Prescription Drug Event (PDE) Maximum Coverage Gap Discount Computer Based Training (CBT) Text-Only Version

1. Introduction

1.1 Introduction

Welcome to the text-only version of the Prescription Drug Event Maximum Coverage Gap Discount (CGD) Computer Based Training (CBT).

The purpose of this course is to provide best practices to common issues surrounding the Maximum Coverage Gap Discount Amount.

This course is designed as a resource for manufacturers and plans. It is important for plans to understand how manufacturers determine the Maximum Coverage Gap Discount for use in evaluating invoices as part of the invoicing process.

The calculations discussed in this module are not utilized for the PDE reporting process.

1.2 Learning Objectives

By the end of this course, participants should be able to: Summarize background and guidance related to the Maximum Coverage Gap Discount Amount, identify guidance as best practices to avoid common issues, identify helpful tips and examples to properly implement guidance, apply knowledge to complete assessment questions.

2. Maximum Coverage Gap Discount

2.1 Overview

The Maximum Coverage Gap Discount Amount section is broken into the following topics: Background, Guidance, Tips, an Example, and Assessment Questions.

2.2 Background

Why Calculate the Maximum Coverage Gap Discount

The purpose of the Maximum Coverage Gap Discount Amount is to provide manufacturers assistance with evaluating invoices. The process for calculating the Maximum Coverage Gap Discount Amount should not be used as a method to determine PDE reporting. The Maximum Coverage Gap Discount Amount is not reported on the PDE Record.

TrOOP Eligible and Non-Eligible Payers

Total Part D drug costs move a beneficiary into the coverage gap. Only out-of-pocket costs incurred by the beneficiary, or counted as if incurred by the beneficiary, move the beneficiary towards the out-of-pocket threshold.

Payers and Their TrOOP Status

TrOOP Eligible	Not TrOOP Eligible
• Beneficiary	• Workers

TrOOP Eligible	Not TrOOP Eligible
• Payments by family, friends, or other qualified entities or individuals on behalf of a beneficiary • Charities or Qualified State Pharmaceutical Assistance Programs (SPAPs) • Low-income cost-sharing subsidy (LICS) • Medicaid payments in lieu of LICS for beneficiaries residing in U.S. territories • AIDS Drug Assistance Program (ADAP) • Indian tribe or tribal organization, or an urban Indian organization (I/T/U Pharmacy) • Reported Gap Discount	Compensation • Governmental programs (VA, Black Lung, TRICARE, other) • Automobile/No-fault/Liability Insurances • Group health plans

Impact of Payment Fields on TrOOP

Seven payment fields report payments that can affect TrOOP. The payment amounts reported in these fields are mutually exclusive, meaning that a given payment amount cannot be reported in more than one field. Four of the payment fields document payments that report beneficiary liability; three report dollars that are included in TrOOP (Patient Pay Amount, Other TrOOP Amount, and LICS), and the fourth reports dollars (Patient Liability Reduction Due To Other Payer Amount (PLRO)) that are excluded from TrOOP. One payment field (Reported Gap Discount) documents payment advanced by a Part D plan at the Point of Sale (POS) on behalf of the manufacturer and is also included in TrOOP. The remaining two payment fields (CPP and NPP) document payment by the Part D plan, and neither of these is included in TrOOP.

Payment Fields and TrOOP Inclusion

FIELD NAME	TrOOP INCLUSION	TrOOP EXCLUSION
Patient Pay Amount	**X**	
Other TrOOP Amount	**X**	
LICS	**X**	
Reported Gap Discount	**X**	
PLRO		**X**
CPP		**X**
NPP		**X**

Coverage Gap Phase

Under the Medicare Coverage Gap Discount Program (Discount Program), manufacturers must provide discounts on the portion of a claim falling in the Medicare Part D Coverage Gap Phase. The maximum discount is dependent on each year's out-of-pocket threshold.

For Coverage Year (CY) 2016, the Coverage Gap Phase begins when the beneficiary reaches the Initial Coverage Limit of $3,310.00 and ends when the beneficiary reaches the True Out-of-Pocket (TrOOP) threshold of $4,850.00.

Coverage Gap Discount

The Coverage Gap Discount only applies when the beneficiary is in the Coverage Gap Phase. While total Part D drug costs move a beneficiary into the Coverage Gap Phase, only out-of-pocket costs incurred by the beneficiary, or counted as incurred by the beneficiary, move the beneficiary towards the annual out-of-pocket threshold, referred to as the True Out-of-Pocket Costs, or TrOOP. Once the TrOOP threshold is met, the beneficiary moves out of the Coverage Gap Phase into the Catastrophic Phase.

Part D Sponsors

Part D sponsors frequently provide benefits that are actuarially equivalent to the Defined Standard Benefit or enhanced with lower (or zero dollar) deductibles and fixed copays resulting in a lower than standard Initial Coverage Limit (ICL). The result is beneficiaries incur varied levels of out-of-pocket spending upon reaching the ICL and entering the Coverage Gap Phase. Beneficiaries can therefore have more or less out-of-pocket spending remaining before reaching the annual out-of-pocket threshold. It is also possible for a beneficiary to reach the ICL without incurring any out-of-pocket spending.

Example

For example, if a beneficiary in 2016 was enrolled in an enhanced alternative plan that had no deductible and a $45.00 copay on a drug that costs $3,310.00, the beneficiary would have $4,805.00 in remaining TrOOP when entering the Coverage Gap before reaching the TrOOP Threshold and entering Catastrophic Coverage if it was the beneficiary's initial claim.

The Defined Standard Benefit
Excluding Low Income Eligible Beneficiaries, 2016

Benefit Phase	Parameters to Define Benefit Phase Year-to-Date (YTD) Gross Covered Drug Costs	Parameters to Define Benefit Phase YTD TrOOP Costs	Beneficiary Cost-Sharing	Plan Liability
Deductible	≤ $360.00	N/A*	100% coinsurance	0%
Initial Coverage	> $360.00 and ≤ $3,310.00	N/A*	25% coinsurance	75%
Coverage Gap	> $3,310.00	≤ $4,850.00	58% coinsurance for generic drugs 45% for brand drugs** 45% of any Dispensing Fee or Vaccine Administration Fee for a brand drug	42% for generic drugs 5% for brand drugs 55% of Dispensing Fee and Vaccine Administration Fee for brand drugs
Catastrophic Phase	N/A***	> $4,850.00 (OOP	Greater of 5% coinsurance or	Lesser of 95% or (Gross Covered

Benefit Phase	Parameters to Define Benefit Phase Year-to-Date (YTD) Gross Covered Drug Costs	Parameters to Define Benefit Phase YTD TrOOP Costs	Beneficiary Cost-Sharing	Plan Liability
		threshold)	$2.95/$7.40 (generic/brand) co-payment	Drug Cost - $2.95/$7.40)****

2.4 Guidance

Determining the Maximum Discount for a Single Claim

Manufacturers can determine the Maximum Coverage Gap Discount Amount for a single claim by multiplying the gap eligible portion of the negotiated price by 50%.

1. TrOOP dollar amount / (beneficiary cost-sharing percentage + manufacturer cost-sharing percentage) = Gap eligible portion of negotiated price
2. Gap eligible portion of negotiated price x 50% = Maximum coverage gap discount for single claim

Determining the Maximum Discount Amount for Multiple Claims

Unlike the maximum discount on a single claim, the maximum discount that a beneficiary can receive from multiple coverage gap claims during a plan year depends upon the availability of secondary payers and the TrOOP status of such payers. If a secondary payer does not have TrOOP eligible status, then the payments it makes do not count towards TrOOP and do not move the beneficiary towards the out-of-pocket threshold. Consequently, this can increase the total discount that a beneficiary could receive during a plan year by extending the time it takes a beneficiary to move through the coverage gap.

The maximum aggregate applicable discount amount that a beneficiary could receive from multiple coverage gap claims is the applicable year's TrOOP. For example, the TrOOP is $4,700.00 in 2015 and $4,850.00 in 2016. Therefore, the maximum discount a beneficiary may receive from multiple claims is $4,700.00 and $4,850.00, respectively.

PDE Analysis and Outliers

When the sum of the Reported Gap Discount Amount on a beneficiary's PDE records exceeds the Out-of-Pocket Threshold for the benefit year, CMS flags all affected records as outliers, which are then withheld from invoicing.

When reporting the TrOOP Accumulator on the PDE, plans should always remember to include the values from all TrOOP eligible fields, which are Patient Pay Amount, Other TrOOP Amount, LICS, and Reported Gap Discount. PDEs with under- or over-reported TrOOP accumulator fields could be subject to additional review and withheld from the invoice.

2.5 Tip

When determining the maximum coverage gap discount, it is important for manufacturers to remember that the maximum aggregate applicable discount amount a beneficiary can receive from multiple coverage gap claims is the applicable year's TrOOP.

It is possible for the Maximum Coverage Gap Discount Amount for multiple PDEs only to equal the applicable year's TrOOP if a beneficiary reaches the Initial Coverage Limit without having incurred any out-of-pocket spending.

2.6 Maximum Coverage Gap Discount Formula

In 2016, the maximum possible discount on a single claim is $2552.63. This is determined by the following two step formula:

> Troop Dollar Amount / (Beneficiary Cost-Sharing Percentage + Manufacturer Cost-Sharing Percentage) = Gap Eligible Portion of Negotiated Price
> $4,850.00 ÷ 0.95% = $5,105.26
>
> Gap Eligible Portion of Negotiated Price X 50% = Maximum Coverage Gap Discount for Single Claim
>
> $5,105.26 x 0.5% = $2,552.63

This section will review how to apply the Maximum Coverage Gap Discount Amount Formula, as manufacturers would to evaluate invoices, and review how the Maximum Coverage Gap Discount Amount varies between the Defined Standard, Basic Alternative, and Enhanced Alternative benefit coverage types.

There is a two-step formula for determining the Maximum Coverage Gap Discount Amount. In 2016, the maximum possible discount on a single claim would be $2,552.63. The first part of the formula is to add the Beneficiary Cost-Sharing and Manufacturer Cost-Sharing Percentages together and divide that into the TrOOP Dollar Amount to get the Gap Eligible Portion of the Negotiated Price. In this formula example, $4,850.00 divided by 95% equals $5,105.26. The second part of the formula is to multiply the Gap Eligible Portion of the Negotiated Price that was just calculated and multiply that by 50% to arrive at the Maximum Coverage Gap Discount for a single claim.

2.6.1 Maximum Coverage Gap Discount Amount

The Maximum Coverage Gap Discount varies between the Defined Standard, Basic Alternative, and Enhanced Alternative benefit coverage types. The next section walks through the steps used to determine the maximum possible discount on this single claim for each of these benefit coverage types using the two step formula.

> Troop Dollar Amount / (Beneficiary Cost-Sharing Percentage + Manufacturer Cost-Sharing Percentage) = Gap Eligible Portion of Negotiated Price

Gap Eligible Portion of Negotiated Price X 50% = Maximum Coverage Gap Discount for Single Claim

2.6.2 Global Note for Calculations

Before reviewing the necessary steps to validate the Maximum Coverage Gap Discount, please note that each example in this module begins with a TrOOP Amount of $0.00. Because these examples illustrate the calculations for a first claim, no TrOOP will have been accumulated.

> TrOOP Accumulator = $0.00

2.6.3 Steps for Validating Manufacture Amounts

There are four steps used to determine the Maximum Coverage Gap Discount Amount possible for a single claim. The only TrOOP eligible field that applies to the following examples is the Patient Pay field. Remember, because each example reflects the calculations for the first claim, the TrOOP Accumulator begins at $0.00. Click on each number to learn more and click each benefit coverage type along the top to walk through each example.

Step 1 – Calculate the Beneficiary Total Cost-Sharing

The first step is to calculate the Beneficiary's Total Cost-Sharing with the following formula: Beneficiary's Cost-Sharing in the Deductible phase + Beneficiary's Cost-Sharing in the Initial Coverage Phase (ICP) (Beneficiary's Cost-Sharing Percentage (25%) x drug costs in the ICP).

Step 2 – Determine Remaining TrOOP Amount

The next step is to determine the Remaining TrOOP Amount:
Out-of-Pocket Threshold – Beneficiary's Total Cost-Sharing = Remaining TrOOP Amount

Step 3 – Determine Gap Eligible Portion of Negotiated Price

The third step is to determine the Gap Eligible Portion of Negotiated Price: TrOOP Dollar Amount/ (Beneficiary Cost-Sharing Percentage + Manufacturer Cost-Sharing Percentage).

Step 4 – Calculate Maximum Coverage Gap Discount Amount for Single Claim

Next you will determine the Maximum Coverage Gap Discount Amount for a Single Claim:
Gap Eligible Portion of Negotiated Price x 50%

2.6.3.1 Basic Alternative Coverage Example

Step 1: Calculate Beneficiary's Total Cost-Sharing

In the first step, in a Basic Alternative Benefit for a non-preferred drug, the beneficiary would pay a $150.00 deductible and $95.00 copay, making the beneficiary's total cost-sharing $245.00. Because this is the first claim, there is no accumulated TrOOP.

Step 2: Determine Remaining TrOOP Amount

In Step 2, we determine the Remaining TrOOP Amount by subtracting the Beneficiary's Total Cost-Sharing from the Out-of-Pocket Threshold. This means the remaining TrOOP before the beneficiary reaches the $4,850.00 TrOOP Threshold would be $4,605.00. The only TrOOP eligible field that applies to this example is the Patient Pay field. Click on the tablet icon to review the PDE record payment fields that effect TrOOP.

Step 3: Determine Gap Eligible Portion of Negotiated Price

To determine the Gap Eligible Portion of the Negotiated Price of the drug in Step 3, the TrOOP Dollar Amount is divided by the sum of the Beneficiary's Cost-Sharing Percentage and the Manufacturer's Cost-Sharing Percentage in the Coverage Gap. In the Coverage Gap Phase in 2016, the Beneficiary's Cost-Sharing Percentage is 45% and the Manufacturer Cost-Sharing Percentage is 50% of the Discount Eligible Cost. Therefore, for this claim, the TrOOP dollar amount is $4,605.00 divided by 95%, which equals $4,847.37, which is the Gap Eligible Portion of the Negotiated Price.

Step 4 – Calculate Maximum Coverage Gap Discount Amount for Single Claim

Finally, in Step 4, we calculate the Maximum Coverage Gap Discount for a Single Claim by multiplying the Gap Eligible Portion of the Negotiated Price by 50%. So, for this scenario under the Defined Standard, it would be $4,847.37 multiplied by 50%, which equals $2,423.69.

2.6.3.2 Enhanced Alternative Coverage Example

Step 1: Calculate Beneficiary's Total Cost-Sharing

In the first step, for a non-preferred drug in an Enhanced Alternative Coverage Benefit there is a $0.00 deductible and the beneficiary would pay a $45.00 copay in the ICP. Because this is the first claim, there is no accumulated TrOOP.

Step 2: Determine Remaining TrOOP Amount

In Step 2, we determine the Remaining TrOOP Amount by subtracting the Beneficiary's Total Cost-Sharing from the Out-of-Pocket Threshold. This means the remaining TrOOP before the beneficiary reaches the $4,850.00 TrOOP Threshold would be $4,805.00. The only TrOOP eligible field that applies to this example is the Patient Pay field.

Step 3: Determine Gap Eligible Portion of Negotiated Price

To determine the Gap Eligible Portion of the Negotiated Price of the drug is Step 3, the TrOOP dollar amount is divided by the sum of the Beneficiary's Cost-Sharing Percentage and the Manufacturer's Cost-Sharing Percentage in the Coverage Gap. In the Coverage Gap Phase in 2016, the Beneficiary's Cost-Sharing Percentage is 45% and the Manufacturer's Cost-Sharing is 50% of the Discount Eligible Cost. Therefore, for this claim, the TrOOP Dollar Amount is $4,805.00 divided by 95%, which equals $5,057.89, which is the Gap Eligible Portion of the Negotiated Price.

Step 4 – Calculate Maximum Coverage Gap Discount Amount for Single Claim

Finally, in Step 4, we calculate the Maximum Coverage Gap Discount for a Single Claim by multiplying the Gap Eligible Portion of the Negotiated Price by 50%. For this scenario under the Defined Standard that would be $5,057.89 multiplied by 50% equals $2,528.95.

2.6.3.3 Defined Standard Example

Step 1: Calculate Beneficiary's Total Cost-Sharing

The first step, in a Defined Standard Benefit for a brand drug, is to calculate the Beneficiary's Total Cost-Sharing. Because this is the first claim, there is no accumulated TrOOP. The beneficiary would pay the $360.00 deductible plus 25% of the remaining claim amount, which is $737.50, which totals $1,097.50.

Step 2: Determine Remaining TrOOP Amount

In Step 2, we determine the Remaining TrOOP Amount by subtracting the Beneficiary's Total Cost-Sharing from the Out-of-Pocket Threshold. This means the remaining TrOOP before the beneficiary reaches the $4,850.00 TrOOP threshold would be $3,752.50. The only TrOOP eligible field that applies to this example is the Patient Pay field.

Step 3: Determine Gap Eligible Portion of Negotiated Price

To determine the Gap Eligible Portion of the Negotiated Price of the drug in Step 3, the TrOOP Dollar Amount is divided by the sum of the Beneficiary's Cost-Sharing Percentage and the Manufacturer's Cost-Sharing Percentage in the Coverage Gap. In the Coverage Gap Phase in 2016, the Beneficiary's Cost-Sharing Percentage is 45% and the Manufacturer Cost-Sharing Percentage is 50% of the Discount eligible Cost.

Therefore, for this claim, the TrOOP Dollar Amount is $3,752.50 divided by 95%, which equals $3,950.00, which is the Gap Eligible Portion of the Negotiated Price.

Step 4 – Calculate Maximum Coverage Gap Discount Amount for Single Claim

Finally, in Step 4, we calculate the Maximum Coverage Gap Discount Amount for a Single Claim by multiplying the Gap Eligible Portion of the Negotiated Price by 50%. So, for this scenario under the Defined Standard that would be $3,950.00 multiplied by 50%, which equals $1,975.00.

2.7 Assessment Question

Multiple Choice Question: The manufacturer determines the maximum coverage gap discount for a single claim by multiplying the ____ by 50%.

A. Beneficiary's total cost-sharing
B. Beneficiary cost-sharing percentage + manufacturer cost-sharing percentage
C. GAP eligible portion of the negotiated price
D. TrOOP dollar amount

The manufacturer determines the maximum coverage gap discount for a single claim by multiplying the gap eligible portion of the negotiated price by 50%.

Maximum Coverage Gap Discount Resources

Table 1: General Links

Resource	Source
Medicare Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections	http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html
PDE Return/Outbound Report File Layout	http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~File%20Layouts?open&expand=1&navmenu=Prescription%5eDrug%5eEvent||
PDE Inbound File Layout	http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~File%20Layouts?open&expand=1&navmenu=Prescription%5eDrug%5eEvent||
1/27/12 HPMS Memo: *Medicare Coverage Gap Discount Program—Maximum Applicable Discounts*	https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CGDPGuidanceMaximumDiscount.pdf
2011 Participant Guide	http://csscoperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~Training?open&expand=1&navmenu=Prescription^Drug^Event||
2014 Part D Webinar (08/19/2014) Slide Presentations – *Invoicing & Outlier Process and Dispute Resolution*	http://csscoperations.com/internet/cssc3.nsf/docsCat/CSSC%20Operations~Prescription%20Drug%20Event~Training
3/4/2014 HPMS Memo: *Medicare Coverage Gap Discount Program—Maximum Applicable Discounts Updates*	3/4/2014 HPMS Memo: Medicare Coverage Gap Discount Program—Maximum Applicable Discounts Updates
PDE Calculation and Reporting Computer Based Training	http://www.csscoperations.com/internet/cssc3.nsf/docsCat/CSSC%20Operations~Prescription%20Drug%20Event~Training
4/6/2015 HPMS Memo: *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*	https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2016.pdf

Table 2: The Defined Standard Benefit Excluding Low Income Eligible Beneficiaries, 2016

Benefit Phase	Parameters to Define Benefit Phase Year-to-Date (YTD) Gross Covered Drug Costs	Parameters to Define Benefit Phase YTD TrOOP Costs	Beneficiary Cost-Sharing	Plan Liability
Deductible	≤ $360.00	N/A*	100% coinsurance	0%
Initial Coverage	> $360.00 and ≤ $3,310.00	N/A*	25% coinsurance	75%
Coverage Gap	> $3,310.00	≤ $4,850.00	58% coinsurance for generic drugs 45% for brand drugs** 45% of any Dispensing Fee or Vaccine Administration Fee for a brand drug	42% for generic drugs 5% for brand drugs 55% of Dispensing Fee and Vaccine Administration Fee for brand drugs
Catastrophic Phase	N/A***	> $4,850.00 (OOP threshold)	Greater of 5% coinsurance or $2.95/$7.40 (generic/brand) co-payment	Lesser of 95% or (Gross Covered Drug Cost - $2.95/$7.40)****

*It is not necessary to achieve a minimum TrOOP balance for transitioning from the Deductible to the Initial Coverage Phase or from the Initial Coverage Phase to the Coverage Gap. These phases are dependent upon YTD gross covered drug costs, regardless of who pays for the drug. Any beneficiary paid amounts will count as TrOOP during these phases of the benefit.

** Assumes the claim falls squarely in the gap and there is no supplemental coverage.

*** It is not necessary to achieve a minimum YTD GCDC balance for transitioning from the Coverage Gap to the Catastrophic Phase. The transition from the Coverage Gap to the Catastrophic Coverage Phase is based upon accumulating TrOOP and exceeding the OOP threshold.

**** If the beneficiary liability is less than the statutory copay amount, the formula changes to Gross Covered Drug Cost minus beneficiary liability.

Table 3: Glossary

Term	Definition
Actual Cost	As defined in 42 CFR §423.100: Actual cost means 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).
Alternative Prescription Drug Coverage	As defined in 42 CFR §423.100: 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— (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 (2) Enhanced Alternative Coverage (alternative coverage that meets the requirements of § 423.104(f)(1)).
Applicable Beneficiary	As defined in 42 CFR §423.100: Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug— (1) Is enrolled in a prescription drug plan or an MA-PD plan; (2) Is not enrolled in a qualified retiree prescription drug plan; (3) Is not entitled to an income-related subsidy under §1860D-14(a) of the Act; (4) Has reached or exceeded the initial coverage limit under §1860D-2(b)(3) of the Act during the year; (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 (6) Has a claim that— (i) Is within the coverage gap; (ii) Straddles the initial coverage period and the coverage gap; (iii) Straddles the coverage gap and the annual out-of-pocket threshold; or (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: Applicable drug means a Part D drug that is— (1)(i) Approved under a new drug application under §505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or (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 (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; (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 (iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

Term	Definition
Basic Alternative (BA) Coverage	As defined in 42 CFR §423.100: Alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under §423.265(d)(2).
Coverage Gap	As defined in 42 CFR §423.100: Coverage Gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.
Covered D Plan Paid Amount (CPP)	This field contains the net amount the plan paid for a Covered Part D drug under the Defined Standard benefit. The Drug Data Processing System (DDPS) will use this field to facilitate reconciliation calculations, especially determining allowable risk corridor costs.
Covered Part D Drug	As defined in 42 CFR §423.100: 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: Dispensing fees means costs that- (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; (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. (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.

Term	Definition
Enhanced Alternative (EA) Coverage	As defined in 42 CFR §423.100: 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 (Ingredient Cost Paid + Dispensing Fee Paid + Vaccine Administration Fee + Total Amount Attributed to Sales Tax) paid to the pharmacy below the OOP threshold for a given PDE for a covered drug. For claims at or below the OOP threshold, this field will list a positive dollar amount. For claims above the OOP threshold, this field will have 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.
Gross Drug Cost Above Out-Of-Pocket Threshold (GDCA)	This field represents the gross covered drug cost (Ingredient Cost Paid + Dispensing Fee Paid + Vaccine Administration Fee + Total Amount Attributed to Sales Tax) paid to the pharmacy above the OOP threshold for a given PDE for a covered drug. For claims at or below the OOP threshold, this field will list a zero dollar amount. For claims above the OOP threshold, this field will have a positive 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 will be a positive dollar amount in the GDCB field.
Low Income Subsidy	There are two types of subsidies for qualifying low-income beneficiaries: premium assistance and cost-sharing assistance. Each month CMS pays plans prospectively a low income subsidy for assistance to certain low-income individuals to supplement the premium and cost-sharing associated with the Part D benefit.
Maximum Coverage Gap Discount Amount	The maximum discount value manufacturers are required to provide beneficiaries on the negotiated price of applicable drugs under the Medicare Coverage Gap Discount Program.
Maximum Gap Discount Amount Formula	The formula used to calculate the maximum coverage gap discount amount for a single claim. The maximum aggregate applicable discount amount that a beneficiary could receive from multiple coverage gap claims is the applicable year's TrOOP. Troop Dollar Amount / (Beneficiary Cost-Sharing Percentage + Manufacturer Cost-Sharing Percentage) = Gap Eligible Portion of Negotiated Price Gap Eligible Portion of Negotiated Price X 50% = Maximum Coverage Gap Discount for Single Claim
Medicare-Medicaid Plans (MMPs)	Medicare-Medicaid Plans serve people who are enrolled in both Medicare and Medicaid, Medicare-Medicaid enrollees, also known as dual eligible.

Term	Definition
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.
Negotiated Price	As defined in 42 CFR §423.100: Negotiated prices means prices for covered Part D drugs that— (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Includes any dispensing fees.
Non-Applicable Drug	Non-applicable drugs are 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)	This is a PDE file 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 OTC drugs. This dollar amount is excluded from risk corridor calculations.
Other Health Insurance (OHI)	OHI refers to a source of coverage other than the Part D plan. Some OHI payments count towards TrOOP, however, many OHI payments are excluded from TrOOP. For example, group health plans, employer-sponsored insurance, non-Part D government-funded programs, Workers' Compensation, and similar third party arrangements. Third party payments made by such entities typically do not count toward a beneficiary's TrOOP. Payments by OHI payers that are not TrOOP eligible are reported in the PLRO field.
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 True Out-of-Pocket Accumulator amount.

Term	Definition
Part D Drug	As defined in 42 CFR §423.100: Part D drug means— (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)— (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. (ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act. (iii) Insulin described in §1927(k)(2)(C) of the Act. (iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze. (v) A vaccine licensed under §351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration. (vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation. (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. (2) Does not include any of the following: (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). (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. (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 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.
Plan Allowance	As defined in 42 CFR §423.100: Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of §423.124(b).
Preferred Drug	As defined in 42 CFR §423.100: Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

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 used for the cost-based reconciliation of the Coverage Gap Discount Program's prospective payments made to each Part D sponsor.
Straddle Claims	Straddle claims are PDEs that fall partially in 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 2 to 4 benefit phases.
Supplemental Benefits	Supplemental benefits consist of: • Reductions in cost-sharing in the coverage gap such that enrollees are liable for less than the coinsurance in the gap for defined standard coverage, and the actuarial value of the benefit provided is increased above the actuarial value of basic prescription drug coverage. • Reductions in cost-sharing that increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage – for example: (1) a reduction in the deductible; (2) a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit and/or above the annual out-of-pocket threshold; and/or (3) an increase in the initial coverage limit. • Supplemental drugs
Total Gross Covered Drug Cost (TGCDC) Accumulator	The Total Gross Covered Drug Cost (TGCDC) Accumulator is 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 Total Gross Covered Drug Cost Accumulator value moves the beneficiary through the deductible phase (if any), the initial coverage period, and into the Coverage Gap. The TGCDC Accumulator is used in combination with the True Out-of-Pocket (TrOOP) Accumulator described below to validate benefit phase. The TGCDC Accumulator field should be left blank on PDEs for OTC or Enhanced drugs.
True Out-Of-Pocket Cost (TrOOP) Accumulator	The TrOOP Accumulator is 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 out-of-pocket 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 out-of-pocket threshold.

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CENTER FOR MEDICARE

TO: Part D Sponsors and Pharmaceutical Manufacturers

FROM: Tracey McCutcheon, Acting Director, Medicare Drug Benefit and C & D Data Group
Cheri Rice, Director, Medicare Plan Payment Group

SUBJECT: Medicare Coverage Gap Discount Program—Maximum Applicable Discounts Updates

DATE: March 4, 2014

On January 27, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a Health Plan Management System (HPMS) memorandum titled, "Medicare Coverage Gap Discount Program—Maximum Applicable Discounts". This guidance explained how the applicable discount amounts specified on the claims-level detail reports provided with the quarterly invoice can be evaluated by manufacturers. The document used examples to illustrate how different benefit designs and supplemental insurance contributed to CMS' establishment of maximum allowable manufacturer discount amounts for 2011 and 2012. We are now updating our guidance to explain how the incremental closing of the coverage gap with increasing coverage under the basic Part D benefit until 2020 changes how maximum allowable manufacturer discounts under the Medicare Coverage Gap Discount Program (Discount Program) are calculated. Because Part D sponsors will share a portion of the negotiated price, remaining True Out-of-Pocket Threshold (TrOOP) cannot be used to determine the maximum possible gap discount amount for a single claim.

To clarify, the definition of the applicable discount, as defined in the manufacturer's agreement has not changed. Part D sponsors are responsible for ensuring that manufacturers are invoiced only for the applicable discount, which is defined as 50 percent of the portion of the negotiated price of the applicable drug of a manufacturer that falls within the coverage gap. Part D sponsors are expected to follow existing PDE guidance for calculating and reporting the Reported Gap Discount amount, this guidance includes the July 9, 2010 HPMS memorandum titled, "Revised Guidance for Prescription Drug Event (PDE) Record Changes Required to Close the Coverage Gap", the 2011 Regional Prescription Drug Event Technical Assistance Participant Guide, the 2013 PDE Reporting and Calculations guidance, and the 2014 PDE Reporting and Calculations guidance. CMS is releasing this update to the January 27, 2012 guidance to clarify the maximum discount dollar amounts that may be invoiced to the manufacturer regardless of the benefit design. This guidance does not change or impact the way sponsors are expected to calculate and report the Reported Gap Discount Amount.

Background

The Part D benefit parameters for defined standard coverage are established annually in accordance with statutory requirements. The Affordable Care Act which established the Discount Program also gradually increased Medicare gap coverage for applicable drugs. Between 2013 and 2020, basic Part D coverage for applicable drugs will gradually increase with a corresponding decrease in beneficiary cost sharing.

In 2013 and 2014, the beneficiary pays 47.5% of the negotiated price of applicable drugs, the Part D plan pays 2.5%, and the pharmaceutical manufacturer pays 50% in the coverage gap. By 2020, the beneficiary portion will decrease to 25%, the Part D plan will pay 25%, and the pharmaceutical manufacturer will continue to pay 50% of the negotiated price of applicable drugs in the coverage gap. The table below illustrates the percentage of coverage from 2012, and the changes that will occur in between 2013 and 2020 within the coverage gap for applicable drugs.

	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Beneficiary pays	50%	47.5%	47.5%	45%	45%	40%	35%	30%	25%
Part D Plan cost sharing	0%	2.5%	2.5%	5%	5%	10%	15%	20%	25%
Manufacturer discount	50%	50%	50%	50%	50%	50%	50%	50%	50%

While total Part D drug costs move a beneficiary into the coverage gap, only true out-of-pocket (TrOOP) costs move the beneficiary towards the annual out-of-pocket threshold. Per CMS guidance sponsors report the additional Medicare Coverage as CPP[1].

Determining the Maximum Discount

Single Claim:

Our prior guidance stated that for 2011 and 2012 dates of service, the maximum allowable discount on a single claim was 50% of the applicable year's TrOOP. This statement was true for 2011 and 2012 because the negotiated price in the coverage gap and remaining TrOOP were the same when determining the maximum discount amount. Both the patient pay amount and reported gap discount amounts are both TrOOP eligible. However, since Medicare Part D plans began to provide coverage in the gap under the basic Part D benefit beginning in 2013, and these dollars do not count towards TrOOP, the maximum discount amounts need to be modified to account for the additional gap coverage.

[1] Prescription Drug Event (PDE) reporting examples for benefit year 2014 from December 2013 posted at http://www.csscoperations.com/internet/cssc3.nsf/files/2014%20PDE%20Reporting%20Guidance%2012-13-2013.pdf/$FIle/2014%20PDE%20Reporting%20Guidance%2012-13-2013.pdf

The revised maximum discount formula incorporates both the annual TrOOP amounts as well as the gradual increase in basic Part D coverage in the coverage gap. For example, in 2013 TrOOP is $4750 and the Medicare plan covers 2.5% of the negotiated drug costs. Therefore, the maximum manufacturer discount is $2435.90 [($4750÷.975) X .50].

The formula starts with remaining TrOOP and is divided by the cost-sharing percentages of the beneficiary and the manufacturer to determine the negotiated price that coincides with remaining TrOOP. Once this amount is determined, then the cost-sharing portions for the manufacturer, beneficiary, and plan can be calculated.

For 2014, TrOOP decreases to $4550 and coverage for applicable drugs remains at 2.5%. Therefore, the maximum possible discount on a single claim is $2333.33 [($4550÷.975) X .50]).

These examples illustrate that beginning in 2013, due to the additional Medicare contribution to drug costs in the gap, the maximum discount for a single claim is to be calculated as follows:

TrOOP dollar amount ÷ (beneficiary + manufacturer gap payment percentages) X .50

This formula can be broken down into two steps:

1. Determine the negotiated price associated with a beneficiary's remaining TrOOP:

   TrOOP dollar amount ÷ (beneficiary + manufacturer gap payment percentages) = gap eligible portion of negotiated price

2. Determine the manufacturer's portion of the negotiated price:

   Gap Eligible Portion of Negotiated Price x .50 = gap discount

Multiple Claims:

As we discussed in our prior guidance, the maximum discount that a beneficiary can receive during a plan year from multiple coverage gap claims depends upon the availability of secondary payers and the TrOOP status of such payers. Nonetheless, the maximum aggregate applicable discount amount that a beneficiary could receive from multiple coverage gap claims is the applicable year's TrOOP. TrOOP was $4750 in 2013 and is $4550 in 2014.

For examples of how discounts are calculated under different benefit designs or with supplemental benefits, manufacturers should consult other documents including the January 2012 guidance referenced above, the PDE guidance referenced above, or Chapter 5 of the Medicare Prescription Drug Benefit manual for additional information on qualified prescription drug coverage and TrOOP costs under the Part D program. If after reviewing those documents you have any further questions about the Part D coverage gap and how applicable discounts are determined under the Discount Program, please direct them to CGDPandmanufacturers@cms.hhs.gov.