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Medicare Plan Payment Group

DATE: April 21, 2015

TO: All Part D Plan Sponsors

FROM: Cheri Rice, Director, Medicare Plan Payment Group

SUBJECT: Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2015 Benefit Year

Reducing fraud and preventing improper payments are top priorities of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS). Accordingly, CMS has a number of initiatives in place to enhance Medicare payment accuracy and ensure program integrity. 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 2015 benefit year that support CMS's efforts to improve the accuracy of sponsors' PDE data. The PDE Reports and PDE Analysis initiatives are both facilitated via secure websites maintained by CMS's contractor, Acumen LLC. The remainder of this memorandum provides overviews of these 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 Acumen's PDE Reports and PDE Analysis Websites.

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 Acumen's 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." In addition, in June 2010, CMS also began providing Part D sponsors with reports on PDE rejects caused by enrollment timing issues through the Eligibility Errors Reports released through Acumen's PDE Reports Website.

Effective April 2015, CMS will begin producing IAP and Eligibility Errors Reports based on PDE data for the 2015 benefit year, in addition to continuing this effort for the 2014 benefit year. Reports for the 2013 benefit year will be discontinued. Attachment A provides a more detailed overview of the PDE Reports initiative, including a description of each set of reports and what actions are expected from sponsors.

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. PDEs are currently posted to Acumen's PDE Analysis Website under the following categories:

- General CGDP Data Quality Review: posted approximately every 4-6 weeks
- Part D Payment Reconciliation Data Quality Review: posted approximately every 4-6 weeks
- PDEs Withheld from the CGDP Invoice: posted quarterly at the same time as invoice distribution
- Manufacturer Disputes: posted quarterly approximately two to three weeks after the manufacturer's dispute submission deadline

CMS issued guidance on each of these categories in an HPMS memorandum released on July 30, 2012 titled "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 initiatives for benefit years 2011 through 2014 and will be beginning these initiatives for benefit year 2015. 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 2015 benefit year.

Action	Date
New 2015 contracts: The Medicare Compliance Officer must complete the user authorization process for the PDE Reports and PDE Analysis Websites via Acumen's User Security Website. Instructions are included in Attachment C. **Contracts continuing from 2014:** 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 Acumen's User Security Website.	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 Officer

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 Acumen's PDE Reports Website 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 2014 IAP Errors Reports, new errors that CMS considers to be immediately actionable – 838, 839, and 880 – will be included in the 2015 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 Acumen's PDE Reports Website.

- **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, and 715.

Sponsors will receive email notification from Acumen when reports are made available for download. All sponsors will receive reports regardless if 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 Acumen's PDE Analysis Website. Sponsors receiving PDE Analysis reports are expected to complete the following actions:

1. **Review Notifications**: Sponsors will receive email notification from Acumen when PDEs require review. This notification will contain 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 will be 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 PDEs.

3. **Research PDEs**: Sponsors are expected to research PDEs to determine the validity and accuracy of the submitted data and to evaluate whether or not 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 to document 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* categories, sponsors are required to submit responses to Acumen 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 to Acumen for all posted PDEs, regardless of whether data are valid or invalid.

   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	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 PDE adjustments or deletions via DDPS in response to PDEs 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 PDEs. Sponsors should review this page on a regular basis 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 four review categories, refer to the HPMS memorandum released on July 30, 2012 titled "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 websites to facilitate the PDE Reports and PDE Analysis initiatives. These secure websites are accessible only to authorized participants, with each sponsor utilizing a space on the site that is separately secure from all other participants.

In accordance with Federal Information Security Management Act (FISMA) regulations, only the Medicare Compliance Officer is authorized to give access to these websites for each contract. To streamline this process, Acumen has developed the User Security Website – a web tool that allows Medicare Compliance Officers to manage their users on the Acumen websites.

In order for your contract to gain access to the PDE Reports and PDE Analysis Websites, your Medicare Compliance Officer must complete the following steps:

1. **Identify individuals who should have access to each website.**

   If your contract is continuing from 2014, previously authorized users will retain their access to the PDE Reports and PDE Analysis Websites. Your contract may choose to keep the same users or your contract may modify users.

   If your contract is new in 2015, your contract must authorize new users for both websites. Your contract may choose to authorize representatives that are currently users on other Acumen websites. However, your contract must complete the user authorization process again, specifically for the PDE Reports and PDE Analysis Websites.

   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 own organization, as one goal of the websites is to help your contract monitor and resolve third party submission errors.

   For security purposes, each contract is limited to five authorized users per website.

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

   If your contract is continuing from 2014, your current Medicare Compliance Officer should already have access to the User Security Website through existing work with Acumen.

   If your contract is new in 2015, your Medicare Compliance Officer should have received or will soon be receiving a welcome email and a letter with login credentials via USPS.

   If your Medicare Compliance Officer does not have access to the User Security Website or requires assistance logging in, please contact Acumen at PDE@acumenllc.com.

3. **Authorize users.**

   Medicare Compliance Officers must submit an Available User Request Form for each proposed user and authorize access permissions for each user.

All authorized users can log on and navigate the websites and receive email notifications regarding report releases. However, access to the PDE Reports Website can vary according to two possible access levels for each user:

- *Summary Report Only*: 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:* 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 websites, 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 Acumen at PDE@AcumenLLC.com.