

DEPARTMENT OF HEALTH & HUMAN  
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Centers for Medicare & Medicaid Services  
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**MEDICARE PLAN PAYMENT GROUP**

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**DATE:** January 17, 2025

**TO:** All Medicare Advantage Organizations, Prescription Drug Plans, Cost Plans, PACE Organizations, and Demonstrations

**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 2025 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 provide an update on the continuation of reporting initiatives for the 2025 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 the CMS Contractor for the Medicare Part D Payment Process.<sup>1</sup> Participating sponsors will continue to use the secure PDE Reports and PDE Analysis websites. The remainder of this memorandum provides overviews of the PDE Reports and PDE Analysis initiatives and describes the actions expected from participating sponsors.

**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 website. 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 website. For information on the IAP and the Eligibility Errors Reports, see the

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<sup>1</sup> For contractor information, see HPMS memorandum, *Contractor Change for the Medicare Part D Payment Process*, November 22, 2024 (available at <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-november-18-22>).

HPMS memorandum, *Update: Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2024 Benefit Year*, August, 20, 2024.

CMS has received feedback from Part D sponsors regarding the IAP and Eligibility Errors Reports. Given sponsors' extensive experience with PDE submissions and with these reports, which were developed early in the Part D program, sponsors have requested updates to the IAP and Eligibility Errors Reports. CMS agrees that improvements can be made to the reports to make them more useful to sponsors, taking into consideration how the needs of the sponsors have changed since the reports were first released. As such, CMS paused the release of the reports in 2024. After consideration of sponsor feedback, CMS and our contractor for the Medicare Part D Payment Process will update the reports in 2025. CMS will announce the changes to the reports in a forthcoming HPMS memorandum.

### **PDE Analysis**

Since the 2009 benefit year, CMS has utilized the PDE Analysis initiative to address data quality outliers 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 outliers on accepted PDE records with positive reported gap discount amounts and to obtain sponsor feedback on gap discount PDE records that have been disputed by pharmaceutical manufacturers. CMS is expanding the initiative again to accommodate the Manufacturer Discount Program (MDP) enacted into law in section 11201 of the Inflation Reduction Act of 2022, Public L. 117-169 (IRA) and codified in sections 1860D-14C and 1860D-43 of the Social Security Act. This PDE Analysis initiative will now also address data quality outliers on accepted PDE records with positive MDP discount amounts and will obtain sponsor feedback on MDP discount PDE records that have been disputed by pharmaceutical manufacturers.

Note that although CGDP has sunset and manufacturers will not incur any liability for discounts under CGDP for dates of service after December 31, 2024, CGDP invoicing will continue through January 31, 2028, to allow for PDE submission run-out, with the distribution of the final CGDP invoice by April 30, 2028.<sup>2</sup> The current CGDP outlier and dispute processes will run concurrently with the MDP outlier and dispute processes until the completion of the activities associated final CGDP invoice.

Categories of outlier and dispute postings to the PDE Analysis website are as follows:

- Part D Payment Reconciliation Data Quality Review: posted approximately two to three times each calendar year (benefit years 2024 - 2025)
- General CGDP Data Quality Review outliers: posted approximately two to three times each calendar year (benefit year 2024)
- General MDP Data Quality Review outliers: posted approximately two to three times each calendar year (benefit year 2025)

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<sup>2</sup> See the CGDP and MDP Calendar, available at [https://tpadministrator.com/internet/tpaw3\\_files.nsf/F/TPACGDP\\_MDP\\_Calendar\\_2024-2028\\_12062024.pdf/\\$FILE/CGDP\\_MDP\\_Calendar\\_2024-2028\\_12062024.pdf](https://tpadministrator.com/internet/tpaw3_files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf).

- CGDP Withheld from Invoice and Invoiced Outliers: posted quarterly at the same time as the invoice distribution (benefit years 2021 - 2024)
- MDP Withheld from Invoice and Invoiced Outliers: posted quarterly at the same time as the invoice distribution (benefit year 2025)
- Manufacturer Disputes related to CGDP: posted quarterly approximately two to three weeks after the manufacturer’s dispute submission deadline (benefit years 2021 - 2024)
- Manufacturer Disputes related to MDP: posted quarterly approximately two to three weeks after the manufacturer’s dispute submission deadline (benefit year 2025)
- Upheld Dispute Tracking Reports related to CGDP: posted quarterly approximately three to four weeks after the manufacturer dispute resolution deadline (benefit years 2019 - 2024)
- Upheld Dispute Tracking Reports related to MDP: posted quarterly approximately three to four weeks after the manufacturer dispute resolution deadline (benefit year 2025)

CMS issued guidance on each of these outlier and dispute categories in the HPMS memorandum, *Prescription Drug Event (PDE) Analysis Website for CMS Data Quality Review Outliers, Withheld and Invoiced Outliers, and Reviews of Invoiced Data Disputed by Manufacturers*, January 17, 2025.

Attachment A to this memorandum provides a more detailed overview of the PDE Analysis initiative.

**PDE Reports and PDE Analysis website Access**

The following table summarizes the expected actions and timelines for the launch of the PDE Reports and PDE Analysis reporting initiatives for the 2025 benefit year. See Attachment B for User Authorization Instructions.

Action	Date
<p><b>New 2025 contracts:</b> The Medicare Compliance Officer must complete the user authorization process for the PDE Reports and PDE Analysis website via the User Security website. Instructions are included in Attachment B.</p>	<p>New user requests and current user verification due <b>March 24, 2025</b></p>
<p><b>Contracts continuing from 2024:</b> 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 websites. If necessary, Medicare Compliance Officers can modify existing user access through the User Security website.</p>	
<p><b>New contracts and continuing contracts that authorize new users:</b> Be prepared to receive login credentials and additional project information.</p>	<p>Rolling basis, following new authorizations and/or access updates completed by Medicare Compliance</p>

CMS appreciates 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 the contractor for the Medicare Part D Payment Process at [PDE@acumenllc.com](mailto:PDE@acumenllc.com).

Thank you.

## ATTACHMENT A: Overview of the PDE Analysis Initiative

When a PDE record successfully passes the Drug Data Processing System (DDPS) editing process and becomes an accepted record, the PDE is still 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 website. Sponsors receiving PDE Analysis reports are expected to complete the following actions:

1. **Review Notifications:** Sponsors receive an email notification from [PDEAnalysis@acumenllc.com](mailto:PDEAnalysis@acumenllc.com) when PDE records require review. This notification contains information about the identified issue, benefit year, response process, and pertinent deadlines for taking action on flagged PDE records. Sponsors will not receive a notification if they do not have PDE records for review.
2. **Download and Review Reports:** Reports are made available for download via the PDE Analysis website. 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 PDE records.
3. **Research PDE records:** Sponsors are expected to research PDE records 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 PDE Analysis website:** 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 PDE records. 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 PDE records flagged under the Part D Payment Reconciliation Data Quality Review, General CGDP Data Quality Review, General MDP Data Quality Review, and CGDP Withheld and Invoiced Outliers, and MDP Withheld and Invoiced Outliers categories, sponsors are required to submit responses via the website when data are valid. Responses are not required for PDE records flagged under these categories when data are invalid and will be corrected; however, responses can be submitted.
  - For PDE records flagged under the Manufacturer Disputes categories for CGDP and MDP, sponsors are required to submit responses via the website for all posted PDE records, 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:

<b>Review Category</b>	<b>Sponsor Determines Data are Valid</b>	<b>Sponsor Determines Data are Invalid</b>
<i>Outliers</i>		
Part D Payment Reconciliation Data Quality	Required	Optional
General CGDP Data Quality	Required	Optional
General MDP Data Quality	Required	Optional
CGDP Withheld and Invoiced Outliers	Required	Optional
MDP Withheld and Invoiced Outliers	Required	Optional
<i>Disputes</i>		
Manufacturer Disputes for CGDP and MDP	Required	Required
Upheld Dispute Tracking Reports for CGDP and MDP	No Response Form	

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 guidance 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 PDE records,'* sponsors have 90 days to make any adjustments or deletions via DDPS in response to PDE records posted to the PDE Analysis website.
6. **Track Resolution:** The PDE Analysis website features a Ticket Tracking page that enables sponsors to monitor the status of flagged PDE records. Sponsors should review this page regularly to ensure that all flagged PDE records have been addressed.

## **ATTACHMENT B: User Authorization Instructions**

DDA 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, DDA has developed the User Security Web Portal – a web tool that allows Medicare Compliance Officers to manage their users’ permissions to DDA’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 2024*, 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 2025*, 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](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 DDA. If your Medicare Compliance Officer does not have access to the User Security web portal or has never logged in, please contact DDA at [PDE@acumenllc.com](mailto: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, DDA 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 web portals, and receive email notifications regarding report releases.

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](mailto:PDE@acumenllc.com) or Acumen's website assistance line at (650) 558-8006.