

Invoicing & Outlier Process and Dispute Resolution



Part D Webinar

*August 19, 2014
10:00 a.m. – 12:00 p.m.*

Agenda

- Invoicing
- Knowledge Test
- Question & Answer (Q&A)
- Outlier Process and Dispute Resolution
- Knowledge Test
- Question & Answer (Q&A)
- Closing Remarks

Invoicing

Objectives

- Identify the timeline for quarterly invoice generation and payment
- Define the payment mechanism for quarterly invoices
- Explain offsets

Coverage Gap Discount Program - Background

- Manufacturers are required to provide applicable beneficiaries with applicable discounts on the negotiated price of applicable drugs in the coverage gap.


Coverage Gap Discount Program (continued)


- Beneficiary immediately receives out-of-pocket cost-sharing reduction at point-of-sale (POS)
- Applicable Beneficiaries
 - Part D enrollees that do not receive income related subsidies
 - Have reached or exceeded the initial coverage limit (ICL)
 - Have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold


CGDP: Calculation of the CGDP Prospective Payment


- Calculated based on projections in each Part D plan's bid and current enrollment.
- In Worksheet 6A of the Part D bids, plans will:
 - project the brand drug cost sharing amounts for non-LIS beneficiaries in the coverage gap.
 - project the monthly prospective CGDP payment for each enrollee by dividing the total projected non-LIS brand cost sharing amounts by the non-LIS enrollment projected in the bid, and multiplying the result by 50%
- CMS will:
 - calculate the monthly prospective CGDP payment for each plan by multiplying the plan-specific prospective CGDP payment amount estimated in the Part D bid by the number of non-LIS beneficiaries enrolled in the Part D plan

Coverage Gap Discount Flow

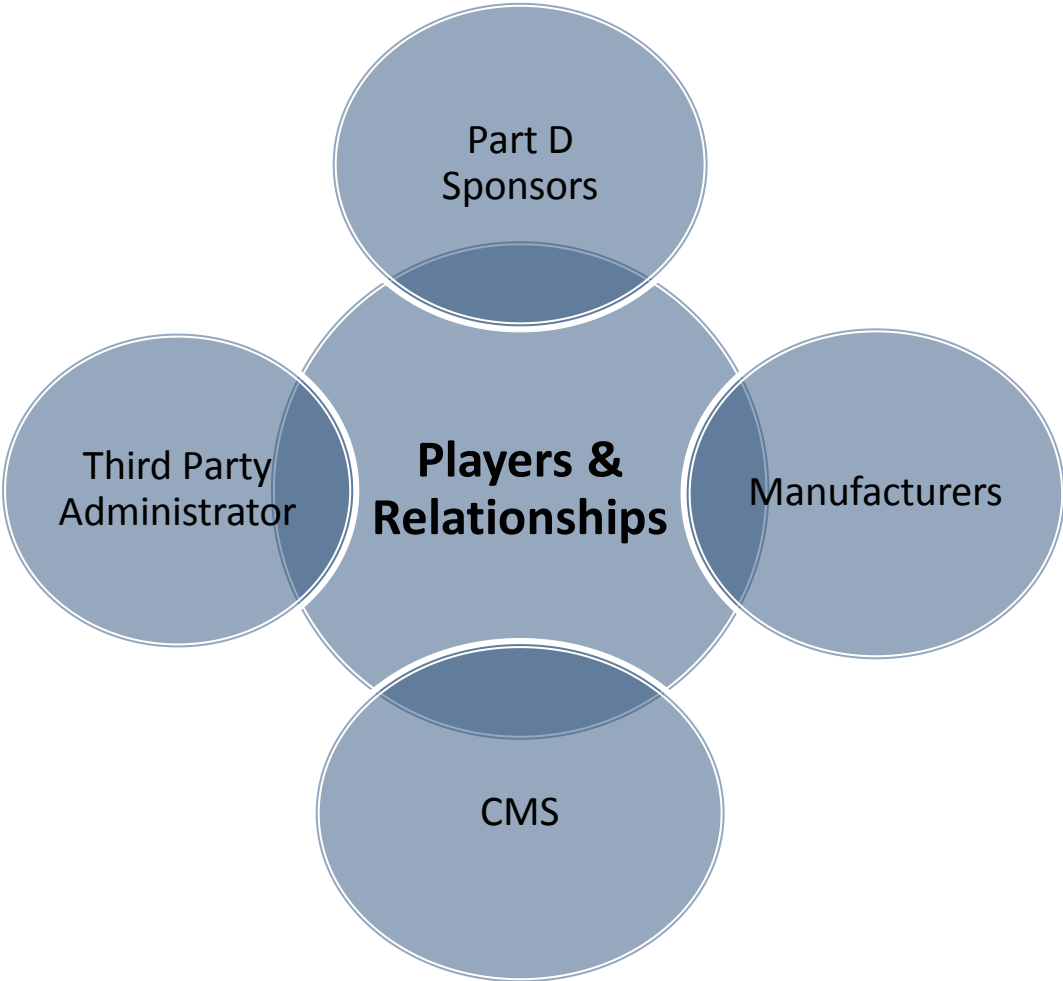
- 
- Part D Sponsors advance Gap Discount at the Point of Sale (POS)
 - Part D Sponsors submit PDEs to CMS recording the Gap Discount amount

- 
- CMS aggregates Prescription Drug Event (PDE) data and sends to Third Party Administrator (TPA)
 - TPA sends quarterly invoice reports to Manufacturers and Part D Sponsors simultaneously

- 
- Manufacturers and sponsors pay invoice amount in full within 38 days
 - Manufacturers and sponsors send confirmation of payment within five (5) days

- 
- Part D Sponsors send confirmation of payment receipt to TPA within 5 days
 - The TPA sends payment confirmation statistics to CMS
 - CMS offsets invoiced and now paid amounts from Part D Sponsors

CGDP: Players & Relationships



TPA Functions

- Liaison between Part D Sponsors and Manufacturers
- Provide customer support
- Establishes connectivity and sets up secure mailboxes
- Collects and distributes EFT information
- Distributes quarterly invoices and associated reports
- Processes payment confirmation reports
- Confirms “paid in full” status
- Maintains a website of CGDP information

Third Party Administrator (TPA) Contact Information

- **Website:**
 - <http://www.tpadadministrator.com>
- **Help Line:**
 - 1-877-534-2772, Option 1
- **Email:**
 - tpaoperations@tpadministrator.com
- **Hours of Operation:**
 - Monday-Friday, 8:00 a.m.- 7:00 p.m. ET

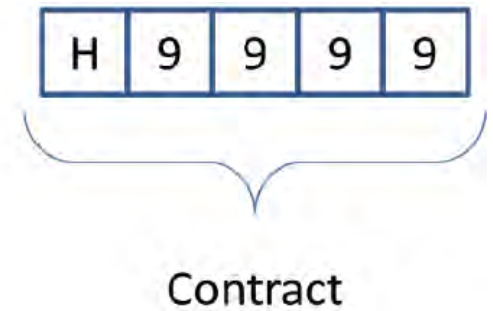
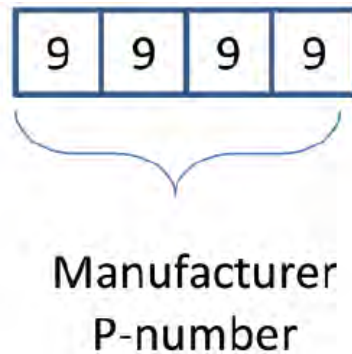
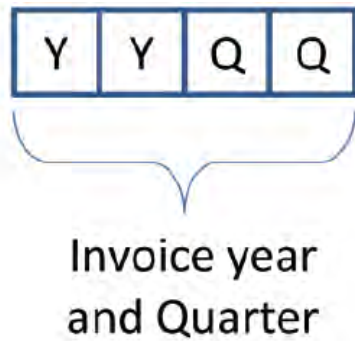
Electronic Funds Transfer (EFT)

The screenshot shows the Palmetto GBA website interface. The header includes the Palmetto GBA logo and the CMS logo. A navigation bar contains links for HOME, CONTACT US, ARCHIVES, and MANAGE LISTSERV PROFILE, along with a search box. The main content area is titled "Third Party Administrator / TPA / Drug Manufacturer / EFT..." and "TPA Drug Manufacturer EFT Information". A table lists various EFT-related documents and forms with their respective dates. A red box highlights the "EFT Information" link in the left sidebar, and another red box highlights the table content with an arrow pointing to the "EFT Online Form (For Manufacturer Use Only)" entry.

Document/Link	Date
EFT Online Form (For Manufacturer Use Only)	07/17/2013
EFT Online Form (For Sponsor Use Only)	07/15/2013
EFT Delimited Sample File	04/25/2012
EFT TEST DELIMITED	04/25/2012
EFT File Layout - Manufacturer	03/22/2012
EFT File Layout - Sponsor	03/22/2012
Descriptive Name Form for EFT	04/15/2011

EFT Information includes the EFT File Layout and Online Forms for both Manufacturers and Part D Sponsors

EFT Individual Identification Number



EFT File Update Timeline

Benefit Year and Quarter	PDE Invoice Reporting Period End	EFT File update cutoff	Updated EFT file distributed	Quarterly Invoice Distribution
2012 Q1	3/31/2012	04/20/2012	04/25/2012	4/30/2012
2012 Q2	6/30/2012	08/17/2012	08/25/2012	8/31/2012
2012 Q3	9/30/2012	10/17/2012	10/25/2012	10/31/2012
2012 Q4	12/31/2012	01/17/2013	01/25/2013	1/31/2013
2013 Q1	3/31/2013	04/17/2013	04/25/2013	4/30/2013
2013 Q2	6/30/2013	08/17/2013	08/25/2013	8/31/2013
2013 Q3	9/30/2013	10/10/2013	10/25/2013	10/31/2013
2013 Q4	12/31/2013	01/10/2014	01/25/2014	1/31/2014
2014 Q1	3/31/2014	04/10/2014	04/25/2014	4/30/2014
2014 Q2	6/30/2014	08/10/2014	08/25/2014	8/31/2014
2014 Q3	9/30/2014	10/10/2014	10/25/2014	10/31/2014
2014 Q4	12/31/2014	01/10/2015	01/25/2015	1/31/2015
2015 Q1	3/31/2015	04/10/2015	04/25/2015	4/30/2015
2015 Q2	6/30/2015	08/10/2015	08/25/2015	8/31/2015
2015 Q3	9/30/2015	10/10/2015	10/25/2015	10/31/2015
2015 Q4	12/31/2015	01/10/2016	01/25/2016	1/31/2016

Quarterly Invoice Reports Distribution Schedule

Quarterly Invoice Report Distribution Schedule

Quarter End Date	Report Distribution Date
March 31	April 30
June 30	August 31
September 30	October 31
December 31	January 31

Quarterly Invoice Reports

From the sponsor's perspective, there are five (5) quarterly invoice reports.

- TPA Responsibility:
 - Data Report
 - Summary Report
 - Tracking Report
- Contract Responsibility:
 - Payment Confirmation Report
- TPA Responsibility:
 - Contract Payment Confirmation Report Response File

Quarterly Invoice Reports - Contract Data Report

Contract Data Report

Field	Description
DET REF NUMBER	Unique record number, remains constant.
PREVIOUS REPORT ID and REPORTED Gap Discount PREVIOUS AMOUNT	Indicates adjusted or deleted records that were previously invoiced.
SUBMITTING CONTRACT NUMBER and SUBMITTING CONTRACT PBP NUMBER	Identifies the contract/PBP that advanced the CGDP discount at POS.

Quarterly Invoice Reports - Contract Summary Report

Contract Summary Report

Field	Description
Manufacturer P NUMBER	Internal CMS number that uniquely identifies the Manufacturer.
EFT INDIVIDUAL IDENTIFICATION NUMBER	External identifier for CGDP payment, quarter, and Manufacturer.
Gap Discount AMOUNT THIS PERIOD	Amount Manufacturer owes Sponsor.

Quarterly Invoice Reports – Coverage Gap Tracking Report

- Cumulative year report
- Identifies status of each Gap Discount PDE
- One (1) report for each benefit year
- **Withheld PDE Reason Codes**
 - Not Pended (Blank)
 - Retro Disenrollment (01)
 - Retro LI (02)
 - Other Data Quality Review (04)
 - Other (99)

Quarterly Invoice Reports - Payment Confirmation Report

- Used to inform TPA that the payment has been received
- Payments are made within 38 days following distribution of quarterly CGDP reports
- TPA collects payment confirmation and confirms amount paid equals amount received

Quarterly Invoice Reports - Contract Payment Confirmation Report Response File

- Two (2) levels of edits by the TPA
 - File level data integrity checks
 - Record level editing to verify reported payment amounts
- Three (3) types of statuses in Response file
 - Accepted
 - Rejected
 - Discrepant

Invoice Payment Process

- Part D Sponsors receive monthly prospective payments from CMS. Prospective payments occur for 12 months, plus one month for adjustments.
- CMS will invoice Manufacturers and Sponsors for discounts provided by Part D Sponsors quarterly.
- Following the invoicing cycle, CMS offsets monthly prospective CGDP payments for discount amount invoiced to Manufacturers. Offsets are completed for six (6) quarters.
- CMS will perform a cost-based reconciliation at the end of the contract year.
- Sponsors may report discounts to CMS for 37 months following the end of the benefit year.

Negative Invoice Amounts

- Manufacturers must provide EFT information to facilitate the repayment of negative amounts.
- Part D Sponsors must follow the manufacturer payment schedule to pay negative amounts to Manufacturers.
- Manufacturers and Part D Sponsors must confirm negative amounts as those amounts are paid by Part D Sponsors and received by Manufacturers.

CMS Offsets

- **Rationale for Offsets**

- CMS makes monthly prospective payments to support cash flow needed to advance CGDP discounts at POS on the Manufacturer's behalf.
- When the Manufacturer pays the invoice, the Sponsor has duplicate payment from two sources for the same expense: the Manufacturer and CMS.
- After receiving the Manufacturer invoice payment, the Sponsor no longer needs the cash flow advance from the prospective payment.

CMS Offsets (continued)

- Processed quarterly through the Automated Plan Payment System (APPS), following invoice cycle
- Appears as negative adjustment to following months prospective payment
- If offset exceeds prospective CGDP payment, CMS will apply the offset to Part D Sponsor's total payment

CMS Offsets (continued)

- Employer Group Waiver Plans (EGWPs)
 - Receive invoiced discount amounts from Manufacturers
 - Do not submit Part D bids
 - Do not receive prospective CGDP payments
 - CMS will not apply offsets for invoiced discount amounts to the payments received by EGWPs

Knowledge Test #1

Please select your response to this question.

- The following organizations all work together in the Coverage Gap Discount Program (CGDP) except:
 - A) Part D Sponsors
 - B) CMS
 - C) Manufacturers
 - D) Food and Drug Administration (FDA)
 - E) Third Party Administrator (TPA)

Knowledge Test #2

Please select your response to this question.

- The quarterly invoice reports consist of three (3) contract reports including the Data Report, Tracking Report, and Payment Confirmation Report. True or False?
 - A) True
 - B) False

Knowledge Test #3

Please select your response to this question.

- Which report do Part D Sponsors use to inform the TPA that they have received payment from the Manufacturer?
 - A) Contract Payment Tracking Report
 - B) Contract Payment Confirmation Report
 - C) Contract Summary Report
 - D) Contract Tracking Report

Question & Answer (Q&A)



Outlier Process and Dispute Resolution

Objectives

- Discuss the Coverage Gap Discount Program Invoice and Data Quality Review
- Define reasons and best practices for PDEs withheld from invoices
- Identify the Manufacturer Dispute Process

Background

- PDE Analysis website in effect since 2009 benefit year
- PDE Analysis website posts PDEs under four categories:
 - General CGDP Data Quality Review
 - PDEs Withheld from the CGDP Invoice
 - Manufacturer Disputes
 - Part D Payment Reconciliation Data Quality Review

PDE Analysis Website

- Outliers or disputed PDEs may be posted to the PDE Analysis website for review and action
- Sponsors are expected to review, investigate, and act on the reports by:
 - Providing a written response with explanation if the PDE is valid
 - Adjusting or deleting the PDE accordingly if the PDE is invalid

PDE Analysis Website (continued)

PDE Issue Response Form

Contract ID:

[Return to Instructions](#)

Form Status
Incomplete

I, , certify that the following information is accurate to the best of my knowledge.

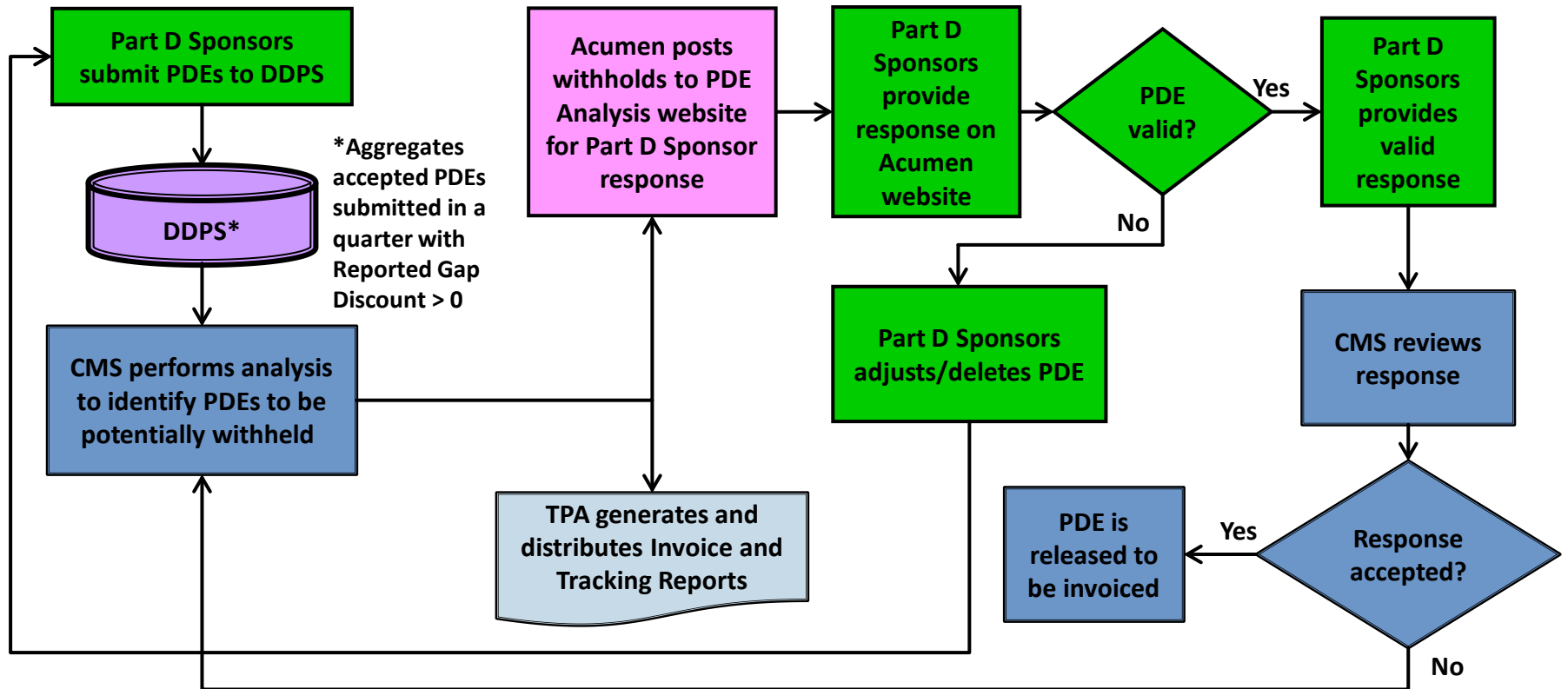
Responder Information

Position	Email	Phone
<input type="text"/>	<input type="text"/>	<input type="text"/>

Enter the Ticket Number(s), select the Status of the ticket (*Valid* or *Needs Correction*), and enter an explanation of the selected status.

Ticket Number	Status of Ticket	Explanation	Status
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Outlier Process Flow



Deadlines

- Part D Sponsors have 14 days, instead of 10, to respond to posted PDEs not involved in disputes.
- Part D Sponsors have 10 days to respond to posted PDEs related to disputes.
- Part D Sponsors must make any PDE adjustments or deletions within 90 days.

PDEs Withheld from Invoice

- On a quarterly basis:
 - CMS aggregates Gap Discount amounts reported on accepted and validated PDE data submitted by Part D Sponsors during the quarter
 - PDE is subjected to additional review and analysis prior to being invoiced
 - PDEs withheld from invoicing are posted to the PDE Analysis website for Sponsor review and action

PDEs Withheld from Invoice (continued)

- Sponsors must respond to withheld PDEs in one of two ways:
 - Adjust or delete PDEs that require correction through the DDPS
 - Sponsors must adjust or delete PDEs within 90 days from the release of the reports
 - If the Sponsor believes that the PDE is valid, complete and submit the Response Form within 14 calendar days of the receipt of the report

PDEs Withheld from Invoice (continued)

- 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
 - Total Reported Gap Discount (RGD) is $>$ the Maximum Total RGD
 - Total Reported Gap Discount is $>$ Remaining TrOOP
 - Total Reported Gap Discount is $>$ the TrOOP Maximum

PDEs Withheld from Invoice - Retroactive Disenrollment of the Beneficiary

- CMS validates beneficiary enrollment on accepted PDEs with gap discounts prior to invoicing
 - CMS identifies periods of no Part D enrollment in any plan on DOS
 - If the beneficiary lost enrollment on the DOS, the affected PDEs are withheld from invoice and posted to the PDE Analysis website
- Deceased beneficiaries
 - CMS also validates the DOS for deceased beneficiaries who received gap discount during the quarter
 - If DOS is greater than 32 days after DOD, the PDE is withheld from invoice and posted to the PDE Analysis website

PDEs Withheld from Invoice - Retroactive LI Status of the Beneficiary

- DDPS validates the LI status of beneficiaries during editing
- Issues reject edit 874 if a PDE reports a Gap Discount amount for a beneficiary who is LI eligible
- If a beneficiary has retroactively become LI eligible, then the affected Gap Discount PDEs are withheld from invoicing

PDEs Withheld from Invoice - PDE Reports a Closed Pharmacy

- Gap Discount PDEs in which the DOS is after the closing date of the pharmacy
 - May occur when a pharmacy has closed or changed ownership
 - The affected Gap Discount PDEs are withheld from invoice and posted to the PDE Analysis website for Sponsor review
 - Sponsors are expected to explain why the PDE is valid or correct the PDEs in question

PDEs Withheld from Invoice - Total RGD is > the Maximum Total RGD

- PDEs with Gap Discount amounts that cause the beneficiary's total Reported Gap Discount (RGD) to exceed the maximum total RGD are withheld from invoicing
- PDEs flagged under this analysis are reviewed at the beneficiary level rather than at the single PDE level
- 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



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

PDEs Withheld from Invoice - Total RGD is > the Maximum Total RGD (continued)

Maximum Total Reported Gap Discount Threshold by Benefit Year

Benefit Year	Maximum Total Reported Gap Discount Amount Threshold (OOP Threshold – ICL)
2011	\$1821.86 +/- \$0.05
2012	\$1,900.20 +/- \$0.05
2013	\$1,999.35 +/- \$0.05
2014	\$1,920.39 +/- \$0.05

PDEs Withheld from Invoice - RGD is > Remaining TrOOP

- The Reported Gap Discount is greater than the remaining TrOOP (RGD > Remaining TrOOP)
 - Conducted at the PDE level
 - Compares Reported Gap Discount on PDE to remaining TrOOP
 - Remaining TrOOP = OOP Max – TrOOP Accumulator Amount
 - Now a reject edit

Remaining TrOOP = OOP Maximum – TrOOP Accumulator Amount

PDEs Withheld from Invoice – RGD > the TrOOP Maximum

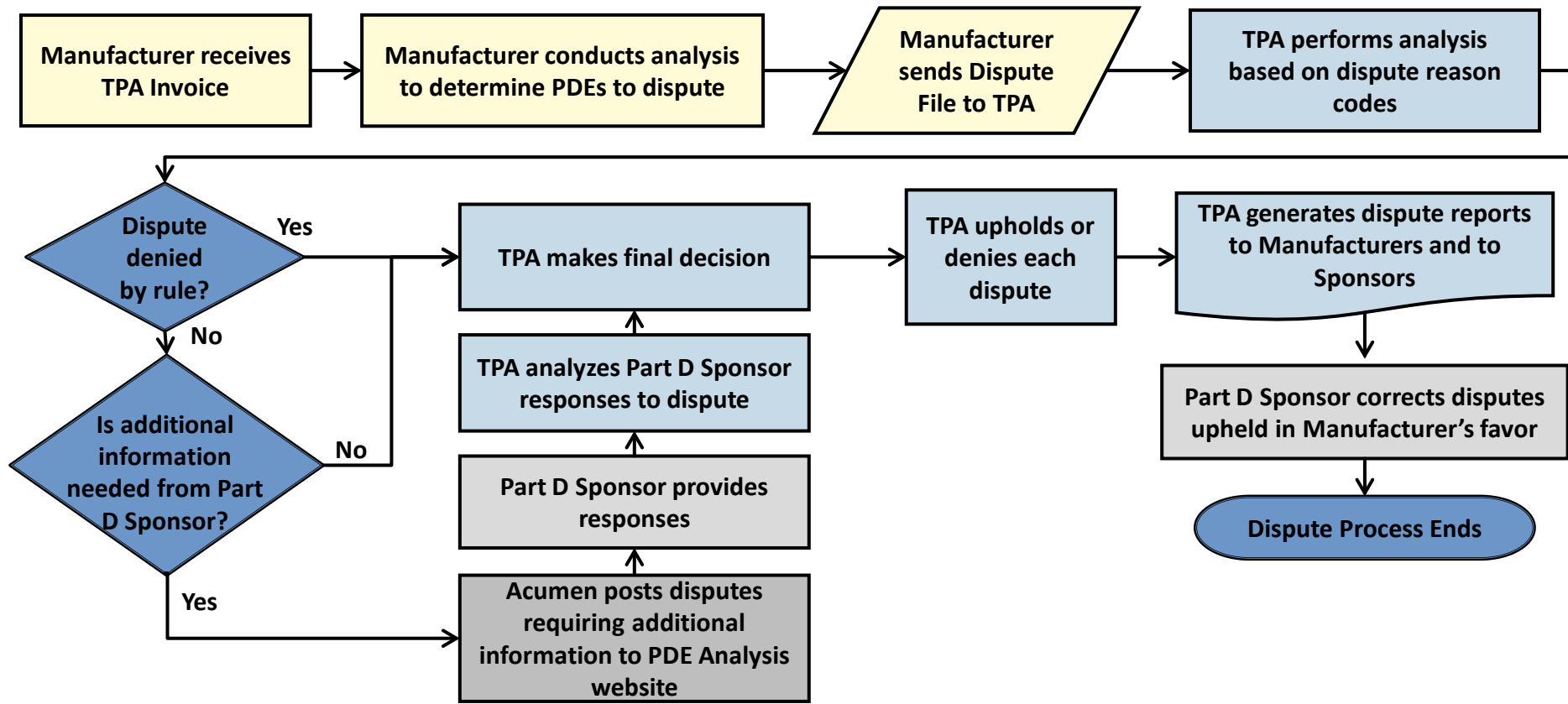
- CMS flags the beneficiary's PDE Record as an outlier if the sum of the reported Gap Discount exceeds the OOP maximum for the benefit year.
- The PDEs with Gap Discounts that cause the beneficiary's total RGD to exceed the max total RGD are withheld from invoicing.

Manufacturer Dispute Process

Overview

- The right for Manufacturers to dispute the quarterly invoice is covered under the Coverage Gap Discount Program Agreement.
 - Section V(e) of the Manufacturer Agreement provides the manufacturers with a regular dispute process
 - Manufacturer must provide supporting evidence that is material, specific, and related to the dispute or issue.
 - Also per Section V(e) of the Agreement, CMS is required to adjust future invoices or implement an alternative process if necessary, pending the outcome of any disputes.
 - 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.

Manufacturer Dispute Process Flow



Manufacturer Dispute Process Deadlines

2014 Coverage Gap Discount Program Manufacturer Dispute Deadlines

Benefit Year and Quarter	Dispute Submission Deadline	Dispute Resolution Deadline	Appeals Submission Deadline	Appeals Resolution Deadline	Admin Appeals Deadline
2014 Q1	06/30/2014	08/29/2014	09/28/2014	12/27/2014	01/26/2015
2014 Q2	10/31/2014	12/30/2014	01/29/2015	04/29/2015	05/29/2015
2014 Q3	12/31/2014	03/01/2015	03/31/2015	06/29/2015	07/29/2015
2014 Q4	04/02/2015	06/01/2015	07/01/2014	09/28/2015	10/29/2015

Manufacturer Dispute Process Overview (continued)

- Manufacturers have the right to dispute invoiced discount payments within 60 days of receipt of invoice
- TPA has 60 days to make a determination on any accepted disputes
 - TPA may uphold the dispute in the favor of the Manufacturer or deny the dispute
- Disputed PDEs may be posted to the PDE Analysis website to obtain information from the Sponsor
 - Sponsors must respond to the disputed PDEs within 10 calendar days
 - Sponsors are required to provide a response by completing and submitting to the PDE Analysis website the Dispute Response Form

Manufacturer Dispute Process

- The Part D Sponsor should provide the status of the PDE for each ticket number and an explanation of the selected status
 - Valid
 - Has been/will be adjusted
 - Has been/will be deleted
- 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
- Adjustments and deletions are subject to the same 90 day timeframe as all other adjustment/deletion activity

Manufacturer Dispute Process (continued)

- Manufacturers can only choose one dispute reason per invoiced PDE
- The most common upheld disputes include:
 - Excessive Quantity (D04)
 - Invalid Days' Supply (D05)
 - High Price of the Drug (D06)
 - Gap Discount for disputed PDE exceeds maximum discount amount for a single PDE (D13)
 - Total accumulated Gap Discounts reported across multiple PDEs for a single beneficiary exceed cumulative maximum discount amount (D14)

Manufacturer Dispute Process - 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

Manufacturer Dispute Process - Dispute Reason Codes (continued)

DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION
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

Manufacturer Dispute Process - Duplicate Invoice Item (D01) and Manufacturer Dispute Process – Closed Pharmacy (D02)

- Duplicate Invoice Item (D01)
 - The manufacturer believes that the invoiced PDE is a duplicate of another invoiced PDE
- Closed Pharmacy (D02)
 - Manufacturers can dispute an invoiced PDE with a service provider ID that became invalid on the DOS after the PDE was edited and saved to the system

Manufacturer Dispute Process - Not Part D Covered Drug (D03)

- Allows Manufacturers to indicate that an NDC should not be covered under the Part D program under any circumstances
- This code should not be used to file a dispute on the basis that the drug is potentially a non-applicable CGDP drug, but otherwise would be covered under Medicare Part D

Manufacturer Dispute Process - Not Part D Covered Drug (D03) (continued)

- Reason code *D09 Marketing Category is Not NDA or BLA* is used to dispute a discount payment on the basis that the drug is a Part D covered drug but ineligible to receive the discount
- Reason code *D07 Last Lot Expiration Date* is used to file disputes on the basis of the last lot expiration date
- Drugs disputed for Part B versus Part D coverage are largely dependent on indication and/or patient setting
 - If a drug can be covered under Part B or Part D and meet the criteria, the disputed PDEs will be denied

Manufacturer Dispute Process - Excessive Quantity (D04)

- Excessive quantity disputes mean that the manufacturer believes the quantity is inconsistent with packaging of the product or is excessive given the days' supply
- The TPA will generally not uphold disputes for quantities that represent doses less than three (3) times the maximum when there is a maximum Food and Drug Administration (FDA) approved labeling

Manufacturer Dispute Process – Days' Supply (D05)

- Days' Supply disputes question if the days' supply is inconsistent with the packaging of the product or whether it represents a days' supply that is unlikely in the Medicare population

Manufacturer Dispute Process – High Price of the Drug (D06)

- Disputes filed for D06 question the per unit price of the disputed NDC
- Per unit price = $\text{Ingredient Cost} / \text{Quantity Dispensed}$
- Relevant PDE fields:
 - Ingredient Cost
 - Quantity Dispensed
 - Product Service ID (NDC)
 - Days' Supply

Manufacturer Dispute Process - Last Lot Expiration Date (D07)

- Disputes for Last Lot Expiration Date question if the DOS post-dates the last-lot expiration date for the NDC.

Manufacturer Dispute Process - Early Fill (D08)

- Part D Sponsor must confirm that the first fill and the early fill were actually dispensed
 - Early prescription fill reasons include:
 - Vacation Supply
 - Replacement for lost or damaged medications
 - Clinically appropriate temporary removal of pharmacy refill too soon edits

Manufacturer Dispute Process - Marketing Category is Not New Drug Application (NDA) or Biologic License Application (BLA) (D09)

- Disputes filed on the basis that the marketing category is neither an NDA nor BLA means that the Manufacturer believes that:
 - the drug product is not an applicable drug due to the marketing category of the product on the date of service; and
 - that the product is therefore ineligible for the Coverage Gap Discount.

Manufacturer Dispute Process - Marketing Category is Not NDA or BLA (D09) (continued)

- PDE edits for coverage Gap Discounts are based upon the marketing category obtained from the FDA
- DOS on or after September 1, 2012
 - Marketing category found in the NSDE file
- DOS prior to September 1, 2012
 - Marketing category found in the new FDA NDC Directory
- The new FDA NDC Directory and the NSDE File identifies only those NDCs that have been electronically listed with the FDA and includes data fields such as:
 - Marketing Category
 - Marketing Start Date
 - Marketing End Date

Manufacturer Dispute Process - Marketing Category is Not NDA or BLA (D09) (continued)

- When performing edits, the CMS system checks the appropriate FDA source for the NDC and uses the listed marketing category.
- After the determination of the source of the marketing category information, the CMS system identifies the marketing category and checks that the date of service for the PDE falls between the Marketing Category Start Date and the Marketing Category End Date.

Manufacturer Dispute Process - Marketing Category is Not NDA or BLA (D09) (continued)

- The TPA will confirm the marketing category at the time of submission and editing for the DOS in question.
- The dispute will be denied if the research shows the marketing category to be NDA or BLA at the time of PDE submission for the DOS.

Manufacturer Dispute Process - Date of Service Prior to 1/1/2011 (D10), PDE Improperly Invoiced Beyond Manufacturer Agreement Invoice Period (D11), Invalid Prescription Service Reference Number (D12)

- Date of Service Prior to 1/1/2011 (D10)
- PDE Improperly Invoiced Beyond Manufacturer Agreement Invoice Period (D11)
- Invalid Prescription Service Reference Number (D12)

Dispute Resolution Process - Gap Discount for Disputed PDE Exceeds Maximum Discount Amount for Single PDE (D13)

- D13 is used if the manufacturer believes the Reported Gap Discount on an invoiced PDE exceeds the maximum gap discount for a single PDE

Dispute Resolution Process - Gap Discount for Disputed PDE Exceeds Maximum Discount Amount for Single PDE (D13) (continued)

- The Gap Discount is equal to 50% of the portion of the negotiated price (excluding dispensing fee) of the applicable drug that falls within the coverage gap
- The revised maximum discount formula for a single PDE includes annual TrOOP amounts and the gradual increase in basic Part D coverage in the coverage gap with plan cost sharing amounts
 - Maximum Manufacturer Discount = \$2,435.90

Dispute Resolution Process - Gap Discount for Disputed PDE Exceeds Maximum Discount Amount for Single PDE (D13) (continued)

- Two Step Formula to determine Max Gap Discount for a Single PDE
 1. Determine the negotiated price associated with a beneficiary's remaining TrOOP:
 - $\text{TrOOP dollar amount} \div (\text{beneficiary} + \text{manufacturer gap payment percentages}) = \text{Gap Eligible Portion Of Negotiated Price}$
 2. Determine the manufacturer's portion of the negotiated price:
 $\text{Gap Eligible Portion of Negotiated Price} \times .50 = \text{Max Gap Discount for a Single PDE}$

Dispute Resolution Process - Gap Discount for Disputed PDE Exceeds Maximum Discount Amount for Single PDE (D13) (continued)

- Maximum gap discount for single PDE
 = TrOOP dollar amount ÷ (beneficiary + manufacturer gap payment percentage) x .50

	2011	2012	2013	2014
Beneficiary pays	50%	50%	47.5%	47.5%
Part D Plan cost sharing	0%	0%	2.5%	2.5%
Manufacturer discount	50%	50%	50%	50%

Maximum gap discount for single PDE for 2014
 $\$4550 \div (.475 + .50) \times .50 = \2333.33

Dispute Resolution Process - Total Accumulated Gap Discounts Reported Across Multiple PDEs for Single Beneficiary Exceed Cumulative Maximum Discount Amount (D14)

- Dispute code D14, is used if the manufacturer believes the Reported Gap Discount on multiple invoiced PDEs exceeds the maximum gap discounts for a single beneficiary
- Identified as “Total Reported Gap Discount” on Acumen website
- High volume dispute type, particularly for calendar year and non-calendar year EGWPs

Knowledge Test #4

Please select your response to this question.

- Sponsors must adjust or delete invalid PDEs within _____ days from the release of the reports in response to withheld PDEs posted to the PDE Analysis website.
 - A) 90 days
 - B) 60 days
 - C) 10 days
 - D) 14 days

Knowledge Test #5

Please select your response to this question.

- Manufacturers can select multiple dispute reasons per invoiced PDE to ensure that all possible reasons will be considered. True or False?
 - A) True
 - B) False

Question & Answer (Q&A)



Feedback Request

- Following this Webinar, you will receive an email requesting your feedback regarding this session.
- Please take a moment to respond to the questions and provide comments.
- This information will assist CMS with meeting your submission needs and enhancing your Webinar participation experience.

YOUR FEEDBACK IS IMPORTANT!

Closing Remarks

- Thank you for attending today's PDE Webinar!
- Please visit TARSC for information about future webinars.