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Centers for Medicare &
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**MEDICARE PLAN PAYMENT GROUP**

**DATE:** April 4, 2018

**TO:** All Part D Plan Sponsors

**FROM:** Jennifer Harlow, Deputy Director
Medicare Plan Payment Group

**SUBJECT:** Updates to the Prescription Drug Event (PDE) Analysis Website and Data Quality Review Process for the Coverage Gap Discount Program, Manufacturer Disputes, and Part D Payment Reconciliation

The purpose of this memorandum is to provide updates to the original guidance released through the Health Plan Management System (HPMS) on July 30, 2012, titled "Prescription Drug Event (PDE) Analysis Website and Data Quality Review Process for the Coverage Gap Discount Program, Manufacturer Disputes, and Part D Payment Reconciliation," and particularly with regard to the Coverage Gap Discount Program (CGDP) Withheld PDE process and to remind Part D sponsors of their roles and responsibilities in regard to these activities.

The Centers for Medicare & Medicaid Services (CMS) conducts data analysis and validation on Prescription Drug Event (PDE) records through the PDE Analysis website maintained by CMS' PDE Data Analysis Contractor. Since 2009, CMS has utilized the PDE Analysis website initiative to address data quality issues on accepted PDE records in advance of the annual Part D payment reconciliation. With the start of the Coverage Gap Discount Program, this initiative was expanded to address data quality issues on accepted PDEs with positive reported gap discount amounts and to obtain sponsor feedback on gap discount PDEs that have been disputed by pharmaceutical manufacturers. This work is necessary for a variety of financial management and oversight purposes. Although these are not audits, sponsors must provide detailed responses and follow timely submission requirements. Without this work CMS believes that more burdensome audit activity would increase.

Questions about this document may be submitted to the following e-mail address: pdejan2011@cms.hhs.gov.

## Updates

CMS has made updates to the CGDP Withheld PDE process to further ensure the validity of the invoiced data. Beginning with the Quarter 1 2018 invoice cycle, PDEs reporting gap discount amounts that have been invoiced to manufacturers will be subject to further analysis and validation if the supporting data has changed or a PDE was resubmitted after being invoiced. Prior to the Quarter 1 2018 invoice cycle, these PDEs were not included in the CGDP Withheld PDE process. Invoiced PDEs that are flagged for data quality issues (i.e., Invoiced Outlier PDEs) will be posted on the PDE Analysis website for sponsor review and action. Invoiced outliers will be included in the existing withheld PDE outlier reports. The outlier reports will be posted on the PDE Analysis website on a quarterly basis under the new name, "PDEs Withheld from the CGDP Invoice and Invoiced Outlier PDEs" (Withheld and Invoiced Outlier Reports).

In addition effective immediately, we have included a new outlier type, Calculated True Out-of-Pocket (TrOOP) Costs exceed the TrOOP Threshold, to the Withheld and Invoiced Outlier PDE process. More information regarding these changes are included in the sections below.

Also beginning with Quarter 4 2017, CMS will provide feedback for PDEs previously addressed by sponsors if the action taken did not adequately resolve the issue that caused the outlier to be pended from the quarterly invoice. This feedback is intended to provide plans with additional information on why the PDE was flagged as an outlier and what steps can be taken to resolve the outlier. This information is provided in the "CMS Response Code" column on each issue tab of the Withheld and Invoiced Outlier Reports. CMS will also provide lag time information so that sponsors can determine how long the outlier has remained unresolved. This information is provided in the "Outlier Lag Period Code" column on each issue tab of the Withheld and Invoiced Outlier Reports. Corresponding CMS response code and lag period code references are included in the "Response and Lag Code Reference" tab of the report and in the reference guide posted on the PDE Analysis website.

Beginning with Quarter 2 2017, plan sponsors began receiving notifications for PDEs posted under the Withheld PDE process categories that neither received valid explanations by the deadlines indicated below nor were corrected within the 90 day window. Part D sponsors have 90 days to make any PDE adjustments or deletions in response to PDEs posted to the PDE Analysis website, in accordance with the timeliness standards established in the HPMS guidance released on October 6, 2011 titled "Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.'"

## Background

When PDEs are flagged for data quality issues, or when a manufacturer disputes an invoiced PDE, the outlier or disputed PDE is posted to the PDE Analysis website for sponsor review and action. Sponsors must review, investigate, and act on the reports by a) providing a written response with an explanation if the PDE is valid or b) adjusting or deleting the PDE accordingly if the PDE is invalid. For manufacturer disputes, sponsors must provide a written response to all posted PDEs regardless of whether the PDE is believed to be valid or invalid. PDEs are currently posted to the PDE Analysis website under the following categories:

- General CGDP Data Quality Review: posted approximately two to three times each calendar year
- Part D Payment Reconciliation Data Quality Review: posted approximately two to three times each calendar year
- PDEs Withheld from the CGDP Invoice and Invoiced Outlier PDEs: posted quarterly at the same time as the invoice distribution
- Manufacturer Disputes: posted quarterly approximately two to three weeks after the manufacturer's dispute submission deadline[1]
- Upheld Dispute Tracking Reports: posted quarterly approximately three to four weeks after the manufacturer dispute resolution deadline[2]

## PDEs Withheld from Invoice and Invoiced Outlier PDEs

The Drug Data Processing System (DDPS) uses certain fields on the PDE during online processing to validate that the Reported Gap Discount (RGD) amount that plans submit on the PDE matches the amount that CMS calculates. If there are discrepancies between the Reported Gap Discount amount and the CMS Calculated Gap Discount amount, several reject and informational edits may be issued.

On a quarterly basis, CMS aggregates gap discount amounts reported on accepted and validated PDE data submitted by Part D sponsors during the quarter. If a PDE record successfully passes the gap discount editing process and becomes an accepted record, the PDE is still subjected to additional review and analysis prior to being invoiced. When CMS withholds gap discount PDEs from the invoice, the withheld PDEs are posted to the PDE Analysis website for sponsor review and action.

[1] For additional information regarding the manufacturer dispute process, please refer to the HPMS memo released on March 5, 2012 titled "Medicare Coverage Gap Discount Program – Dispute Resolution"
[2] For additional information regarding the Upheld Dispute Tracking Reports, please refer to the guidance released through HPMS on September 17, 2015 titled "Contract Dispute Tracking Reports"

Furthermore, starting with the Quarter 1 2018 invoice cycle, PDEs which have previously been invoiced to manufacturers may be subject to further analysis and validation if the supporting data has changed or a PDE was adjusted or resubmitted after being invoiced. Invoiced PDEs that are flagged for data quality issues (i.e., Invoiced Outlier PDEs) will also be posted on the PDE Analysis website for sponsor review and correction. Outlier reports posted under the new name, "PDEs Withheld from the CGDP Invoice and Invoiced Outlier PDEs", will include a column on each issue tab to indicate whether the PDE is a withheld outlier or an invoiced outlier. Additionally, CMS will provide feedback for PDEs previously addressed by sponsors if the action taken did not adequately resolve the issue that caused the outlier to be pended from the quarterly invoice. This feedback is found in the "CMS Response Code" column with clarifying explanations found in the "Response and Lag Code Reference" tab. Sponsors are required to review, investigate, and act on the outliers either by providing an explanation if the PDE is valid, or by adjusting or deleting the PDE if the PDE is invalid, regardless of invoice status.

Withheld and Invoiced Outlier PDEs are posted to the PDE Analysis website on a quarterly basis on the same schedule as the release of the manufacturer invoice and the Coverage Gap Tracking report. Once a PDE is withheld from invoice and posted to the sponsor on the PDE Analysis website, it will remain pended from the current and future invoices until the issue that caused it to be pended is resolved. Plan sponsors will also receive notifications for posted PDEs that have not received valid explanations by the deadlines indicated or were invalid and not corrected within the 90 day window. Sponsors may find detailed information regarding the age of the pended PDE in the "PDEs Withheld from the CGDP Invoice and Invoiced Outlier PDEs" report in the "Outlier Lag Period Code" column with clarifying explanations found in the "Response and Lag Code Reference" tab.

For PDEs that require correction, the sponsor adjusts or deletes the PDE through DDPS. Sponsors have 90 days from the release of the reports to make adjustments or deletions in response to withheld or invoiced outlier PDEs posted to the PDE Analysis website, in accordance with the timeliness standards established in the HPMS guidance released on October 6, 2011, titled "Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.'" Plan sponsors have the option to provide the anticipated PDE action and expected date of action in the Withheld or Invoiced Outlier PDE Response Form, in addition to making the required PDE correction.

If the sponsor believes that the PDE is valid, the sponsor must complete and submit the Response Form included in the report package indicating that the PDE is valid to the PDE Analysis website within fourteen (14) calendar days of the receipt of the report. Sponsors should refer to the Coverage Gap Tracking Report released with each quarterly invoice for the status of each gap discount PDE submitted within the quarter. PDEs can be withheld from invoice, or flagged as an outlier after having been invoiced, for a variety of data quality issues, including:

- Retroactive disenrollment of the beneficiary;
- Retroactive low-income status of the beneficiary;

- The PDE reports a closed pharmacy or inactive Service Provider ID;
- Total Reported Gap Discount is greater than the Maximum Allowed Reported Gap Discount;
- The Reported Gap Discount is greater than the Maximum Allowed Reported Gap Discount;
- The Total Reported Gap Discount is greater than the TrOOP maximum; and,
- The Calculated TrOOP exceeds the True-out-of-Pocket Threshold.

The following describes the analyses listed above that CMS undertakes to validate that individual and total gap discount amounts are valid.

Retroactive Disenrollment of the Beneficiary:

DDPS confirms the Part D enrollment of the beneficiary during online processing and issues edit 705, "The Beneficiary must be enrolled in Part D on the date of service (DOS)," if the beneficiary is not enrolled in Part D on the DOS reported on the PDE. Because there can be a lag between when the PDE is processed and edited and when the invoices are created, CMS also validates the beneficiary's Part D enrollment prior to placing the PDE on the invoice and after the PDE has been invoiced if the supporting data has changed or a PDE adjustment was submitted after being invoiced to check for retroactive losses of enrollment. If the analysis uncovers that the beneficiary is no longer enrolled on the date(s) of service due to a retroactive loss of enrollment, then the affected gap discount PDEs are flagged as withheld or previously invoiced outliers and posted to the PDE Analysis website for sponsor review.

DDPS compares the DOS to the date of death (DOD) and issues edits when the DOS is greater than 14 days after the DOD of a beneficiary using a retail pharmacy and living at home (edit code 753), or 32 days after the DOD of the beneficiary (edit code 704). Similar to the checks for enrollment described above, CMS evaluates the DOS compared to the DOD to account for changes in DOD that may have occurred after the PDE processed but prior to creating the invoice. Effective July 2017, if the analysis uncovers that the DOS on the PDE is greater than 14 days after the DOD of a beneficiary using a retail pharmacy and living at home, or 32 days after the DOD of the beneficiary otherwise, then the affected PDEs with Reported Gap Discount amounts are identified as outliers (withheld or invoiced) and posted to the PDE Analysis website. In both situations, the sponsor is required to briefly explain why the PDE is valid on the Response Form or correct the PDEs and/or enrollment information in question.

Retroactive Low-Income Status of the Beneficiary:

DDPS also validates the low-income (LI) status of the beneficiary during editing. If a PDE reports a gap discount amount for a beneficiary who is low-income eligible, DDPS issues edit 874, "Reported Gap Discount is > zero. The sponsor provided LICS based on Best Available Evidence. Low income beneficiaries are not eligible to receive a Coverage Gap Discount. However, due to lags between PDE submission and invoice generation, CMS validates the low-income status of beneficiaries with reported gap discount amounts prior to placing the PDE on the invoice and after the PDE has been invoiced if the supporting data has changed or a PDE adjustment was submitted after being invoiced to verify that the beneficiary has not received retroactive LI status during the quarter. If a beneficiary has retroactively become LI eligible, then the affected gap discount PDEs are flagged as withheld or previously invoiced outliers and posted to the PDE Analysis website. In instances of retroactive LI eligibility, the sponsor is required to briefly explain why the PDE is valid using the Response Form or correct the PDEs and/or eligibility information in question.

The PDE Reports a Closed Pharmacy or Inactive Service Provider ID:

In this analysis, we identify gap discount PDEs in which the DOS is after the closing date of the pharmacy. Gap discount PDEs in which the DOS of the PDE is after the closing date of the pharmacy's Service Provider ID may occur when a pharmacy has closed or changed ownership. When the change in ownership has been reported to the National Council for Prescription Drug Programs (NCPDP), a 60-day grace period applies before PDEs are flagged as a withheld or invoiced outlier, in order to assure the most up-to-date information about the pharmacy is obtained. Affected gap discount PDEs flagged as outliers (withheld or invoiced) are posted to the PDE Analysis website for Part D sponsor review. In these instances, the sponsor is required to explain why the PDE is valid or correct the PDEs in question. The PDE must be deleted if the pharmacy is closed or resubmitted with the new Service Provider ID if there was a change in ownership.

Total Reported Gap Discount (RGD) is Greater than the Maximum Allowed Reported Gap Discount (Total RGD > Maximum Allowed RGD):

For beneficiaries where the Patient Liability Reduction Due to Other Payer (PLRO) for all PDEs is zero, the total gap discount amounts are reviewed. CMS identifies beneficiaries whose total RGD for the benefit year exceeds the Maximum Allowed RGD amount. The Maximum Allowed RGD is calculated as 50% of the remaining coverage gap before the beneficiary reaches TrOOP after the beneficiary has paid the deductible and co-insurance in the initial coverage period.

For example, the TrOOP for 2018 is $5000 and the cost sharing percentage for the beneficiary is 35% and the manufacturer is 50%. For Defined Standard Benefit (DSB) plans, the beneficiary deductible is $405 and the beneficiary portion of the ICL is $836.25 (($3,750 - $405) x 0.25).

The Maximum Allowed RGD for DSB plans is calculated as:

*(($5000 – $405 - $836.25) / (0.35 + 0.5)) * 0.5* or **$2,211.03**.

The Maximum Allowed RGD for non-DSB plans is calculated as:

*(($5000 / (0.35 + 0.5)) * 0.5* or **$2,941.18**.

**Table 1: Maximum Allowed Reported Gap Discount by Benefit Year**

| Benefit Year | Maximum Total Reported Gap Discount Amount Threshold | |
|---|---|---|
| | DSB Plans | Non-DSB Plans |
| 2015 | $1,957.89 +/- $0.05 | $2,473.68+/- $0.05 |
| 2016 | $1,975.00 +/- $0.05 | $2,552.63+/- $0.05 |
| 2017 | $2,069.44 +/- $0.05 | $2,750.00 +- $0.05 |
| 2018 | $2,211.03 +/- $0.05 | $2,941.18 +/-$0.05 |

PDEs with gap discount amounts that cause the beneficiary's total RGD to exceed the Maximum Allowed RGD are flagged as outliers (withheld or invoiced) and posted to the PDE Analysis website. For PDEs flagged for this reason, sponsors are required to either briefly explain why the PDE(s) are valid or correct the gap discount PDE(s) that caused the discrepancy even if the PDEs that need correction have not been individually flagged and withheld from invoice. For these outliers, plans must carefully review all of the beneficiary's gap discount PDEs to determine the cause of the issue prior to taking action to respond to the analysis.

To date, we have received explanations from sponsors that speak only to the individual PDE that has been flagged. First, we want to emphasize that PDEs flagged under this analysis are reviewed at the beneficiary level rather than at the single PDE level. Additionally, it is important that Part D sponsors note that any of the beneficiary's gap discount PDEs for the benefit year could cause the discrepancy whether the gap discount PDE is flagged and withheld from invoice or not, as the Maximum Allowed RGD is used as a way to flag the beneficiary as an outlier and identify a threshold to withhold PDEs, or flag them as invoiced outliers.

The Reported Gap Discount is greater than the Maximum Allowed Reported Gap Discount (RGD>Maximum Allowed RGD):

For this outlier analysis, we look at each PDE individually and flag as outliers any PDEs whose gap discount amounts exceed the maximum allowed RGD for a given year (see the section on *Total Reported Gap Discount (RGD) is Greater than the Maximum Allowed Reported Gap Discount* for more information regarding the Maximum Allowed Reported Gap Discount.). This analysis was conducted at the PDE level. PDEs that met this outlier criteria were withheld from invoicing and posted to the PDE Analysis website for Part D sponsor review. This outlier analysis applied to PDEs submitted prior to February 2015. Beginning in February 2015, an edit was implemented to reject PDEs meeting this criteria.

The Total Reported Gap Discount is Greater than the TrOOP Maximum (Total RGD > TrOOP Maximum):

In this outlier analysis, CMS reviews all PDEs submitted for a beneficiary with Reported Gap Discount amounts. If the sum of the reported gap discounts exceeds the OOP maximum for the benefit year, this analysis flags the beneficiary as an outlier. To determine which PDEs to withhold from invoice, or flag after invoicing for resubmitted gap discount PDEs, CMS uses the Maximum Allowed Reported Gap Discount as a threshold (see the section on *Total Reported Gap Discount (RGD) is Greater than the Maximum Allowed Reported Gap Discount* for more information regarding the Maximum Allowed Reported Gap Discount). In this analysis, the PDEs with gap discounts which caused the beneficiary's total RGD to exceed the Maximum Allowed RGD are flagged as withheld or previously invoiced outliers, and posted to the PDE Analysis website.

Sponsors are required to either briefly explain why the PDE(s) are valid or correct the gap discount PDE(s) that caused the discrepancy even if the PDEs that need correction have not been individually flagged and withheld from invoice. For these outliers, plans must carefully review all of the beneficiary's gap discount PDEs to determine the cause of the issue prior to taking action to respond to the analysis.

To date, we have received responses from sponsors to this outlier type that speak only to the individual PDE rather than all of the beneficiary's gap discount PDEs. As with the Total RGD > Maximum Allowed RGD outlier type, this outlier analysis is conducted at the beneficiary level and any of the beneficiary's gap discount PDEs could cause the discrepancy whether flagged and withheld from the invoice or not.

The Calculated TrOOP exceeds the True Out-of-Pocket Threshold (Calculated TrOOP > TrOOP Threshold):

For beneficiaries with gap discount amounts, calculated TrOOP amounts are evaluated and compared to the TrOOP threshold. In this outlier analysis, CMS reviews all PDEs for a beneficiary with Reported Gap Discount amounts and flags any PDEs with a Reported Gap Discount amount after the beneficiary has already reached the maximum TrOOP Threshold for the benefit year. Gap discount PDEs where the beneficiary's calculated TrOOP amount exceeds the TrOOP Threshold for the benefit year are flagged as withheld or previously invoiced outliers, and posted to the PDE Analysis website.

This analysis flags the beneficiary as an outlier. Sponsors are required to either briefly explain why the PDE(s) are valid or correct the gap discount PDE(s) that caused the discrepancy even if the PDEs that need correction have not been individually flagged and withheld from invoice. For these outliers, plans must carefully review all of the beneficiary's PDEs to determine whether the accumulated TrOOP is being calculated correctly. Plans must also review all of the beneficiary's gap discount PDEs to determine the cause of the issue prior to taking action to respond to the analysis.

## General CGDP Data Quality Review

The General CGDP data quality review process allows CMS to identify PDE data quality issues that could potentially lead to inaccurate invoices and/or to manufacturer disputes and to provide sponsors with the opportunity to address these data issues. These outlier types are currently not being withheld from invoice, but potentially could be in the future. CGDP outliers are posted to the PDE Analysis website approximately two to three times each calendar year.

Pricing Errors in High Cost Drugs – Per Unit Price (PUP) Outliers:

CMS uses an algorithm based on unit cost to identify PDEs with potentially erroneous pricing. This algorithm flags PDEs in which the per-unit price of the drug is substantially different from the program-wide average for the given NDC. Per unit price is defined as the Ingredient Cost divided by Quantity Dispensed. For CGDP outliers, this algorithm is applied to PDEs with a positive reported gap discount.

Misreported Quantities – Quantity (QTY) Outliers:

CMS flags as outliers PDEs with a potentially misreported Quantity Dispensed field on the PDE. We first identify PDEs in which the daily dosage on the PDE, calculated as Quantity Dispensed divided by Days' Supply, differs substantially from the daily dosage for the given NDC. The algorithm is applied to claims that have a positive reported gap discount amount.

Potential Duplicate PDEs – Duplicate (DUP) Outliers:

Duplicate PDEs are defined as PDEs for the same beneficiary, date of service, and drug (reported as an NDC). These PDEs have different values in one or more of the other claim identifiers, and thus are not rejected immediately upon submission. (Online editing uses DOS, Service Provider ID, Service Provider ID Qualifier, Prescription Service Reference Number, and Fill Number to identify and reject duplicates after verifying Health Insurance Claim Number (HICN).)

The algorithm excludes potential vacation fills and other possible legitimate scenarios which may register as duplicate submissions. Moreover, the sum of the Total Gross Drug Cost (TGDC) across the PDEs in the set of duplicates must be at least $100. This algorithm is applied when at least one of the PDEs in the set of duplicates has a positive reported gap discount amount.

## Manufacturer Disputes

Manufacturers have the right to dispute invoiced discount payments within 60 days of receipt of invoice, and the Third Party Administrator (TPA) has 60 days to make a determination on any accepted disputes. CMS requires that a notice of dispute be accompanied by supporting evidence that is material, specific, and related to the dispute or issue. The TPA can either uphold the dispute in the favor of the manufacturer or deny the dispute. If the dispute is upheld, the sponsor must adjust or delete the PDE accordingly.

To assist the TPA in its determination, disputed PDEs may be posted to the PDE Analysis website to obtain information from the sponsor. Sponsors must respond to the posted disputed PDEs within ten (10) calendar days. For disputed PDEs, sponsors are required to provide a response by completing and submitting to the PDE Analysis website the Dispute Response Form found in the sponsor's PDE Analysis reporting package regardless of whether the PDE is valid or requires correction.

For each ticket number, the sponsor needs to provide the status of the PDE (valid, or has been/will be adjusted/deleted) and provide an explanation of the selected status for each ticket number. If the PDE requires an adjustment or deletion, the sponsor must report the date of action by which the PDE will be adjusted or deleted through DDPS. Any adjustments or deletions are subject to the same ninety (90) day timeframe as all other adjustment/deletion activity. It is important to note that any response (or non-response) that the sponsor provides will factor into the TPA's determination of the manufacturer's dispute.

Effective April 2017, Non-Calendar Year Employer Group Waiver Plans (Non-CY EGWPs) are also required to provide the benefit year start and end dates for all PDEs disputed with a D14 dispute reason code "Excessive Gap Discount for Multiple PDEs – total accumulated gap discounts for a single beneficiary exceed the cumulative maximum discount." For additional information regarding this change, please refer to our guidance issued through HPMS on April 7, 2017 titled "Updates to the Manufacturer Dispute Postings for Non-Calendar Year Employer Group Waiver Plans (EGWPs)."

Manufacturers can dispute invoiced PDEs for a variety of reasons, but can only choose one dispute reason per invoiced PDE. Please see the manufacturer dispute reasons in the Attachment. The TPA requires additional information from the sponsor most often for disputes submitted on the basis of Aberrant Quantity/Invalid Days' Supply (D04) and High Price of the Drug (D06).

Sponsors should also note that the manufacturer dispute reasons align with the outlier types found under the General CGDP Data Quality. For the current list of dispute reasons, please refer to our guidance issued through HPMS on January 27, 2015 titled "Updates to the Medicare Coverage Gap Discount Program Manufacturer Dispute and Appeals Submission Process." If a disputed PDE was posted under the General CGDP Data Quality review, the Data Analysis Contractor will share with the TPA any response the sponsor provided to these outlier types and/or the status of any PDE correction activity that the sponsor might have undertaken rather than re-posting the disputed PDE.

Since the Quarter 2 2012 invoicing cycle, CMS has provided a manufacturer dispute resolution report to sponsors on a quarterly basis to let sponsors know which invoiced PDEs have been disputed and the TPA's determination of the disputed PDE (upheld in the manufacturer's favor or denied).

## Part D Payment Reconciliation Data Quality Review

The purpose of the Reconciliation Data Quality Review process is to identify PDE data issues in advance of the Part D payment reconciliation that occurs at the end of a benefit year. These are posted to the PDE Analysis website approximately two to three times per year.

### High Cost Drugs – Total Gross Drug Cost (GDC) Outliers:

CMS flags any PDEs reporting TGDC greater than $50,000 as a high cost outlier. TGDC is calculated as the sum of ingredient cost, dispensing fee, sales tax, and vaccine administration fee. For PDEs with TGDC between $20,000 and $50,000, we will also flag the claim as an outlier if the TGDC is substantially higher than the median TGDC for the given National Drug Code (NDC).

### Pricing Errors in High Cost Drugs – Per Unit Price (PUP) Outliers:

CMS uses an algorithm based on unit cost to identify PDEs with potentially erroneous pricing. This algorithm flags PDEs not captured in the GDC outliers, where the per-unit price of the drug, defined as the Ingredient Cost divided by Quantity Dispensed, is substantially different from the program-wide average for the given NDC. Additionally, the claim must not have a positive reported gap discount amount to be captured as a Reconciliation outlier.

Misreported Quantities – Quantity (QTY) Outliers:

CMS flags as outliers PDEs with a potentially misreported amount in the Quantity Dispensed field in the PDE data. We first identify PDEs in which the daily dosage on the PDE, calculated as Quantity Dispensed divided by Days' Supply, differs substantially from typical values for the given NDC. The claim must not have a positive reported gap discount amount to be captured as a Reconciliation outlier.

Potential Duplicate PDEs – Duplicate (DUP) Outliers:

Duplicate PDEs are defined as PDEs for the same beneficiary, date of service, and drug (reported as an NDC). These PDEs have different values in one or more of other claim identifiers, and thus are not rejected immediately upon submission. The algorithm excludes potential vacation fills and other possible legitimate scenarios which may register as duplicate submissions. Moreover, the sum of the TGDC across the PDEs in the set of duplicates must be at least $200. For Reconciliation outliers, none of the PDEs in the set have a positive reported gap discount amount.

Attachment and Catastrophic CPP Issues – Attachment CPP (ACP) and Catastrophic CPP (CCP) Outliers:

CMS identifies Attachment Point and Catastrophic claims where the Covered D Plan Paid (CPP) amount on the PDE is zero and Low-Income Cost-Sharing (LICS) is positive. These claims are expected to show approximately 95% of the catastrophic drug cost in CPP and 5% in LICS. In addition, the Gross Drug Cost Above Out-of-Pocket threshold (GDCA) exceeds $100.

Medicare as Secondary Payer Issues – Medicare as Secondary Payer (MSP) Outliers:

CMS identifies PDEs for the same beneficiary, drug (NDC), and date of service which have different Pricing Exception Codes (one in which Pricing Exception Code = "M", and another in which Pricing Exception Code = "blank"). These PDEs may be potential duplicates and/or have erroneous Pricing Exception Codes. The algorithm is applied to pairs where the combined GDC of the claims is at least $200.

Attachment

Coverage Gap Discount Program Dispute Reason Codes

| DISPUTE REASON CODE | DISPUTE REASON DESCRIPTION |
|---|---|
| D01 | Duplicate Invoice Item |
| D02 | Closed Pharmacy |
| D03 | Not PART D Covered Drug |
| D04 | Aberrant Quantity/Invalid Days' Supply |
| D06 | High Price of the Drug |
| D07 | Last Lot Expiration Date |
| D09 | Marketing Category is not NDA or BLA |
| D11 | PDE improperly invoiced beyond Manufacturer Agreement Invoice period |
| D13 | Excessive Gap Discount for Single PDE – disputed PDE exceeds maximum discount amount for a PDE |
| D14 | Excessive Gap Discount for Multiple PDEs - total accumulated gap discounts for a single beneficiary exceed cumulative maximum discount amount |
| D99 | Other |