DEPARTMENT OF HEALTH & HUMAN SERVICES
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MEDICARE PLAN PAYMENT GROUP

DATE: September 19, 2025

TO: All Part D sponsors (include PACE)

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

SUBJECT: **Update:** Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2025 Benefit Year

This memorandum updates the January 17, 2025, HPMS memorandum, *Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2025 Benefit Year*, by announcing the following: (1) discontinuation of the Immediately Actionable PDE (IAP) Errors Reports and the Eligibility Errors Reports, and (2) introduction of ad hoc outlier reports.

CMS has several initiatives in place to enhance Medicare payment accuracy and support program integrity goals. The PDE Reports and PDE Analysis initiatives, which are both facilitated by the CMS Contractor for the Medicare Part D Payment Process[1], support the accuracy and integrity of Prescription Drug Event (PDE) data by identifying records that require Part D sponsor correction or research. Because Medicare Part D payment accuracy is tied to properly submitted PDE data, CMS strongly encourages sponsors to take an active and consistent approach when submitting PDE data and resolving potential errors. CMS also encourages sponsor input on the utility of the information provided through these initiatives and uses this feedback to continuously evaluate its approach.

The remainder of this memorandum provides an overview of the PDE Reports and PDE Analysis initiatives, explains changes based on sponsor feedback, and describes the actions expected from sponsors.

PDE Reports *(Updated)*

CMS provided sponsors with reports on the quality, timeliness, and accuracy of their PDE data submission and error resolution efforts through the IAP Errors Reports[2] released through the

[1] 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).
[2] *See* HPMS memorandum, *Prescription Drug Event Reports and Website*, November 8, 2007.

PDE Reports website[3]. 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.[4] CMS received feedback from Part D sponsors about the IAP and Eligibility Errors Reports. Given their experience, sponsors requested updates to make these reports more useful. CMS agreed and paused the release of the reports in 2024 to review and update them based on sponsors' evolving needs.

After reviewing the reports, considering CMS's and sponsors' experience with the Part D program, and examining sponsor feedback, CMS has decided to discontinue the IAP and Eligibility Errors Reports. These reports are no longer required to enhance the accuracy of PDE data. Most of the actionable information previously available in the IAP and Eligibility Errors Reports can be accessed by sponsors through other reports/information that are distributed more frequently and often contain more up-to-date information.

The IAP Reports included a subset of rejected PDE records for which CMS expected plans to take immediate, regular, and consistent action to correct and resubmit. However, all PDE rejects must be reviewed by sponsors upon receiving the Drug Data Processing System (DDPS) Return File, which is produced daily and provides feedback on every processed PDE record. Sponsors are required to resolve rejected PDE records within 90 days of receiving the reject notice from the DDPS Return File.[5]

The Eligibility Errors Reports provided details on PDE records rejected due to enrollment or eligibility discrepancies for a specified date of service. Sponsors can address these issues using the Daily Transaction Reply Report (DTRR), which includes eligibility and enrollment information, along with the low-income subsidy status of a beneficiary. Plans are expected to reconcile their beneficiary records with the DTRR and promptly submit corrected transactions to CMS.[6] Corrections to PDE records stemming from updated enrollment and eligibility information must be made within 90 days of discovering or being notified of the enrollment and eligibility updates.[7]

Feedback from sponsors confirms that they are utilizing the DDPS reports, DTRR, and other more timely reports instead of the IAP and Eligibility Errors Reports to achieve the intended results envisioned by CMS when these reports were developed early in the Part D program. We value this feedback and have decided to concentrate our efforts on reports and outreach initiatives that will more significantly impact the accuracy of PDE data.

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[3] *See* Attachment B of this memorandum.
[4] For information on the IAP and the Eligibility Errors Reports, see the HPMS memorandum, *Update: Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2024 Benefit Year*, August 20, 2024.
[5] *See* HPMS memorandum, *Revision to Previous Guidance Titled "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,"* October 6, 2011, and 42 C.F.R. 423.325(a)(3).
[6] See MAPD Plan Communications User Guide v18.5 (PDF) and the Medicare Prescription Drug Eligibility and Enrollment guidance Downloads available at https://www.cms.gov/medicare/enrollment-renewal/part-d-enrollment-eligibility.
[7] *See* HPMS memorandum, *Revision to Previous Guidance Titled "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,"* October 6, 2011, and 42 C.F.R. 423.325(a)(2).

PDE Reports - Ad Hoc Outliers *(New)*

CMS uses the PDE Analysis website for ad hoc outlier outreach, most recently to identify PDE records needing correction due to a corrected phase-in status for a labeler code[8], inaccurately reported Paxlovid PDE records under the USG PAP, and PDE records exceeding the maximum out of pocket threshold for 2024 and 2025. Notified sponsors were asked to review and adjust or delete PDE records via DDPS. In the future, CMS may request sponsor responses via a Response Form (similar to the outlier and dispute process described in Attachment A of this memorandum) to better understand analysis results and refine processes. These efforts aim to improve Medicare payment accuracy and program integrity. We appreciate the sponsors' participation.

PDE Analysis *(No changes since the 1/17/25 memorandum)*

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 ended 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.[9] The current CGDP outlier and dispute processes will run concurrently with the MDP outlier and dispute processes until the completion of the activities associated the 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)
- CGDP Withheld from Invoice and Invoiced Outliers: posted quarterly at the same time as the invoice distribution (benefit years 2021 - 2024)

[8] HPMS memorandum, *Medicare Part D Manufacturer Discount Program: Correction to Prescription Drug Event (PDE) Records for Labeler Code 70720*, April 23, 2025.
[9] 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.

- 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 *(Updated to remove the 2025 due dates for obtaining access to the PDE Reports and PDE Analysis websites)*

See Attachment B for User Authorization Instructions.

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.

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 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:

Review Category	Sponsor Determines Data are Valid	Sponsor Determines Data are Invalid
Outliers		
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
Disputes		
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).**

   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. 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 webs 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 or Acumen's website assistance line at (650) 558-8006.