |
| TrOOP Accumulator | $196.40 |
| Beginning Benefit Phase | N |
| Patient Pay Amount | $0.00 |
| CPP | $0.00 |
| NPP | $3.60 |
| LICS | $96.40 |
| PLRO | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | N |

# 6. Biosimilars Overview

## *6.1 Biosimilars Overview*

Before we begin this section, we will review the definition of biosimilar drugs. Biosimilars are a type of biological product licensed, and approved, by the Food and Drug Administration, or FDA.

**Biosimilars: Definition**

They are highly similar and do not have any clinically meaningful differences, to an already FDA-approved biological product.

Biosimilars are highly similar to an already FDA-approved biological product, known as the biological reference product (reference product), and have been shown to have no clinically meaningful differences from the reference product. Although Biosimilars are approved by the FDA under the same Biologics License Application or BLA as Biologics, Biosimilars are non-applicable drugs for purposes of establishing coverage gap cost-sharing under the basic Part D benefit, and are not discounted or otherwise subject to Discount Program requirements.

**Biosimilars: Reporting of Biosimilars**

In other words, biosimilar drugs are reported as Brand, but are ineligible for the Coverage Gap Discount. Therefore, biosimilar drugs receive generic cost-sharing amounts in the Coverage Gap Phase. The Drug Data Processing System or DDPS will not reject a PDE record that is populated for a biosimilar drug, reported as a brand drug on the PDE in Field 47 - Brand/Generic Code, but with no value reported in the Coverage Gap Discount.

There are also special cost-sharing requirements regarding copays for biosimilars.

When sponsors submit a PDE record for a biosimilar drug with a value populated for the Coverage Gap Discount amount, the PDE record will be rejected with Edit 867.

**Biosimilars: Cost-sharing and Copays**

Biosimilars are subject to the Brand cost-sharing amount for LI (Low Income) beneficiaries with cost-sharing. Additionally, for biosimilars filled in the Catastrophic Phase, the Brand copay applies for non-LIS beneficiaries and should be compared to 5% of the drug cost falling in the Catastrophic Phase to determine the appropriate cost-sharing.

**Error 867**

When sponsors submit a PDE record for a biosimilar drug with a value populated for the Coverage Gap Discount amount, the PDE record will be rejected with Edit 867.

Edit 867, a reject edit, is received when, “FDA does not designate this drug as NDA or BLA, or this drug is a biosimilar drug; therefore it is ineligible for the coverage gap discount.” Sponsors should review and adjust the PDE record accordingly.

# 7. Biosimilars - Example 1

## *7.1 Biosimilar Example #1 - Defined Standard Plan, Coverage Gap*

Now that you have a general understanding of biosimiliars, let's go through examples of PDE records submitted for biosimilar drugs. Each example explains a scenario, the PDE report, resolution of the error and a prevention strategy. In this next example, we will cover a Defined Standard Plan in the Coverage Gap.

## *7.2 Scenario*

In 2016, a beneficiary in a Defined Standard Plan purchases a $100.00 biosimilar drug. The beneficiary is squarely in the Coverage Gap, as the TGCDC Accumulator is $6,000.00 and the TrOOP Accumulator is $3,850.00. An excerpt of the submitted PDE Record is illustrated below.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| Brand/Generic | B |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $6,000.00 |
| TrOOP Accumulator | $3,850.00 |
| Beginning Benefit Phase | G |
| Patient Pay Amount | $45.00 |
| CPP | $5.00 |
| NPP | $0.00 |
| Reported Gap Discount | $50.00 |
| Ending Benefit Phase | G |

### *7.3 Report*

When the Part D sponsor receives their PDE Return File, the Detail Record indicates REJ for the Record ID indicating that the file includes Reject errors. When the error portion of this file is reviewed, it includes Edit 867: FDA does not designate this drug as NDA or BLA, or this drug is a biosimilar drug; therefore, it is ineligible for the coverage gap discount.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| Brand/Generic | B |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $6,000.00 |
| TrOOP Accumulator | $3,850.00 |
| Beginning Benefit Phase | G |
| Patient Pay Amount | $45.00 |
| CPP | $5.00 |
| NPP | $0.00 |
| Reported Gap Discount | $50.00 |
| Ending Benefit Phase | G |
| Error 1 | 867 |

### *7.4 – 7.5 Resolution*

In this scenario, why was there an Edit 867 identified? In this particular example, the PDE record field Reported Gap Discount should be $0.00, since the biosimilar drug is not eligible for the Gap Discount. The beneficiary cost-sharing and plan cost-sharing must be recalculated to reflect cost-sharing for a generic drug.

In this scenario, the plan should resubmit the PDE record after repopulating the following fields: Patient Pay Amount, CPP, and Reported Gap Discount. When the DDPS receives the claim, it should process as if there are no other errors. However, the Reported Gap Discount amount will be $0.00, because biosimilar drugs are not eligible for the Coverage Gap Discount. It is imperative that plans populate PDE records correctly.

| Field | Value | Adjusted Value |
|---|---|---|
| Drug Coverage Status Code | C | |
| Adjustment/Deletion | | **A** |
| Brand/Generic | B | |
| GDCB | $100.00 | |
| GDCA | $0.00 | |
| TGCDC Accumulator | $6,000.00 | |
| TrOOP Accumulator | $3,850.00 | |
| Beginning Benefit Phase | G | |
| Patient Pay Amount | $45.00 | $58.00 |
| CPP | $5.00 | |
| NPP | $0.00 | $42.00 |
| Reported Gap Discount | $50.00 | $0.00 |
| Ending Benefit Phase | G | |
| | | |

The plan would submit an Adjustment PDE with A in the Adjustment/Deletion Code field. The Patient Pay Amount is changed to $58.00. Because biosimilar drugs are not eligible for the Gap Discount, the beneficiary cost-sharing amount is calculated to reflect cost-sharing for a generic drug. The CPP is changed 0to $42.00 and the Reported Gap Discount is changed to $0.00**.** As previously indicated, biosimilar drugs are not eligible for the Coverage Gap Discount.

### *7.6 Prevention*

It is important to remember that although Biosimilars are brand drugs (Brand/Generic code = B) they are not eligible for the gap discount. Generic cost-sharing is applied to biosimilars in the coverage gap phase and a $0.00 amount for the Reported Gap Discount for all biosimilar drugs.

| Field | Value |
|---|---|
| Drug Coverage Status Code | C |
| Brand/Generic | B |
| GDCB | $100.00 |
| GDCA | $0.00 |
| TGCDC Accumulator | $6,000.00 |
| TrOOP Accumulator | $3,850.00 |
| Beginning Benefit Phase | G |
| Patient Pay Amount | $58.00 |
| CPP | $42.00 |
| NPP | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | G |

Plans should ensure the PDE record submitted displays cost-sharing amounts and a $0.00 dollar amount for the Reported Gap Discount for all biosimilar drugs – regardless of benefit phase.

The DDPS processing takes into consideration drugs marked as Brand with a code of “B” since biosimilars are still BLAs and that have $0.00 populated in the Reported Gap Discount field. These records will not reject based on this condition.

# 8. Biosimilars - Example 2

## *8.1 Biosimilar Example #2 - Coverage Gap to Catastrophic Phase*

In example two, we will review a PDE Record submitted for a biosimilar drug that straddles the Coverage Gap to Catastrophic Phases.

## *8.2 Scenario*

In 2016, the beneficiary has $4,821.00 in TrOOP before the PDE record is received. The non-LIS beneficiary purchases a $150.00 biosimilar drug and straddles the Gap to Catastrophic Phase. In the Catastrophic Phase, the brand copay applies; therefore, the beneficiary pays the greater of 5% or the copay. In this example, the beneficiary pays the higher copay of $7.40.

| Field | Value – Coverage Gap Phase | Value – Catastrophic Phase | Value on PDE Record |
|---|---|---|---|
| Drug Coverage Status Code | | | C |
| Brand/Generic | | | B |
| GDCB | | | $50.00 |
| GDCA | | | $100.00 |
| TGCDC Accumulator | | | $7,012.50 |
| TrOOP Accumulator | | | $4,821.00 |
| Beginning Benefit Phase | | | G |
| Patient Pay Amount | $29.00 | $7.40 | $36.40 |
| CPP | $21.00 | $92.60 | $113.60 |
| NPP | | | $0.00 |
| Reported Gap Discount | $0.00 | | $0.00 |
| Ending Benefit Phase | | | C |

### *8.3 Report*

This particular PDE Record does not receive an edit from the DDPS. When the Part D sponsor receives their PDE Return File, the Detail Record indicates ACC for the Record ID indicating that the file is accepted and there are no errors.

Note that as a biosimilar drug, with a "B" for the Brand/Generic code, if a dollar value had been populated in the Reported Gap Discount field of the PDE Record, this claim would have received an REJ and Edit 867. The resolution would have been to submit an adjustment record and recalculate the cost-sharing to remove the Reported Gap Discount from the reporting on the PDE Record to arrive at the result presented in the scenario as we are presenting here.

| Field | Value on PDE Record |
|---|---|
| Drug Coverage Status Code | C |
| Brand/Generic | B |
| GDCB | $50.00 |
| GDCA | $100.00 |
| TGCDC Accumulator | $7,012.50 |
| TrOOP Accumulator | $4,821.00 |
| Beginning Benefit Phase | G |
| Patient Pay Amount | $36.40 |
| CPP | $113.60 |
| NPP | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | C |
| Error 1 | |

### *8.4 – 8.5 Resolution*

In this scenario, why was there no error identified. The DDPS processing takes into consideration biosimilar drugs marked as Brand with a code of "B" and that have $0.00 populated in the Reported Gap Discount field since both Biosimilars and Biologics are BLAs according to the FDA. These records will not reject based on this condition.

| Field | Value on PDE Record |
|---|---|
| Drug Coverage Status Code | C |
| Brand/Generic | B |
| GDCB | $50.00 |
| GDCA | $100.00 |
| TGCDC Accumulator | $7,012.50 |
| TrOOP Accumulator | $4,821.00 |
| Beginning Benefit Phase | G |
| Patient Pay Amount | $36.40 |
| CPP | $113.60 |
| NPP | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | C |

### *8.6 Prevention*

Biosimilar drugs are non-applicable drugs under the Coverage Gap Discount Program (CGDP). The Gap Discount does not apply to Biosimilar drugs adjudicated partially or entirely in the Coverage Gap Phase.

When determining the catastrophic cost-sharing for a biosimilar drug, the brand copayment for non-LI beneficiaries should be compared to 5% of the drug cost falling in the Catastrophic Phase to determine the cost-sharing that should apply.

In all phases of the benefit, when an LI beneficiary has a copayment, the brand LI copayment applies to biosimilars.

| Field | Value on PDE Record |
|---|---|
| Drug Coverage Status Code | C |
| Brand/Generic | B |
| GDCB | $50.00 |
| GDCA | $100.00 |
| TGCDC Accumulator | $7,012.50 |
| TrOOP Accumulator | $4,821.00 |
| Beginning Benefit Phase | G |
| Patient Pay Amount | $36.40 |
| CPP | $113.60 |
| NPP | $0.00 |
| Reported Gap Discount | $0.00 |
| Ending Benefit Phase | C |

## 9. Conclusion

Thank you for completing the Common PDE Reporting Edits and Solutions CBT.

# Common Prescription Drug Event (PDE) Reporting Edits and Solutions
# Computer Based Training (CBT) Text-Only Version

## Resources

## Table 1: General Links

| Resource | Source |
|---|---|
| 2011 Prescription Drug Event Data (PDE) Participant Guide | http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~Training?open&expand=1&navmenu=Prescription^Drug^Event\|\| |
| Centers for Medicare & Medicaid Services (CMS) | http://www.cms.gov |
| CMS website's Medicare-Medicaid Coordination Office | *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/index.html* |
| Code of Federal Regulations (CFR): 42 CFR §423 – Voluntary Medicare Prescription Drug Benefit | http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=069e43ffce0d8f5ae52e30b22802a415&ty=HTML&h=L&r=PART&n=pt42.3.423 |
| Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) | http://www.gpo.gov/fdsys/pkg/BILLS-108hr1enr/pdf/BILLS-108hr1enr.pdf |
| Patient Protection and Affordable Care Act (ACA) | http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/content-detail.html |
| PDE Inbound File Layout - DET Record | http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~File%20Layouts?open&expand=1&navmenu=Prescription^Drug^Event\|\| |
| PDE Reporting and Calculations Guidance | http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~Training?open&expand=1&navmenu=Prescription^Drug^Event\|\| |
| Prescription Drug Event Edit Code Listing | http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~Edits?open&expand=1&navmenu=Prescription^Drug^Event\|\| |
| U.S. Food and Drug Administration (FDA), Information for Consumers (Biosimilars) | http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm |

## Table 2: Crosswalk for Reporting Benefit Phase Indicators

| Plan Type | Rule for Reporting Benefit Phase Indicators |
|---|---|
| Defined Standard (DS) | Report as DS |
| Actuarially Equivalent (AE) | Report as DS |
| Basic Alternative (BA) | Report as DS |
| Enhanced Alternative (EA) | Report as EA |
| Medicare-Medicaid Plan (MMP) | Report dollar fields as DS; Report Benefit Phase according to benefit structure |
| Employer Group Waiver Plan (EGWP) | Report as DS regardless of the benefit structure of the Other Health Insurance (OHI) benefit (As of 1/1/2014 CY)<br>*Source: 2014 PDE Guidance memo* |

***Note:*** *Payment reporting on the PDE Record is mapped to the Defined Standard for all plan types.*

# Common Prescription Drug Event (PDE) Reporting Edits and Solutions
# Computer Based Training (CBT) Text-Only Version
## Glossary

| Term | Definition |
|---|---|
| Actual Cost | As defined in 42 CFR §423.100:<br>The negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with §423.124(a). |
| Adjustment/<br>Deletion Code | This field is used to identify records for either deletion or adjustment. If neither action is required, the field is left blank.<br><br>When the Adjustment/Deletion Code is populated, the Drug Data Processing System (DDPS) recognizes that a record is being either adjusted or deleted. In order for one of these actions to take place, the record submitted with the adjustment/<br>Deletion code field populated must match the record in the database to be adjusted or deleted with a specific nine field match. Please reference the source below for additional information on adjusting or deleting a PDE.<br><br>***(Source:** 2011 PDE Participant Guide, page 3-21 and 3-28**)*** |
| Alternative Prescription Drug Coverage | As defined in 42 CFR §423.100:<br>Coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of §423.104(e). The term alternative prescription drug coverage must be either—<br>(1) Basic Alternative Coverage (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or<br>(2) Enhanced Alternative Coverage (alternative coverage that meets the requirements of § 423.104(f)(1)). |

# Common Prescription Drug Event (PDE) Reporting Edits and Solutions Computer Based Training (CBT) Text-Only Version

| Term | Definition |
|---|---|
| Applicable Beneficiary | As defined in 42 CFR §423.100:<br>Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—<br>(1) Is enrolled in a prescription drug plan or an MA-PD plan;<br>(2) Is not enrolled in a qualified retiree prescription drug plan;<br>(3) Is not entitled to an income-related subsidy under §1860D-14(a) of the Act;<br>(4) Has reached or exceeded the initial coverage limit under §1860D-2(b)(3) of the Act during the year;<br>(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in §1860D-2(b)(4)(B) of the Act; and<br>(6) Has a claim that—<br>(i) Is within the coverage gap;<br>(ii) Straddles the initial coverage period and the coverage gap;<br>(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or<br>(iv)Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold. |
| Applicable Drug | As defined in 42 CFR §423.100:<br>Applicable drug means a Part D drug that is—<br>(1)(i) Approved under a new drug application under §505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or<br>(ii) In the case of a biological product, licensed under §351 of the Public Health Service Act (other than a product licensed under subsection (k) of such §351); and<br>(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;<br>(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or<br>(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary. |
| Basic Alternative (BA) Coverage | As defined in 42 CFR §423.100:<br>Alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under §423.265(d)(2). |

# Common Prescription Drug Event (PDE) Reporting Edits and Solutions Computer Based Training (CBT) Text-Only Version

| Term | Definition |
|---|---|
| Beginning Benefit Phase | The plan-defined phase that is in effect for the beneficiary at the time the plan begins adjudication of the claim being reported. This field is reported for covered drugs only.<br><br>***(Source: 2011 PDE Participant Guide, page 3-14)*** |
| Biosimilar Drugs | A biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.<br><br>***(Source: U.S. Food and Drug Administration, Information on Biosimilars)*** |
| Brand/Generic Code | This PDE field identifies whether the plan adjudicated the claim as a brand or generic drug. It is required on PDEs with dates of service January 1, 2011 and forward. For PDEs prior to January 1, 2011, the field must be blank. It applies to covered drugs only. Valid values include “B”=brand, “G”=generic, blank for non-covered drugs.<br><br>***(Source: 2011 PDE Participant Guide, page 3-23)*** |
| Catastrophic Coverage Phase | True Out-of-Pocket (TrOOP) costs determine when a beneficiary is eligible to receive Catastrophic Coverage and when the beneficiary is no longer in the Coverage Gap. After a beneficiary has accumulated year-to-date (YTD) TrOOP costs equal to the out-of-pocket (OOP) threshold, Catastrophic Coverage provisions begin for both the beneficiary and the plan.<br><br>***(Source: 2011 PDE Participant Guide, page 5-4)*** |
| Coverage Gap | As defined in 42 CFR §423.100:<br><br>Coverage Gap means the period in prescription drug coverage that occurs between the initial coverage limit and the OOP threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative (BA), enhanced alternative or actuarially equivalent Part D benefit designs. |
| Covered D Plan Paid Amount (CPP) | The net Medicare covered amount, which the plan has paid for a Part D covered drug under the Basic benefit. Amounts paid for supplemental drugs, supplemental cost-sharing and Over-the-Counter drugs are excluded from this field.<br><br>***(Source:2011 PDE Participant Guide, page 4-10)*** |

| Term | Definition |
|---|---|
| Covered Part D Drug | As defined in 42 CFR §423.100:<br>Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §§423.566, 423.580, and 423.600, 423.610, 423,620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with §423.124. |
| Dispensing Fees | As defined in 42 CFR §423.100:<br>Dispensing fees means costs that-<br>(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;<br>(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with §423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.<br>(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies. |
| Defined Standard Benefit | There are four benefit phases: the Deductible Phase, the Initial Coverage Phase, the Coverage Gap, and the Catastrophic Coverage Phase. Year-to-Date (YTD) gross covered drug costs determine when the beneficiary is in the Deductible Phase and the Initial Coverage Phase, and when the beneficiary enters the Coverage Gap. However, entry into the Catastrophic Coverage Phase is determined by beneficiary accumulation of TrOOP costs greater than the OOP threshold amount.<br>***(Source: 2011 PDE Participant Guide, page 1-8)*** |

# Common Prescription Drug Event (PDE) Reporting Edits and Solutions Computer Based Training (CBT) Text-Only Version

| Term | Definition |
|---|---|
| Edit 787 | Beginning and Ending Benefit Phase combination does not match the True Out-of-Pocket Accumulator and/or Total Gross Covered Drug Cost Accumulator values.<br><br>This Edit is effective for dates of service January 1st, 2011 and forward. Edit 787 is bypassed for calendar year Employer Group Waiver Plans, also known as EGWPs, with dates of service prior to January 1st, 2014 and bypassed for non-calendar year EGWPs for all dates of service. It applies to Covered Drugs only.<br><br>***(Source:** DDPS Edit Spreadsheet November Release – Effective November 8, 2015)* |
| Edit 867 | FDA does not designate this drug as NDA or BLA, or this drug is a biosimilar drug; therefore, it is ineligible for the coverage gap discount.<br><br>***(Source:** DDPS Edit Spreadsheet November Release – Effective November 8, 2015)* |
| Ending Benefit Phase | The plan-defined phase that is in effect at the time the plan completes adjudication of the claim being reported. This field is reported for covered drugs only.<br><br>***(Source:** 2011 PDE Participant Guide, page 3-14)* |
| Enhanced Alternative (EA) Coverage | As defined in 42 CFR §423.100:<br>Alternative coverage that meets the requirements of §423.104(f)(1). |
| Gross Drug Cost Below Out-Of-Pocket Threshold (GDCB) | This field represents the gross covered drug cost that is below or at the OOP threshold. For covered drugs, the GDCB field always has a positive dollar amount if the OOP threshold is not yet reached or if the threshold is reached during this event. Once the beneficiary exceeds the OOP threshold plans must populate the GDCB field with a zero dollar value. For a claim that straddles the OOP threshold in a single PDE, there will be a positive dollar amount in this field and there is likely to be a positive dollar amount in the GDCA field.<br><br>***(Source:** 2011 PDE Participant Guide, page 4-9)* |

# Common Prescription Drug Event (PDE) Reporting Edits and Solutions Computer Based Training (CBT) Text-Only Version

| Term | Definition |
|---|---|
| Gross Drug Cost Above Out-Of-Pocket Threshold (GDCA) | This field represents the gross covered drug cost that exceeds the OOP threshold. For claims at or below the OOP threshold, this field will list a zero dollar amount. For covered drugs, this field is always populated with a positive dollar amount after the OOP threshold is crossed. If the threshold is reached during this event, GDCA will usually have a positive value. If the beneficiary has not reached the OOP threshold, the GDCA field will have a zero dollar value entered. For a claim that straddles the OOP threshold in a single PDE, there will be a positive dollar amount in this field and there will be a positive dollar amount in the GDCB field.<br><br>***(Source:** 2011 PDE Participant Guide, page 4-9**)*** |
| Medicare-Medicaid Plans (MMPs) | Plans that serve people who are enrolled in both Medicare and Medicaid, Medicare-Medicaid enrollees, also known as dual eligible.<br><br>***(Source:** CMS' Website: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/index.html)* |
| Medicare Secondary Payer (MSP) | The term generally used when the Medicare program does not have primary payment responsibility - that is, when another entity has the responsibility for paying before Medicare.<br><br>***(Source:** CMS' Glossary: http://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/Medicare-Secondary-Payer/Medicare-Secondary-Payer.html)* |
| Non-Applicable Drug | Covered Part D drugs that do not meet the definition of an applicable drug. Non-applicable drugs are subject to "generic" Coverage Gap cost-sharing. |
| Non-Covered Plan Paid Amount (NPP) | A PDE field that is used to report the dollar amount paid by plans for benefits beyond the Defined Standard benefit, called supplemental or enhanced benefits, or for over-the-counter (OTC) drugs. This dollar amount is excluded from risk corridor calculations. |
| Other Troop Amount | Other health insurance payments by TrOOP-eligible other payers. This field records all third party payments that contribute to a beneficiary's TrOOP except LICS, Patient Pay Amount, and Reported Gap Discount. This amount increments the TrOOP Accumulator amount.<br><br>Source: PDE Inbound File Layout |

| Term | Definition |
|---|---|
| Part D Drug | As defined in 42 CFR §423.100:<br>Part D drug means—<br>(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in §1860D-2(e)(4) of the Act)—<br>(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.<br>(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.<br>(iii) Insulin described in §1927(k)(2)(C) of the Act.<br>(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.<br>(v) A vaccine licensed under §351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.<br>(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.<br>(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in paragraphs (1)(i), (ii), (iii), or (v) of this definition.<br>(2) Does not include any of the following:<br>(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).<br>(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.<br>(iii) Medical foods, defined as a food that is formulated to be consumed or administered orally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act. |
| Patient Pay Amount | This field lists the dollar amount the beneficiary paid directly (e.g., copayments, coinsurance, deductible, or other patient pay amounts). It excludes amounts paid by other parties on behalf of the beneficiary. This amount contributes to a beneficiary's TrOOP only when it is a payment for a covered Part D drug. Plans are responsible for ensuring that beneficiaries are charged amounts that are consistent with their benefit packages as approved in the bidding process. |

| Term | Definition |
|---|---|
| Reported Gap Discount | This field is used by Part D sponsors to report the manufacturer discount made available to a beneficiary at the point of sale under the Coverage Gap Discount Program. The amounts reported are invoiced to manufacturers on a quarterly basis. |
| Straddle Claims | Straddle claims are PDEs that fall partially in at least two different benefit phases. For example, a PDE may fall in the Deductible phase at the start of the claim but end in the Initial Coverage Phase at the end of the claim. A straddle claim could straddle anywhere from two (2) to four (4) benefit phases. |
| Total Gross Covered Drug Cost (TGCDC) Accumulator | One of two values Part D sponsors maintain in real time in order to adjudicate a beneficiary's claim in the correct benefit phase. The TGCDC Accumulator is the sum of the beneficiary's covered drug costs for the benefit year known immediately before the sponsor begins adjudication of an individual claim. The TGCDC Accumulator value moves the beneficiary through the deductible phase (if any), the initial coverage period, and into the Coverage Gap Phase. The TGCDC Accumulator is used in combination with the TrOOP Accumulator to validate the benefit phase. The TGCDC Accumulator field should be left blank on PDEs for OTC or Enhanced drugs.<br><br>***(Source: 2011 PDE Participant Guide, page 4-7)*** |
| True Out-Of-Pocket Cost (TrOOP) Accumulator | The second value Part D sponsors maintain in real time in order to adjudicate a beneficiary's claim in the correct benefit phase. The TrOOP Accumulator is the sum of the beneficiary's incurred costs for the benefit year known immediately before the sponsor begins adjudication of an individual claim. Incurred costs are reported in the existing PDE as Patient Pay, Low Income Cost-Sharing Subsidy (LICS), Other TrOOP, and Reported Gap Discount. By definition, TrOOP costs apply only to Part D Covered drugs. After the TrOOP Accumulator reaches the OOP threshold, the beneficiary enters the catastrophic phase of the benefit. The TrOOP Accumulator field should be left blank on PDEs for OTC or Enhanced drugs. The TrOOP Accumulator does not increase after the beneficiary reaches the OOP threshold.<br><br>***(Source: 2011 PDE Participant Guide, page 4-7)*** |

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services Center for Medicare
7500 Security Boulevard
Baltimore, Maryland 21244-1850

DATE: January 15, 2016

TO: Medicare-Medicaid Plans

FROM: Cheri Rice, Director
Medicare Plan Payment Group, Center for Medicare

Sharon Donovan, Director
Program Alignment Group, Medicare-Medicaid Coordination Office

SUBJECT: Clarification on Prescription Drug Event (PDE) reporting for Medicare-Medicaid Plans (MMPs)

In annual guidance to Medicare-Medicaid Plans (MMPs), including most recently in the April 13, 2015 Health Plan Management System (HPMS) memorandum titled "Medicare-Medicaid Plan Submission of Plan Benefit Packages for Contract Year 2016," CMS has required MMPs to submit plan benefit packages in HPMS as Enhanced Alternative (EA) plans to allow the system to generate plan descriptions that most closely reflect what the full-benefit dual eligible MMP enrollees experience. We wish to clarify, however, that MMPs are defined standard (DS), not EA, plans, for purposes of PDE reporting and, therefore, should follow previously published Prescription Drug Event (PDE) instructions applicable to DS plans. MMPs are encouraged to review PDE reporting materials posted on the www.csscoperations.com website under Prescription Drug Event → Training. MMPs with further questions regarding PDE reporting may send questions to PDEJan2011@cms.hhs.gov.

While we do not believe there is an issue with PDE editing, we are aware from recent data analysis that MMPs are populating PDEs differently, which results in incorrect PDE reporting for some MMPs. We are aware that MMPs may need to make corrections to previously submitted PDE data as a result of this clarification. MMPs should refer to the October 6, 2011 HPMS memo titled "Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,'" which allows for 90 days from the date of discovery of a PDE reporting error for the plan to correct affected PDEs.

In order to further clarify how costs are to be reported on the PDE for MMPs, we are issuing the additional examples listed below. In all examples, the MMP benefit parameters are the same as for a DS plan.

**Example 1: LIS Level 3, Deductible, Brand Drug**
In 2015, an LIS Level 3 (no deductible, no copay) beneficiary purchases a $100.00 covered brand drug while in the Deductible phase of an MMP.

**Step 1:** Calculate the non-LI cost-sharing amount and the Covered D Plan Paid (CPP) Amount.

Since the beneficiary is in the Deductible phase, the non-LIS cost sharing is the full cost of the drug or $100.00. There is no CPP amount in the deductible.

**Step 2:** Determine the LI beneficiary's maximum cost-sharing amount that corresponds to the category of assistance for which the beneficiary is eligible.

Because the beneficiary is LIS level 3, there is no beneficiary cost sharing.

**Step 3:** Perform the "lesser of" test by comparing the amount of non-LI cost-sharing (step 1) to the amount of LI cost-sharing (step 2). The lesser of these two amounts is the beneficiary liability, reported in the Patient Pay Amount field.

The maximum LIS cost sharing of $0.00 is less than the non-LIS cost sharing of $100.00. There is no beneficiary liability.

**Step 4:** Using the LICS Amount formula (LICS amount = Non-LI beneficiary cost-sharing- LI beneficiary cost-sharing), calculate the difference between the non LI-beneficiary cost-sharing and the LI beneficiary cost-sharing. This amount represents the amount of subsidy advanced by the plan at the POS and is reported as the LICS Amount on the PDE record.

The difference between the non-LI cost sharing and the LI cost sharing is $100.00 - $0.00 = $100.00. Therefore, $100.00 is reported as LICS on the PDE record.

The table provides the cost-sharing amounts that will be reported on the PDE:

| Patient Pay | LICS | CPP | NPP |
|---|---|---|---|
| $0.00 | $100.00 | $0.00 | $0.00 |

Patient Pay and LICS are True out-of-pocket (TrOOP) eligible costs and are added to the TrOOP Accumulator in preparation for adjudicating the next claim.

**Example 2: LIS Level 3, Initial Coverage Period, Brand Drug**
In 2015, an LIS Level 3 beneficiary purchases a $100.00 covered brand drug while in the Initial Coverage Phase (ICP) of an MMP.

**Step 1:** Calculate the non-LI cost-sharing amount and the Covered D Plan Paid (CPP) Amount.

Since the beneficiary is in the ICP, the non-LIS cost sharing is 25% cost of the drug cost falling in the ICP, or $100.00 * .25 = $25.00. The covered plan paid amount is 75% of the drug cost falling in the ICP, or $100.00 * .75 = $75.00.

**Step 2:** Determine the LI beneficiary's maximum cost-sharing amount that corresponds to the category of assistance for which the beneficiary is eligible.

Because the beneficiary is LIS level 3, there is no beneficiary cost sharing.

**Step 3:** Perform the "lesser of" test by comparing the amount of non-LI cost-sharing (step 1) to the amount of LI cost-sharing (step 2). The lesser of these two amounts is the beneficiary liability, reported in the Patient Pay Amount field.

The maximum LIS cost sharing of $0.00 is less than the non-LIS cost sharing of $25.00. There is no beneficiary liability.

**Step 4:** Using the LICS Amount formula (LICS amount = Non-LI beneficiary cost-sharing- LI beneficiary cost-sharing), calculate the difference between the non LI-beneficiary cost-sharing and the LI beneficiary cost-sharing. This amount represents the amount of subsidy advanced by the plan at the POS and is reported as the LICS Amount on the PDE record.

The difference between the non-LIS cost sharing and the LIS cost sharing is $25.00 - $0.00 = $25.00. Therefore, $25.00 is reported as LICS on the PDE record.

The table provides the cost-sharing amounts that will be reported on the PDE:

| Patient Pay | LICS | CPP | NPP |
|---|---|---|---|
| $0.00 | $25.00 | $75.00 | $0.00 |

Patient Pay and LICS are TrOOP eligible costs and are added to the TrOOP Accumulator in preparation for adjudicating the next claim.

**Example 3: LIS-2, Deductible, Brand Drug**
In 2015, an LIS Level 2 beneficiary purchases a $100.00 covered brand drug while in the Deductible phase of an MMP. The MMP reduces beneficiary cost sharing to $0.00 for brand drugs.

**Step 1:** Calculate the non-LI cost-sharing amount and the Covered D Plan Paid (CPP) Amount.

Since the beneficiary is in the Deductible, the non-LIS cost sharing is the full cost of the drug or $100.00. There is no CPP amount in the deductible.

**Step 2:** Determine the LI beneficiary's maximum cost-sharing amount that corresponds to the category of assistance for which the beneficiary is eligible.

Because the beneficiary is LIS level 2, the maximum LIS cost sharing for a brand drug in 2015 is $3.60.

**Step 3:** Perform the "lesser of" test by comparing the amount of non-LI cost-sharing (step 1) to the amount of LI cost-sharing (step 2). The lesser of these two amounts is the beneficiary liability, reported in the Patient Pay Amount field.

The maximum LIS cost sharing of $3.60 is less than the non-LIS cost sharing of $100.00. The preliminary beneficiary liability is $3.60 (prior to further reduction by the MMP).

**Step 4:** Using the LICS Amount formula (LICS amount = Non-LI beneficiary cost-sharing- LI beneficiary cost-sharing), calculate the difference between the non LI-beneficiary cost-sharing and the LI beneficiary cost-sharing. This amount represents the amount of subsidy advanced by the plan at the POS and is reported as the LICS Amount on the PDE record.

The difference between the non-LIS cost sharing and the LIS cost sharing is $100.00 - $3.60 = $97.40. Therefore, $97.40 is reported as LICS on the PDE record.

**Step 5:** If a Medicare-Medicaid Plan wishes to further reduce cost sharing for an LIS beneficiary beyond the LIS cost-sharing statutory maximum, this is done after CPP and LICS are calculated on the PDE. The Patient Pay Amount on the PDE becomes the reduced cost sharing amount. The difference between the original Patient Pay amount (calculated in Step 3) and the reduced amount is reported on the PDE as Non-Covered Plan Paid Amount (NPP).

Finally, the MMP reduces the beneficiary cost sharing to $0.00, which is an amount below the LIS cost sharing maximum for this beneficiary, for this drug. The updated Patient Pay amount of $0.00 is reported in the final PDE. The difference between the original beneficiary liability calculated in Step 3 and the reduced patient pay amount offered by the MMP ($3.60 - $0.00 = $3.60) is reported on the PDE as NPP.

The table provides the cost-sharing amounts that will be reported on the PDE:

| Patient Pay | LICS | CPP | NPP |
|---|---|---|---|
| $0.00 | $97.40 | $0.00 | $3.60 |

Patient Pay and LICS are TrOOP eligible costs and are added to the TrOOP Accumulator in preparation for adjudicating the next claim.

**Example 4: LIS-2, Initial Coverage Period, Brand Drug**
In 2015, an LIS Level 2 beneficiary purchases a $100 covered brand drug while in the Initial Coverage Phase (ICP) of an MMP. The MMP reduces beneficiary cost sharing to $0.00 for brand drugs.

**Step 1:** Calculate the non-LI cost-sharing amount and the Covered D Plan Paid (CPP) Amount.

Since the beneficiary is in the ICP, the non-LIS cost sharing is 25% cost of the drug cost falling in the ICP, or $100.00 * .25 = $25.00. The covered plan paid amount is 75% of the drug cost falling in the ICP, or $100.00 * .75 = $75.00.

**Step 2:** Determine the LI beneficiary's maximum cost-sharing amount that corresponds to the category of assistance for which the beneficiary is eligible.

Because the beneficiary is LIS level 2, the maximum LIS cost sharing for a brand drug in 2015 is $3.60.

**Step 3:** Perform the "lesser of" test by comparing the amount of non-LI cost-sharing (step 1) to

the amount of LI cost-sharing (step 2). The lesser of these two amounts is the beneficiary liability, reported in the Patient Pay Amount field.

The maximum LIS cost sharing of $3.60 is less than the non-LIS cost sharing of $25.00. The preliminary beneficiary liability is $3.60 (prior to further reduction by the MMP).

**Step 4:** Using the LICS Amount formula (LICS amount = Non-LI beneficiary cost-sharing- LI beneficiary cost-sharing), calculate the difference between the non LI-beneficiary cost-sharing and the LI beneficiary cost-sharing. This amount represents the amount of subsidy advanced by the plan at the POS and is reported as the LICS Amount on the PDE record.

The difference between the non-LIS cost sharing and the LIS cost sharing is $25.00 - $3.60 = $21.40. Therefore, $21.40 is reported as LICS on the PDE record.

**Step 5:** If a Medicare-Medicaid Plan wishes to further reduce cost sharing for an LIS beneficiary beyond the LIS cost-sharing statutory maximum, this is done after CPP and LICS are calculated on the PDE. The Patient Pay Amount on the PDE becomes the reduced cost sharing amount. The difference between the original Patient Pay amount (calculated in Step 3) and the reduced amount is reported on the PDE as Non-Covered Plan Paid Amount (NPP).

Finally, the MMP reduces the beneficiary cost sharing to $0.00, which is an amount below the LIS cost sharing maximum for this beneficiary, for this drug. The updated Patient Pay amount of $0.00 is reported in the final PDE. The difference between the original beneficiary liability calculated in Step 3 and the reduced patient pay amount offered by the MMP ($3.60 - $0.00 = $3.60) is reported on the PDE as NPP.

The table provides the cost-sharing amounts that will be reported on the PDE:

| Patient Pay | LICS | CPP | NPP |
|---|---|---|---|
| $0.00 | $21.40 | $75.00 | $3.60 |

Patient Pay and LICS are TrOOP eligible costs and are added to the TrOOP Accumulator in preparation for adjudicating the next claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES
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**CENTER FOR MEDICARE**

TO: Part D Sponsors

FROM: Amy K. Larrick
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Requirements for Biosimilar Follow-On Biological Products

DATE: March 30, 2015

The Affordable Care Act amends section 351 of the Public Health Service Act (PHS Act) adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either "biosimilar" to or "interchangeable" with a Food and Drug Administration (FDA) licensed reference biological product.[1] This memorandum clarifies the application of Part D formulary review policies, low-income subsidy (LIS) and catastrophic cost sharing rules, and Coverage Gap Discount Program (Discount Program) requirements regarding "biosimilar" follow-on biological products covered under Medicare Part D. Additional guidance may be issued for "interchangeable" biological products at a later date.

**Medicare Part D Formulary Review Policies**

Biosimilars may provide Part D sponsors with new products that create formulary design options to help control costs while still ensuring beneficiaries have access to the medications they need. Our existing formulary review and formulary change policies provide Part D sponsors with the flexibility to promote the appropriate use of biosimilars through their formulary and drug utilization management strategies when designing their Part D benefits. CMS will evaluate formulary change requests involving biosimilars on an individual basis and will determine if they meet the requirements of our formulary review and approval process based on information in the FDA-approved label and statutory compendia. However, the reference and biosimilar products will not be considered as different drugs for the purposes of satisfying the two distinct drugs requirement for each of the submitted categories and classes, except as provided in 42 CFR § 423.120(b)(2)(ii).

Biosimilars may be added to plan formularies at any time as a formulary enhancement. Formulary changes involving the addition of the biosimilar and removal of the reference biological product will generally be considered a non-maintenance change. These formulary

[1] Follow-on biological products approved under subsection (k) will be listed in the FDA's new *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm. Part D sponsors are also encouraged to monitor the FDA's website for new BLA approvals at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu.

changes will be evaluated, as are all non-maintenance changes, on a case-by-case basis, and allowed if the formulary continues to meet the formulary review standards with the corresponding addition of the biosimilar. Because biosimilars are not interchangeable with the reference biological product, CMS expects that Part D sponsors' Pharmacy and Therapeutics (P&T) committees will review newly approved biosimilars in accordance with section 30.1.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual.

For the purposes of Part D transition supply and notice requirements, biosimilars and the reference biological product should be treated like different products. Part D enrollees taking the reference biological product should receive a transition supply when only a biosimilar is available on the formulary. Similarly, Part D enrollees taking the biosimilar should receive a transition supply when the reference biological product is the only formulary product.

**Low Income Subsidy (LIS) and Catastrophic Cost Sharing**

Section 1860D-14(a) of the Social Security Act specifies lower maximum copayments for LIS eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in §1927(k)(7)(A)(i) of the Social Security Act) than available for all other Part D drugs. Biosimilars do not meet the CMS definition of a generic drug in 42 CFR §423.4 or the §1927(k)(7) definition of a multiple source drug. Consequently, biosimilars are subject to the higher maximum copayments for LIS eligible individuals applicable to all other Part D drugs. In 2015, the maximum copayment would be either $3.60 or $6.60 depending upon the individual's subsidy level.

Similarly, lower minimum copayments specified in §1860D-2(b)(4) for non-LIS individuals in the catastrophic coverage portion under the standard Part D benefit for generic drugs and preferred drugs that are multiple source drugs would not apply to biosimilars. Nevertheless, CMS generally expects that non-LIS individuals will pay the 5% coinsurance for biosimilars in the catastrophic portion of the standard Part D benefit in accordance with§1860D-2(b)(4) requirements.

**Applicability to the Medicare Part D Coverage Gap Discount Program**

The Affordable Care act established the Discount Program by adding sections 1860D-43 and 1860D-14A of the Social Security Act. When defining "applicable drugs" that are discounted under the Discount Program, the statute specifically excludes follow-on biological products receiving FDA approval under subsection (k) of section 351 of the PHS Act. Consequently, biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the basic Part D benefit, and are not discounted or otherwise subject to Discount Program requirements.

If you have any questions regarding this memorandum, please contact Stephanie Hammonds at Stephanie.Hammonds@cms.hhs.gov or (410) 786-1646.