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**DATE:** September 17, 2015

**TO:** Part D Sponsors and Pharmaceutical Manufacturers

**FROM:** Cheri Rice, Director, Medicare Plan Payment Group

**SUBJECT:** Contract Dispute Tracking Reports

The purpose of this memorandum is to announce the upcoming release of Upheld Dispute Tracking Reports for Part D sponsors. These reports, which will be released via Acumen's Prescription Drug Event (PDE) Analysis Website, will contain details of invoiced Coverage Gap Discount Program (CGDP) PDEs which were disputed by the drug manufacturer, upheld by the Third Party Administrator (TPA), and require follow-up corrective action by the Part D sponsor. The reports will be released on a quarterly basis beginning October 2015. The remainder of this memorandum provides background on the manufacturer dispute process and details the content, timing, and required actions of these reports.

**Background**

As part of the Coverage Gap Discount Program, manufacturers have the right to dispute invoiced discount payments within sixty (60) days of receipt of invoice. The TPA then has sixty (60) days to make a determination of whether to uphold a dispute in favor of the manufacturer or to deny the dispute. To assist with this determination, disputed PDEs may be posted to Acumen's PDE Analysis Website to obtain additional information from the sponsor. Sponsors are required to research these PDEs and submit responses indicating the validity of the disputed PDEs. Any response (or non-response) that the sponsor provides will factor into the TPA's determination of the manufacturer's dispute. For disputes that are ultimately upheld by the TPA, sponsors are expected to take corrective action, such as deleting the PDE or adjusting the relevant financial and/or non-financial field(s) that lead to the error. In accordance with CMS guidance, adjustments or deletions to upheld disputes are subject to the same ninety (90) day timeframe from the time of notification as all other adjustment/deletion activity.<sup>1</sup>

Sponsors are notified of the final determinations of their disputed PDEs via two methods:

- *Dispute Resolution Reports:* Beginning with the 2012 Quarter 2 invoicing cycle, the TPA has released quarterly Dispute Resolution Reports to provide sponsors with information on

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<sup>1</sup> For more information on CMS's guidance for timely submission of adjustments/deletions, refer to the October 6, 2011 Health Plan Management System (HPMS) memorandum titled "Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.'"

which of their invoiced PDEs have been disputed, the Dispute Reason Code submitted by the manufacturer with each dispute, and the TPA's final determination.<sup>2</sup> In April 2014, the TPA also retroactively released Dispute Resolution Reports for the 2011 benefit year, which contained details of the disputed PDEs that had been upheld in favor of the manufacturer.<sup>3</sup> In accordance with CMS guidance, the 90 day adjustment/deletion timeframe begins with the release of the Dispute Resolution Reports.

- *Acumen's PDE Analysis Website:* As previously mentioned, disputed PDEs that require input from the Part D sponsor will be posted to Acumen's PDE Analysis Website during the dispute resolution period for sponsor review. Final determinations for all posted disputes are made available on the PDE Analysis Website Ticket Tracking page under a similar timeframe as the release of the Dispute Resolution Reports. As a reminder, not all disputed PDEs are posted to Acumen's website for sponsor review; therefore, sponsors should refer to the Dispute Resolution Reports to obtain the final determinations on all of their disputed PDEs.

### **Upheld Dispute Tracking Reports**

To enforce that timely corrective action is being taken on all upheld disputes, sponsors will begin receiving quarterly reports containing the details of any disputed PDEs that were upheld by the TPA but have not yet been corrected by the sponsor. These reports contain information on all upheld disputes which require correction from the sponsor for all benefit years and quarters. The purpose of these reports is to ensure that sponsors are submitting the appropriate corrections to their upheld disputes, as such, corrections are necessary to ensure that the invoiced amount is properly credited to the manufacturer after an upheld dispute or that inaccurate financial or non-financial data on the PDE leading to the dispute has been corrected.

These reports will be made available to sponsors via Acumen's PDE Analysis Website. Access to Acumen's website is restricted to authorized users; therefore, only authorized PDE Analysis Website users will be able to download these reports. If sponsors need to make changes to the staff that is authorized to access Acumen's website, Medicare Compliance Officers must make those changes via Acumen's User Security Website. Additional instructions on user authorization for Acumen's website can be found in Attachment A.

Upheld Dispute Tracking Reports will only include upheld disputes that still require follow-up corrective action from the sponsor. If a dispute was upheld but adequate corrective action has already been taken by the sponsor, which resolved the issue that led to the successful dispute, that disputed PDE will not be included in the tracking report. This means that all PDEs included in the Upheld Dispute Tracking Reports should be considered actionable by the sponsor.

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<sup>2</sup> For more information on the Dispute Resolution Reports, refer to the July 30, 2012 HPMS memorandum titled "Contract Dispute Disposition Report and Updates to the Coverage Gap Tracking Report."

<sup>3</sup> For more information on the benefit year 2011 Dispute Resolution Reports, refer to the April 7, 2014 HPMS memo titled "Availability of Contract Dispute Resolution Reports for Benefit Year 2011."

Sponsors will not submit responses to the identified PDEs contained in this report; however, sponsors are required to proceed with making appropriate corrections via the Drug Data Processing System (DDPS). The following actions are expected from sponsors as a participant in this process:

- *Review Notifications:* Authorized PDE Analysis Website users will receive notification from Acumen when reports are made available for download. Sponsors without any upheld disputes that require follow-up corrective action as of the analysis date will not receive a report.
- *Download and Review Reports:* Reports will be accessed via the Download Files page of Acumen’s PDE Analysis Website, and will be separated by year of service. Each report will contain information on the dispute(s) in question, including the invoice quarter in which the PDE was disputed, the original dispute reason, and the PDE data element values.
- *Research PDEs:* Sponsors are expected to research the PDEs included in the Upheld Dispute Tracking Reports to determine the appropriate action that must be taken to address the issue.
- *Take Corrective Action:* Unlike other issues reported to sponsors via Acumen’s website, sponsors will not be submitting responses to PDEs included in the Upheld Dispute Tracking Reports. Sponsors are instead required to proceed directly in making the appropriate corrections to the PDE data. These corrections must be relevant to the financial and/or non-financial PDE field(s) that lead to the dispute and to the error. The following table presents the PDE fields considered especially relevant to each dispute reason; while the list is not comprehensive, sponsors should consider these fields when taking corrective action on their upheld disputes.

<b>Dispute Reason</b>	<b>Relevant PDE Fields</b>
D01 - Duplicate invoice item	Product Service ID
D02 - Closed pharmacy	Service Provider ID Service Provider ID Qualifier Date of Service
D03 - Not a Part D covered drug	Drug Coverage Status Code Product Service ID
D04 - Excessive quantity	Quantity Dispensed Days’ Supply Product Service ID
D05 - Invalid days’ supply	Days’ Supply Product Service ID
D06 - High price of drug	Ingredient Cost Quantity Dispensed Product Service ID
D07 - Last lot expiration date	Product Service ID Date of Service
D09 - Marketing category is not NDA or BLA	Product Service ID
D12 - Invalid prescription service reference	Prescription Service Reference

<b>Dispute Reason</b>	<b>Relevant PDE Fields</b>
number	Number
D13 - Gap discount for disputed PDE exceeds maximum discount amount for a single PDE	Reported Gap Discount Amount
D14 - Total accumulated gap discounts reported across multiple PDEs for a single beneficiary exceed cumulative maximum discount amount	Reported Gap Discount Amount (analyzed at the beneficiary level)
D99 - Other	Varies based on manufacturer's explanation for the dispute

Please note that sponsors do not have the ability to contest the TPA's determination to uphold a dispute, and that sponsors must take adequate corrective action regardless if the sponsor agrees with the upheld determination. Such corrections will be monitored on a regular basis to ensure that action is being taken by the sponsor. Failure to complete the necessary actions in accordance with CMS's timeliness standards may result in compliance action.

General questions regarding the CGDP invoicing or dispute processes should be directed to CMS at [PDEJan2011@cms.hhs.gov](mailto:PDEJan2011@cms.hhs.gov). Questions regarding the Upheld Dispute Tracking Reports or the PDE Analysis Website should be sent to Acumen at [PDEAnalysis@acumenllc.com](mailto:PDEAnalysis@acumenllc.com).

