DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: July 30, 2012

TO: All Part D Plan Sponsors

FROM: Cheri Rice, Director, Medicare Plan Payment Group

SUBJECT: **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 Centers for Medicare & Medicaid Services (CMS) conducts data analysis and validation on Prescription Drug Event (PDE) records through the PDE Analysis website maintained by Acumen, LLC. On February 24, 2012, CMS released guidance titled "Prescription Drug Event (PDE) Reporting and Websites" announcing the continuation of this initiative for benefit year 2012.

This work is necessary for a variety of financial management and oversight purposes. However, these are not audits and are not intended to yield compliance actions. CMS believes that this work helps to correct potential issues before they become a compliance matter. CMS has continued to use the data quality review initiative through the PDE Analysis website to ensure the validity of plan-reported Part D financial data used in the Part D payment reconciliation process. Without this work CMS believes the more burdensome audit activity would increase.

In addition, for the coverage gap discount program (CGDP) pharmaceutical manufacturers have the right to dispute invoiced gap discount payments within 60 days of receipt of the invoice. If the Third Party Administrator (TPA) confirms that the gap discount is correct and therefore denies the dispute, the manufacturer may appeal the unfavorable determination from the TPA to the Independent Review Entity (IRE). [1] For this and other reasons, CMS performs PDE data

[1] For more information regarding the manufacturer dispute process, please refer to guidance released through HPMS titled "Medicare Coverage Gap Discount Program – Dispute Resolution." For more information regarding the manufacturer appeals process, please refer to guidance released through HPMS titled "Medicare Coverage Gap Discount Program Appeals Guidance."

quality prior to the creation of the invoice on all PDEs with gap discounts to provide an added layer of validation to these invoices with the goal of reducing the perceived need for drug manufacturers to file disputes.

Plan sponsors have expressed concern with the turnaround deadlines for responding to posted PDEs. We have determined that more flexibility is possible when the PDEs are not involved with disputed gap discounts. Therefore, we are announcing that Part D Sponsors will have fourteen (14) calendar days to respond to PDEs posted to the PDE Analysis website instead of the original timeframe of ten (10) days. The manufacturer dispute response window of ten (10) calendar days will remain the same. Part D sponsors will continue to 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.

CMS is currently reviewing its methodologies for this important analytic work and would appreciate any suggestions that you may have to improve the efficacy and resource effectiveness of the work. The remainder of this memorandum provides additional context and background to help facilitate comments. Comments or methodological suggestions may be submitted to the following e-mail address: pdejan2011@cms.hhs.gov.

Background

Since benefit year 2009, CMS has utilized the PDE Analysis website to address data quality issues on accepted PDE records in advance of the Part D payment reconciliation. With the start of the Coverage Gap Discount Program (CGDP), this data initiative has been expanded to address data quality issues on accepted PDEs with gap discount amounts, and to obtain sponsor feedback on gap discount PDEs that have been disputed by pharmaceutical manufacturers. PDEs are currently posted to the PDE Analysis website under the following categories:

- General CGDP Data Quality Review
- PDEs Withheld from the CGDP Invoice
- Manufacturer Disputes
- Part D Payment Reconciliation Data Quality Review

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 are expected to review, investigate, and act on the reports by a) providing a written response with 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 Withheld from Invoice

Last year, the PDE record layout was enhanced to include data elements that allow for the administration and validation of the coverage gap discount amount. New fields include Reported

Gap Discount Amount, Beginning and Ending Benefit Phase, True-Out-of-Pocket (TrOOP) Accumulator, and Total Gross Covered Drug Cost Accumulator. The Drug Data Processing System (DDPS) uses these and other existing and newly added fields 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.

Withheld PDEs are posted to the Acumen website on a quarterly basis on roughly 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 website, it will remain pended from the current and future invoices until the issue that caused it to be pended is resolved. Sponsors must respond to the withheld PDEs in one of two ways.

For PDEs that require correction, the sponsor can adjust or delete the PDE through the DDPS=. Sponsors have 90 days from the release of the reports to make adjustments or deletions in response to withheld 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." Beginning with the Quarter 2 2012 withheld from invoice PDEs posting, sponsors will have the option to provide the anticipated PDE action and expected date of action in the Response Form, in addition to making the required PDE correction.

If the sponsor believes that the PDE is valid, the sponsor should 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 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
- The beneficiary's total Reported Gap Discount is greater than the maximum accumulated Reported Gap Discount
- The Reported Gap Discount is Greater than remaining TrOOP
- The Reported Gap Discount is greater than the TrOOP maximum

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 DOS," if the beneficiary is not enrolled in Part D on the date of service 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 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 withheld from invoice and posted to the PDE Analysis website for sponsor review.

In addition, CMS validates the date(s) of service (DOS) on the PDE for deceased beneficiaries who have received the gap discount during the quarter. If the analysis uncovers that the DOS on the PDE is greater than 32 days after the date of death (DOD) of the beneficiary, then the affected PDEs with Reported Gap Discount amounts are withheld from the invoice and posted to the PDE Analysis website. In both situations, the sponsor is expected 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 status of the beneficiary during editing and issues edit 874, if a PDE reports a gap discount amount for a beneficiary who is low income eligible. However, due to lags between PDE submission and invoice generation, CMS validates the low income status of beneficiaries with positive reported gap discount amounts prior to placing the PDE on the invoice 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 withheld from invoice and posted to the PDE Analysis website. In instances of retroactive LI eligibility, the sponsor is expected 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

In this analysis, we identify gap discount PDEs in which the DOS is after the closing date of the pharmacy. This may occur when a pharmacy has closed or changed ownership. If the analysis identifies PDEs with DOS after the pharmacy has closed or changed ownership, then the affected gap discount PDEs are withheld from invoice and posted to the PDE Analysis website for sponsor review. In these instances, the sponsor is expected to explain why the PDE is valid or correct the PDEs in question.

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

CMS identifies beneficiaries in Defined Standard Benefit plans whose total RGD for the benefit year exceeds the maximum total RGD amount. This maximum total 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.

The max total RGD is calculated as 50% of the total covered Part D spending at the OOP threshold for applicable beneficiaries less the Initial Coverage Limit (ICL). For example, the total covered Part D spending at the OOP threshold for 2012 is $6,730.39. After subtracting the ICL (which is $2930 in 2012), $3,800.39 is left in remaining coverage gap. The maximum total RGD is 50% of that amount or $1,900.20.

Table: Maximum Total Reported Gap Discount Threshold by Benefit Year

Benefit Year	Maximum Total Reported Gap Discount Amount Threshold
2011	$1821.86 +/- $0.05
2012	$1,900.20 +/- $0.05
2013	$1,999.35 +/- $0.05

PDEs with gap discount amounts that cause the beneficiary's total RGD to exceed the maximum total RGD are withheld from invoice and posted to the PDE Analysis website. For PDEs flagged for this reason, sponsors are expected to briefly explain why the PDE is valid using the Response Form or correct the gap discount PDE(s) that have caused the inconsistency (regardless of whether the PDE(s) are flagged or not).

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 total RGD is used as a way to flag the beneficiary as an outlier and to identify a threshold to withhold PDEs. For this outlier type, the sponsor should review the entire PDE history for the beneficiary to determine the cause of the issue prior to taking action to respond to the analysis.

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

In this analysis, we look at each PDE individually and flag as outliers any PDEs whose gap discount amounts exceed the amount of TrOOP remaining for the beneficiary. We determine the remaining TrOOP by subtracting the TrOOP Accumulator Amount reported on the PDE from the OOP Maximum for the benefit year.

Remaining TrOOP = OOP Max – TrOOP Accumulator Amount

This type of outlier is commonly found on straddle claims. Sponsors should carefully review the information reported on the PDE that was used to calculate the Reported Gap Discount. For PDEs flagged for this reason, sponsors are expected to briefly explain why the PDE is valid using the Response Form or correct the gap discount PDE(s) that have caused the inconsistency (regardless of whether the PDE(s) are flagged or not).

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

In this outlier analysis, CMS reviews all PDEs submitted for a beneficiary with Reported Gap Discount amounts and verifies that the sum of the reported gap discounts does not exceed the OOP maximum for the benefit year. This analysis flags the beneficiary as an outlier. To determine which PDEs to withhold from invoice, CMS uses the Total Maximum Reported Gap Discount as a threshold (see the section on Total Reported Gap Discount (RGD) is Greater than the Maximum Total Reported Gap Discount for more information regarding the Total Maximum Reported Gap Discount.) In this analysis, the PDEs with gap discounts that cause the beneficiary's total RGD to exceed the max total RGD are withheld from invoice and posted to the PDE Analysis website.

Responses received from sponsors to this outlier type have referenced the individual PDE rather than the whole of the beneficiary's gap discount PDEs. As with the Total RGD > Maximum Total 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.

Sponsors are expected 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 should 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.

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 four to six weeks.

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 higher than the program-wide median 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 amount and a Gross Drug Cost (GDC) of $100 or higher.

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, exceeds the maximum daily dosage listed in commercial drug databases for the given NDC. Additionally, the daily dosage on the PDE must substantially exceed the program-wide median daily dosage for the NDC. The algorithm is applied to claims that have a positive reported gap discount amount and that exceed $100 in TGDC.

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. (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 HICN.)

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 $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

As previously mentioned, 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 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 is expected to 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 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 should 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 (memo). 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.

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 Excessive Quantity (D04), Invalid Days' Supply (D05), and High Price of the Drug (D06). Sponsors should also note that these dispute reasons align with the outlier types found under the General CGDP Data Quality. If a disputed PDE was posted under the General CGDP Data Quality review, Acumen 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.

Beginning with the Q2 2012 invoicing cycle, CMS will provide a manufacturer dispute resolution report to sponsors on a quarterly basis to let sponsors know which invoiced PDEs have been disputed and 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. Reconciliation outliers are posted to the PDE Analysis website approximately every four weeks.

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

CMS flags any PDEs reporting Total Gross Drug Cost (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 higher than the program-wide median for the given NDC. This algorithm is applied to PDEs with Gross Drug Cost (GDC) of $100 or higher. 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 Quantity Dispensed fields in the PDE data. We first identify PDEs in which the daily dosage on the PDE, calculated as Quantity Dispensed divided by Days Supply, exceeds the maximum daily dosage listed in commercial drug databases for the given NDC. Additionally, the daily dosage on the PDE must substantially exceed the program-wide median daily dosage for the NDC. To eliminate overlap with CGDP QTY outliers, this algorithm is applied to claims without a positive reported gap discount amount that exceed $2,000 in TGDC.

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 $100. 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, and 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.

Drugs Potentially Not Covered Under Part D – Covered Drug (CVD) Outliers

CMS identifies PDEs that may not be covered under Part D. The algorithm used checks for PDE submissions for specific drugs or labeler codes.

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	Excessive Quantity
D05	Invalid Days Supply
D06	High Price of the Drug
D07	Last Lot Expiration Date
D08	Early Fill
D09	Marketing Category is not NDA or BLA
D10	Date of Service prior to 01/01/2011
D11	PDE improperly invoiced beyond Manufacturer Agreement Invoice period
D12	Invalid Prescription Service Reference Number
D13	Gap discount for disputed PDE exceeds maximum discount amount for a single PDE
D14	Total accumulated gap discounts reported across multiple PDEs for a single beneficiary exceed cumulative maximum discount amount
D99	Other