DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

MEDICARE PLAN PAYMENT GROUP

DATE: April 28, 2023

TO: All Part D Plan Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2023 Benefit Year

CMS has several initiatives in place to enhance Medicare payment accuracy and support program integrity goals. In Medicare Part D, correct payment is dependent on the accuracy of the Prescription Drug Event (PDE) data submitted by Part D sponsors. For this reason, CMS strongly encourages sponsors to take an active and consistent approach to ensuring the accuracy of submitted PDE data and resolving errors that lead to PDE rejections.

The purpose of this memorandum is to announce the continuation of two reporting initiatives for the 2023 benefit year that support CMS' efforts to improve the accuracy of sponsors' PDE data. The PDE Reports and PDE Analysis initiatives are both facilitated by CMS' contractor, Acumen, LLC, and participating sponsors will continue to use the secure PDE Reports and PDE Analysis web portals. The remainder of this memorandum provides overviews of the PDE Reports and PDE Analysis initiatives and describes the actions expected from participating sponsors. Attachment A provides details of the PDE Reports initiative. Attachment B supplies further information on the PDE Analysis process. Attachment C explains the steps that sponsors must complete to authorize users for the PDE Reports and PDE Analysis web portals.

PDE Reports

Since the 2007 benefit year, CMS has been providing sponsors with reports on the quality, timeliness, and accuracy of their PDE data submission and error resolution efforts through the Immediately Actionable PDE (IAP) Errors Reports released through the PDE Reports web portal. CMS issued guidance on the IAP Errors Reports in a Health Plan Management System (HPMS) memorandum released on November 8, 2007, titled "Prescription Drug Event Reports and Website." Also, in June 2010, CMS began providing Part D sponsors with reports on PDE rejects caused by enrollment timing issues through the Eligibility Errors Reports released through the PDE Reports web portal.

In February 2023, CMS began producing IAP and Eligibility Errors Reports based on PDE data for the 2023 benefit year, in addition to continuing this effort for the 2022 benefit year. Reports for the 2021 benefit year have been discontinued. Attachment A provides a more detailed overview of the PDE Reports initiative, including a description of each set of reports and the actions expected from sponsors as part of this process.

PDE Analysis

Since the 2009 benefit year, CMS has utilized the PDE Analysis 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 (CGDP), this initiative was expanded in March 2011 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.

Starting with the 2018 Quarter 1 CGDP Invoice cycle, CMS began reporting data quality issues on PDEs that have been invoiced to manufacturers as part of the Withheld and Invoiced Outliers cycle. Prior to this invoice cycle, PDEs that had been invoiced to manufacturers were not submitted to further analysis and validation. This update further ensures the validity of invoiced PDE data.

PDEs are currently posted to the PDE Analysis web portal under the following categories:

- General CGDP Data Quality Review: posted approximately two to three times each calendar year (benefit years 2022 - 2023)
- Part D Payment Reconciliation Data Quality Review: posted approximately two to three times each calendar year (benefit years 2022 - 2023)
- PDEs Withheld from the CGDP Invoice and Invoiced Outliers: posted quarterly at the same time as the invoice distribution (benefit years 2019 - 2023)
- Manufacturer Disputes: posted quarterly approximately two to three weeks after the manufacturer's dispute submission deadline (benefit years 2019 - 2023)
- Upheld Dispute Tracking Reports: posted quarterly approximately three to four weeks after the manufacturer dispute resolution deadline (benefit years 2017 - 2023)

CMS issued guidance on each of these categories in an HPMS memorandum released on April 4, 2018, titled "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." CMS will be continuing these efforts for benefit years 2017 through 2022 and will be beginning these initiatives for benefit year 2023.

Attachment B provides a more detailed overview of the PDE Analysis initiative.

Summary

The following table summarizes the expected actions and timelines for the launch of the PDE Reports and PDE Analysis reporting initiatives for the 2023 benefit year.

Action	Date
New 2023 contracts: The Medicare Compliance Officer must complete the user authorization process for the PDE Reports and PDE Analysis web portal via the User Security web portal. Instructions are included in Attachment C. **Contracts continuing from 2022:** No action is necessary if your contract has no changes in authorized users or their levels of access. Previously authorized users will retain their access to the PDE Reports and PDE Analysis web portals. If necessary, Medicare Compliance Officers can modify existing user access through the User Security web portal.	New user requests and current user verification due **two weeks from the date of this memorandum**
New contracts and continuing contracts that authorize new users: Be prepared to receive login credentials and additional project information.	Rolling basis, following new authorizations and/or access updates completed by Medicare Compliance

CMS and Acumen appreciate your continued cooperation in making the PDE Reports and PDE Analysis initiatives a success. If you have any questions, concerns, or feedback regarding these projects, please contact Acumen at PDE@acumenllc.com.

ATTACHMENT A: Overview of the PDE Reports Initiative

The reports released through the PDE Reports web portal contain metrics based on sponsors' submitted, accepted, and rejected PDEs. The metrics in the scorecards and reports allow sponsors to compare their status to program averages and to monitor progress in improving PDE submission and error resolution efforts over time.

Two types of reports are produced each month:

- **Immediately Actionable PDE (IAP) Errors Reports:** IAPs are a subset of PDEs for which CMS expects sponsors to take immediate and consistent action to correct and resubmit. These errors include rejections for formatting mistakes, data inconsistencies, and failure to grant low income cost-sharing subsidies, among other issues.

  In addition to the current errors included in the 2022 IAP Error Reports, new errors that CMS considers to be immediately actionable – 732, 774, 796, 820, 900, and 901 – are included in the 2023 IAP Reports. A complete listing of errors included in the IAP Errors Reports can be found in the IAP Errors Report Guide, available in the Help Documents library on the PDE Reports web portal.

- **Eligibility Errors Reports:** A PDE is rejected with an Eligibility Error when the enrollment information on the PDE for the given date of service is invalid according to CMS's enrollment records. This includes cases in which the beneficiary does not have Part D enrollment, as well as cases in which the beneficiary is enrolled in a different contract or plan than indicated on the PDE.

  The errors included in the Eligibility Errors Reports are 705, 706, 707, 715, and 723.

Sponsors receive an email notification from PDE@acumenllc.com when reports are made available for download. All sponsors receive reports regardless of whether they have PDEs with IAP or Eligibility Errors.

Sponsors are not expected to submit any information to Acumen in response to the IAP or Eligibility Errors Reports. After reviewing the reports, sponsors should proceed with correcting and resubmitting PDEs through the Drug Data Processing System (DDPS) or following up on outstanding discrepancies.

These reports should in no way replace the ongoing review that sponsors are expected to conduct to monitor their PDE submissions and rejections. CMS expects that sponsors will continue with error resolution efforts for all errors regardless of whether they are classified as IAP or Eligibility Errors.

ATTACHMENT B: Overview of the PDE Analysis Initiative

When a PDE record successfully passes the editing process and becomes an accepted record, the PDE can still be subjected to additional review and analysis. The PDE Analysis initiative alerts sponsors to potential data quality issues identified in accepted PDE records. When a PDE requires review under this process, it will be posted to the sponsor through the PDE Analysis web portal. Sponsors receiving PDE Analysis reports are expected to complete the following actions:

1. **Review Notifications**: Sponsors receive an email notification from PDEAnalysis@acumenllc.com when PDEs require review. This notification contains information about the identified issue, benefit year, response process, and pertinent deadlines for taking action on flagged PDEs. Sponsors will not receive a notification if they do not have PDEs for review.

2. **Download and Review Reports**: Reports are made available for download via the PDE Analysis web portal. These reports include a description of the category of issue identified, further specifics regarding each data issue, and a list of PDE identifying elements to enable sponsors to research the flagged PDEs.

3. **Research PDEs**: Sponsors are expected to research PDEs to determine the validity and accuracy of the submitted data and to evaluate whether a data issue exists. Sponsors should specifically determine whether:

    - *Data are valid*, indicating that the data are accurate as submitted and that no corrections are required to the PDE or other corresponding data (e.g., enrollment information), or

    - *Data are invalid*, indicating that the data are incorrect and that the sponsor will be adjusting, deleting, reversing, or reprocessing the PDE or correcting other corresponding data (e.g., enrollment information).

4. **Submit Responses to Acumen:** The report package downloaded during Step 2 of this process will contain a Response Form that sponsors should complete documenting the results of their research of flagged PDEs. Whether or not a response is required will vary based on the category of the flagged PDE and the results of the sponsor's research.

    - For PDEs flagged under the *General CGDP Data Quality Review*, *Part D Payment Reconciliation Data Quality Review,* and *PDEs Withheld from the CGDP Invoice and Invoiced Outlier* categories, sponsors are required to submit responses via the web portal when data are valid. Responses are not required for PDEs flagged under these categories when data are invalid and will be corrected; however, responses can be submitted.

    - For PDEs flagged under the *Manufacturer Disputes* category, sponsors are required to submit responses via the web portal for all posted PDEs, regardless of whether data are valid or invalid.

    - Sponsors are not required to submit responses for the *Upheld Dispute Tracking Reports*.

The following table outlines the PDE Analysis response requirements based on the category of review and the results of the sponsor's research:

Review Category	Sponsor Determines Data are Valid	Sponsor Determines Data are Invalid
General CGDP Data Quality	Required	Optional
Part D Payment Reconciliation Data Quality	Required	Optional
PDEs Withheld from the CGDP Invoice and Invoiced Outliers	Required	Optional
Manufacturer Disputes	Required	Required

5. **Take Corrective Action**: When sponsors identify that data are invalid, they are required to submit the necessary data corrections. In accordance with the timeliness standards established in the HPMS memorandum released on October 6, 2011, titled "Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,'" Part D sponsors have 90 days to make any adjustments or deletions via DDPS in response to PDEs posted to the PDE Analysis web portal. Sponsors who fail to submit corrected data within 90 days may be subject to compliance actions.

6. **Track Resolution**: The PDE Analysis web portal features a Ticket Tracking page that enables sponsors to monitor the status of flagged PDEs. Sponsors should review this page regularly to ensure that all flagged PDEs have been addressed.

For additional information on the PDE Analysis data quality review process, including more detailed descriptions of the five review categories, refer to the HPMS memorandum released on April 4, 2018, titled "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."

ATTACHMENT C: User Authorization Instructions

Acumen has created the PDE Reports and PDE Analysis web portals to facilitate the PDE Reports and PDE Analysis initiatives. These secure web portals are accessible only to authorized participants, with each sponsor utilizing a space on the portal that is separately secure from all other participants.

In accordance with Federal Information Security Management Act (FISMA) regulations, only the authorizing agent – in this case, the contract's Medicare Compliance Officer – is authorized to give access to the web portal for each contract. To streamline this process, Acumen has developed the User Security Web Portal – a web tool that allows Medicare Compliance Officers to manage their users' permissions to Acumen's web portals.

For your contract to gain access to the PDE Reports and PDE Analysis web portals, your Medicare Compliance Officer must complete the following steps:

1. **Identify individuals who should have access to each web portal.**

   If your contract is continuing from 2022, previously authorized users will retain their access to the PDE Reports and PDE Analysis web portals. Your contract may choose to keep the same users or your contract may modify users.

   If your contract is new in 2023, your contract must authorize new users for both web portals. Your contract may choose to authorize representatives that are currently users on other Acumen web portals. However, your contract must complete the user authorization process again, specifically for the PDE Reports and PDE Analysis web portals.

   Appropriate website users are staff who are either directly involved in the process of PDE data submission and resolution or who oversee a third-party submitter. If a third-party organization is involved in PDE submission, your contract may assign a member of this organization as a user. However, we recommend your contract include at least one internal user from your organization, as one goal of the web portals is to help your contract monitor and resolve third-party submission errors.

   For security purposes, each contract is limited to five authorized users for each web portal.

2. **Log onto the User Security Web Portal (https://partd.programinfo.us/user_security).**

   The latest Medicare Compliance Officer on record in the Health Plan Management System (HPMS) for each contract has been granted access to the User Security web portal. Compliance Officers should have access to the User Security web portal through existing work with Acumen. If your Medicare Compliance Officer does not have access to the User Security web portal or has never logged in, please contact Acumen at PDE@acumenllc.com. If your Medicare Compliance Officer on record in HPMS is incorrect, please update HPMS directly.

3. **Designate users and authorize access permissions via the User Security web portal.**

   Medicare Compliance Officers must complete the user authorization process by reviewing and/or updating current user access settings or authorizing access permissions for new users on the User Security web portal.

   To designate users and authorize access permissions, Medicare Compliance Officers must complete the following steps on the User Security web portal:

   1. Add an existing and/or new user.
   2. Select the Web Portal and contract(s) for each user.
   3. Authorize access permissions for each user.

   Following completion of the user authorization process, Acumen will send authorized web portal users:

   - A Welcome Email with the relevant Web Portal User Guide, Getting Started Guide, and Web Portal URL
   - A Credential Email with a unique One-Time Password Link and login username

   More information on adding users can be found under the Help Documents section of the User Security web portal. Note that all authorized users can log on, navigate the webs portals, and receive email notifications regarding report releases. However, access to the PDE Reports web portal can vary according to two possible access levels for each user:

   - *Summary Report Only*: The user can access a version of the IAP Errors Reports with summary information on PDE submission, rejection, and error resolution statistics. Users with *Summary Report Only* permissions will not be able to access the Eligibility Errors Reports.
   - *Summary and Confidential Beneficiary Reports:* The user can access confidential beneficiary information in the IAP and Eligibility Errors Reports, in addition to the summary version of the IAP Errors Reports.

To ensure timely access to the web portals, Medicare Compliance Officers must complete all steps of the user authorization process no later than two weeks from the date of this memorandum.

If you have any questions or require assistance with the user authorization process, please contact PDE@acumenllc.com or Acumen's website assistance line at (650) 558-8006.