DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services Center for Medicare 7500 Security Boulevard, Mail Stop C1-13-07 Baltimore, Maryland 21244-1850



Medicare Plan Payment Group

Date: October 6, 2011

To: All Part D Plan Sponsors

From: Cheri Rice /s/

Director

Subject: Revision to Previous Guidance Titled "Timely Submission of Prescription Drug

Event (PDE) Records and Resolution of Rejected PDEs"

On May 16, 2011, CMS released an HPMS memo titled "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs". This memo outlined PDE submission timeframes, however due to feedback received through our dedicated mailbox and through comments/questions received at the Technical Assistance conferences held over the summer; we are revising the submission timeframes as follows:

- Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is greater);
- Resolve rejected records and re-submit within 90 days following receipt of rejected record status from CMS; (prior guidance stated 45 days)
- Submit adjustments 90 days of discovery (prior guidance stated 45 days); and
- Submit adjustments and deletions within 90 days following discovery of issue requiring change. (prior guidance stated 45 days)

CMS will approach monitoring these new standards in phases. Currently, we are developing our analysis protocol for monitoring timeliness of original PDEs. We will share the technical specifications behind how the report is developed with Part D sponsors. We will monitor the results of this analysis for the remainder of this year to better understand the current lag in PDE data submission across all Part D organizations and take note of trends showing improvement in meeting the 30 day requirement. We do not plan to implement compliance activity associated with this analysis during the remainder of the year, however we may contact organizations to offer technical assistance if we see patterns that suggest an issue. We recognize there are a number of factors that impact the timeliness of PDEs submitted to CMS, therefore we will determine an outlier threshold for outreach and compliance based on program-wide analysis results gathered in the remainder of 2011, and implement compliance activities beginning in 2012.

Concurrently, CMS is also developing an analysis protocol for monitoring the timeliness of resolving rejected records. We are analyzing all potential rejection reasons to determine which rejected PDEs can be resubmitted and which PDEs were rejected appropriately or for a reason outside of the sponsor's control. This will be taken into account in the analysis design and will also be published to

Part D sponsors. Similarly, we will monitor Part D sponsors on timeliness of resolving PDE rejects for the remainder of 2011, and begin compliance activities in 2012 based on identified outliers.

Analyzing adjustment/deletion timeliness is significantly more complicated because oftentimes CMS does not know the date of the event that necessitated the change to the original PDE. In our second phase of timeliness analysis, CMS will develop a methodology for identifying adjustments and deletions that we believe can and should be submitted within 90 days. Again, CMS plans to publish this methodology to Part D sponsors. We do not currently have a timeline for completing the report design, monitoring organization performance over time, and implementing compliance action based on a threshold determined using program-wide data.

Questions or comments regarding the timeliness of PDE submissions can be directed to PDEJan2011@cms.hhs.gov.