

PDE ANALYSIS PROCESS GUIDE: PDES WITHHELD FROM CGDP INVOICE AND INVOICED OUTLIER PDES

As part of the Coverage Gap Discount Program (CGDP) invoice process, CMS aggregates gap discount amounts reported on accepted and validated PDE data submitted by Part D sponsors during the quarter. If the 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 due to data quality issues, the withheld PDEs are posted to the PDE Analysis Portal for sponsor review and action. Additionally, starting with the Quarter 1 2018 invoice cycle, PDEs which are accepted and invoiced to manufacturers may be subject to further analysis and validation if the supporting data have changed. Invoiced PDEs that are flagged for data quality issues (Invoiced Outlier PDEs) will also be posted on the PDE Analysis web portal for sponsor review and correction. This document provides a guide to the PDE Analysis process for addressing PDEs withheld from CGDP invoice, and invoiced outlier PDEs.

Authorized PDE Analysis Portal users will receive email notification from the PDE Analysis support team when withheld or invoiced outlier PDEs require review by their contract(s). Follow the instructions below to navigate your contract’s PDE Analysis Package and take action to address withheld PDEs:

1. **Open** the ZIP file. **Select *Extract*** and **save** files to your computer.

2. **Open** the extracted *PDE Analysis Package* folder. You will see Excel files entitled:
 - *PDE Issue Report* – List of withheld PDEs that have been excluded from the current invoice, or previously invoiced PDEs which have been flagged as outliers.
 - *Response Form* – Form which contracts must submit to respond to PDEs found to be valid, and which contracts may submit to respond to PDEs found to need correction.

Do not change the names of the files. In order to use the links within the files, they must be saved with exactly the same names as when downloaded.

3. **Open** the PDE Issue Report in the *PDE Analysis Package* folder. The report contains the following tabs:
 - *Instructions*: Instructions for addressing disputed PDEs.
 - *Issue Types*: List of PDE details for withheld or invoiced outlier PDEs by type of data issue.
 - *Data Element Reference*: The following table provides detailed information about the data elements found in the PDEs Withheld from CGDP Invoice and Invoiced Outlier PDEs report:

Data Elements	PDE Field Name	Field Definition
Contract Number	CONTRACT NUMBER	This field contains the unique number CMS assigns to each contract that a Part D plan has with CMS.
Medicare beneficiary identifier	Medicare beneficiary identifier	This field contains the unique number identifying the primary beneficiary under the Social Security Administration and Railroad Retirement Board (RRB) programs. Effective April 1, 2018, this field will be populated with the beneficiary’s Medicare Beneficiary Identifier (MBI), or with the

		Health Insurance Claim Number (HICN) if the MBI is unavailable.
Date of Service	DATE OF SERVICE (DOS)	This field contains the date on which the prescription was filled.
Product Service ID	PRODUCT/SERVICE IDENTIFIER	This field identifies the dispensed drug using a National Drug Code (NDC).
Quantity Dispensed	QUANTITY DISPENSED	This field indicates how many dosage units of the medication were dispensed in the current drug event.
Days' Supply	DAYS' SUPPLY	This field indicates the number of days' supply of medication dispensed by the pharmacy and will consist of the amount the pharmacy enters for the prescription.
Claim Control Number	CLAIM CONTROL NUMBER	This field is an optional, free-form field. It is intended for use by plans to identify unique events or for other plan purposes.
PBP ID	PLAN BENEFIT PACKAGE (PBP) IDENTIFIER	This field contains the unique number CMS assigns to identify a specific PBP within a contract.
Prescription Service Ref Number	PRESCRIPTION SERVICE REFERENCE NO	This field contains the prescription reference number assigned by the pharmacy at the time the prescription is filled.
Fill Number	FILL NUMBER	This field indicates the number fill of the current dispensed supply.
Service Provider Identifier	SERVICE PROVIDER ID	This field identifies the pharmacy where the prescription was filled.
Service Provider Identifier Qualifier	SERVICE PROVIDER ID QUALIFIER	This field identifies the type of provider identifier used in the Service Provider Identifier field.
Ingredient Cost Paid	INGREDIENT COST PAID	This field contains the amount paid to the pharmacy for the drug itself. Dispensing fees or other costs are not to be included in this amount except as allowed on non-standard format claims.
Dispensing Fee Paid	DISPENSING FEE PAID	This field contains amounts paid to the pharmacy for dispensing the medication. This field should only contain the activities related to the transfer of possession of the drug from pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead as delineated in the final rule and the preamble to the rule. No other costs shall be included in this field. This fee may be negotiated with pharmacies at the plan or PBP level.
Vaccine Administration Fee	VACCINE ADMINISTRATION FEE	The fee reported by a pharmacy, physician, or provider to cover the cost of administering a vaccine, excluding the ingredient cost and dispensing fee.
Sales Tax	TOTAL AMOUNT ATTRIBUTED TO SALES TAX	This field contains the sum of all amounts paid to the pharmacy to cover sales tax.
Reported Gap Discount Amount	REPORTED GAP DISCOUNT AMT	The reported amount that the sponsor advances at point-of-sale for the Gap Discount. Part D sponsors advance the Gap Discount at point-of-sale to applicable beneficiaries who purchase an applicable drug that falls, in part or in full, in the Coverage Gap.
Patient Pay Amount	PATIENT PAY AMOUNT	This field lists the dollar amount the beneficiary paid that is not reimbursed by a third party (e.g., copayments, coinsurance, deductible or other patient pay amounts).
Other TrOOP Amount	OTHER TROOP AMOUNT	This field records all qualified third party payments that contribute to a beneficiary's TrOOP, except for LICS and Patient Pay Amount. Examples include payments made on behalf of a beneficiary by a qualified State Pharmacy Assistance Program, charities, or other TrOOP-eligible parties.
LICS Subsidy Amount	LOW INCOME COST SHARING SUBSIDY AMOUNT (LICS)	This field contains plan-reported LICS amounts per drug event so that CMS systems can reconcile prospective LICS payments made to plans with actual LICS amounts incurred by the plan at Point of Sale.

PLRO Amount	PATIENT LIABILITY REDUCTION DUE TO OTHER PAYER AMOUNT (PLRO)	This field takes into account coordination of benefits that results in reduced patient liability, excluding any TrOOP-eligible payers.
Gross Drug Cost Below Out of Pocket (OOP) Threshold	GROSS DRUG COST BELOW OUT-OF-POCKET THRESHOLD (GDCB)	This field represents the gross drug cost paid to the pharmacy below the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a positive dollar amount. For claims above the attachment point, this field will contain a zero dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 31 (GDCA).
Gross Drug Cost Above Out of Pocket (OOP) Threshold	GROSS DRUG COST ABOVE OUT-OF-POCKET THRESHOLD (GDCA)	This field represents the gross drug cost paid to the pharmacy above the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a zero dollar amount. For claims above the attachment point, this field will contain a positive dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 30 (GDCB).
Covered D Plan Paid Amount (CPP)	COVERED D PLAN PAID AMOUNT (CPP)	This field contains the net amount the plan paid for standard benefits (covered Part D drugs).
Non Covered Plan Paid Amount (NPP)	NON COVERED PLAN PAID AMOUNT (NPP)	This field contains the net amount paid by the plan for benefits beyond the standard benefit.

- *Response and Lag Code Reference:* The following table provides detailed information about the codes found in the CMS Response Code (column D) and Outlier Lag Period Code (column E) fields within the issue tabs in PDEs Withheld for CGDP Invoice and Invoiced Outlier PDEs report:

Withheld and Invoiced Outlier PDE Report CMS Outlier Response Codes

CMS Response Code	CMS Response Description	CMS Suggested Action
0	None provided	None provided
1	Based on LI enrollment, beneficiary was retroactively identified as Low Income on the Date of Service.	Reported Gap Discount should be removed from the PDE or the beneficiary's LI enrollment data should be corrected.
2	Beneficiary's address indicates they do not live in a US territory and, based on LI enrollment, the beneficiary was retroactively identified as Low Income on the Date of Service.	Reported Gap Discount should be removed from the PDE or the beneficiary's LI enrollment data should be corrected or the beneficiary residence should be corrected.
3	Based on enrollment, beneficiary was retroactively identified as having no enrollment on the Date of Service.	PDE should be deleted or the beneficiary's enrollment data should be corrected.
4	Based on enrollment, beneficiary was retroactively identified as having an audited enrollment record on the Date of Service.	PDE should be deleted or the beneficiary's enrollment data should be corrected.

CMS Response Code	CMS Response Description	CMS Suggested Action
5	Date of Service on PDE is greater than the Date of Death + 32 days.	PDE should be deleted or the beneficiary's Date of Death should be corrected.
6	Date of Service on PDE is equal to or greater than 07/01/2017, pharmacy is a Community/Retail Pharmacy Service, the beneficiary lives at home, and Date of Service is greater than the Date of Death + 14 days.	PDE should be deleted or the beneficiary's Date of Death should be corrected.
7	NPI provided in the Service Provider ID field is inactive on the Date of Service. Note: PDEs for brand drugs in the Gap will be withheld from invoice when there is no change in ownership reported and the Date of Service is after the reported NPI is inactive.	If Pharmacy is closed, PDE should be deleted. If Pharmacy has change in ownership, PDE should be deleted and resubmitted with the active NPI for the pharmacy.
8	NPI provided in the Service Provider ID field is inactive within 60 days of Date of Service. Pharmacy has a change in ownership.	PDE should be deleted and resubmitted with the active NPI for the pharmacy. Note: PDEs for brand drugs in the Gap will be withheld from invoice when there is a change in ownership and the Date of Service is more than 60 days after the reported NPI is inactive.
9	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$1,848.77) for benefit year 2014. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
10	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,333.38) for benefit year 2014. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
11	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$1,957.94) for benefit year 2015. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
12	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this

CMS Response Code	CMS Response Description	CMS Suggested Action
	(\$2,473.73) for benefit year 2015. (Max GD = (TrOOP/Brand Cost Share) x 50%)	PDE or on another PDE for the beneficiary being identified.
13	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$1,975.05) for benefit year 2016. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
14	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,552.68) for benefit year 2016. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
15	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,069.49) for benefit year 2017. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
16	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,750.05) for benefit year 2017. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
17	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,211.08) for benefit year 2018. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
18	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,941.23) for benefit year 2018. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
19	The Reported Gap Discount on the PDE is greater than the maximum allowed Gap Discount amount (\$2,435.95) for benefit year 2013. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Reported Gap Discount should be corrected.

CMS Response Code	CMS Response Description	CMS Suggested Action
20	The Reported Gap Discount on the PDE is greater than the maximum allowed Gap Discount amount (\$2,333.38) for benefit year 2014. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Reported Gap Discount should be corrected.
21	The Reported Gap Discount on the PDE is greater than the maximum allowed Gap Discount amount (\$2,473.73) for benefit year 2015. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Reported Gap Discount should be corrected.
22	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,550) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$1,848.77) for benefit year 2014. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
23	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,550) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,333.38) for benefit year 2014. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
24	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,700) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$1,957.94) for benefit year 2015. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
25	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,700) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,473.73) for benefit year 2015. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
26	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,850) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$1,975.05) for benefit year 2016. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.

CMS Response Code	CMS Response Description	CMS Suggested Action
27	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,850) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,552.68) for benefit year 2016. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
28	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,950) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,069.49) for benefit year 2017. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
29	Total Reported Gap Discount exceeds the TrOOP Threshold (\$4,950) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,750.05) for benefit year 2017. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
30	Total Reported Gap Discount exceeds the TrOOP Threshold (\$5,000) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2211.08) for benefit year 2018. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
31	Total Reported Gap Discount exceeds the TrOOP Threshold (\$5,000) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,941.23) for benefit year 2018. (Max GD = (TrOOP/Brand Cost Share) x 50%)	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
32	The Calculated TrOOP amounts exceed the TrOOP Threshold (\$4,550) for benefit year 2014.	Plan should review the entire PDE history for the beneficiary to determine if accumulated TrOOP should be corrected either on this PDE or on another PDE for the beneficiary being identified.
33	The Calculated TrOOP amounts exceed the TrOOP Threshold (\$4,700) for benefit year 2015.	Plan should review the entire PDE history for the beneficiary to determine if accumulated TrOOP should be corrected either on this PDE or on another PDE for the beneficiary being identified.

CMS Response Code	CMS Response Description	CMS Suggested Action
34	The Calculated TrOOP amounts exceed the TrOOP Threshold (\$4,850) for benefit year 2016.	Plan should review the entire PDE history for the beneficiary to determine if accumulated TrOOP should be corrected either on this PDE or on another PDE for the beneficiary being identified.
35	The Calculated TrOOP amounts exceed the TrOOP Threshold (\$4,950) for benefit year 2017.	Plan should review the entire PDE history for the beneficiary to determine if accumulated TrOOP should be corrected either on this PDE or on another PDE for the beneficiary being identified.
36	The Calculated TrOOP amounts exceed the TrOOP Threshold (\$5,000) for benefit year 2018.	Plan should review the entire PDE history for the beneficiary to determine if accumulated TrOOP should be corrected either on this PDE or on another PDE for the beneficiary being identified.
37	CMS will follow-up with the Plan	None provided
38	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,824.92) for benefit year 2019. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 70%).	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
39	PLRO > 0 for all PDEs and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$3,757.94) for benefit year 2019. (Max GD = (TrOOP/Brand Cost Share) x 70%).	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
40	Total Reported Gap Discount exceeds the TrOOP Threshold (\$5,100) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$2,824.92) for benefit year 2019. (Max GD = (TrOOP-(Deductible + Beneficiary ICL Amount)/Brand Cost Share) x 70%).	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.
41	Total Reported Gap Discount exceeds the TrOOP Threshold (\$5,100) and the accumulated Reported Gap Discount for the beneficiary is greater than the maximum allowed Gap Discount amount (\$3,757.94) for benefit year 2019. (Max GD = (TrOOP/Brand Cost Share) x 70%).	Plan should review the entire PDE history for the beneficiary to determine if Reported Gap Discount should be corrected either on this PDE or on another PDE for the beneficiary being identified.

CMS Response Code	CMS Response Description	CMS Suggested Action
42	The Calculated TrOOP amounts exceed the TrOOP Threshold (\$5,100) for benefit year 2019.	Plan should review the entire PDE history for the beneficiary to determine if accumulated TrOOP should be corrected either on this PDE or on another PDE for the beneficiary being identified.

Withheld and Invoiced Outlier PDE Report Outlier Lag Period Codes

CMS Lag Period Code	Outlier Lag Period
0	None provided.
1	Outlier has been unresolved for at least 90 days.
2	Outlier has been unresolved for at least 365 days.
3	Outlier has been unresolved for at least 730 days.

4. **Review** the PDE details presented on the *Issue Type* tab(s) of your PDE Issue Report.

For PDEs that are valid:

Concluding that a withheld or invoiced outlier PDE is valid means that you do not plan to adjust, delete, or reprocess the claim. **You are required to submit a response to the PDE Analysis Support team for withheld or invoiced outlier PDEs that are determined to be valid.**

5. **Open** the Response Form in the *PDE Analysis Package* folder.
6. **Complete** the Response Form, including the following information:
 - *Responder Information:* Responder's name, position, email, and phone number.
 - *Ticket Number:* Ticket Number(s) of valid PDE(s).
 - *Status of PDE:* Select 'PDE is Valid' to indicate that the PDE is valid.
 - *Explanation:* Detailed explanation substantiating validity of PDE(s).

For PDEs that require correction:

Concluding that a withheld or invoiced outlier PDE requires correction means that you plan to adjust, delete, or reprocess the claim. **You are required to submit corrections to the Drug Data Processing System (DDPS) for withheld or invoiced outlier PDEs**

that are determined to need correction, and may also elect to submit a response to the PDE Analysis Support team in this scenario (responses to withheld or invoiced outlier PDEs that will be corrected are not required).

7. **Adjust** or **delete** PDEs through the Drug Data Processing System (DDPS).
8. Should you choose to submit a response for PDEs that will be corrected, **complete** the Response Form, including the following information:
 - *Responder Information*: Responder's name, position, email, and phone number.
 - *Ticket Number*: Ticket Number(s) of PDE(s) that will be corrected.
 - *Status of PDE*: Select the action that has been/will be taken to correct PDE(s)
 - PDE has been deleted
 - PDE will be deleted
 - PDE has been adjusted
 - PDE will be adjusted
 - *Date of Action*: Date by which selected action has/will take place.
 - *Explanation*: Explanation of error for PDE(s).

For all responses:

9. **Confirm** that the *Form Status* states **Complete**. An **Incomplete** status indicates there are missing or invalid fields on the form.
10. **Save** the Response Form to your computer and **return** it to an authorized PDE Analysis Website user for submission through the Upload Files page of the PDE Analysis Website.

If you have any questions about the PDE Analysis process for addressing withheld or invoiced outlier PDEs, please contact the PDE Analysis Support team at PDEAnalysis@AcumenLLC.com or (650) 558-8006. For questions about the CGDP manufacturer invoicing process, please contact CMS directly at PDEJan2011@cms.hhs.gov.