DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



MEDICARE PLAN PAYMENT GROUP

TO: All Part D Plan Sponsors

FROM: Cheri Rice, Director

Medicare Plan Payment Group

SUBJECT: Updates to the Part D Potential Exclusion Warning Report

DATE: February 23, 2017

The Centers for Medicare & Medicaid Services (CMS) released the Part D Potential Exclusion Warning Report ("Warning Report") ¹ to Part D sponsors on February 16, 2017 in preparation for the 2016 Part D payment reconciliation. Like the previous Warning Reports, this report was distributed through the existing mailboxes used for the Monthly Drug Data Processing System (DDPS) reports. We remind sponsors that Warning Reports identifies issues that the Part D sponsors should already be identifying through their ongoing analysis. CMS provides this report as a courtesy.

We expect that Part D sponsors will address the PDEs in the Warning Report within 90 days of release of the report to remain compliant with CMS requirements. This timing is consistent with our previous guidance on the timely submission of PDEs and resolution of rejected PDEs.² Part D sponsors should use their best judgment to determine if PDEs need to be adjusted or deleted. It is possible that a PDE flagged on the Warning Report may no longer need to be adjusted or deleted due to, for example, changes in enrollment data that may have occurred after the report was created.

Since the release of the first Warning Reports in 2014, there have been updates to the categories of flagged PDEs on the reports. The chart below is a comprehensive list of flagged PDE categories to date. Information regarding additional categories or changes to the existing categories will be released in future HPMS memorandum.

Questions regarding this memorandum or the Warning Reports may be emailed to CMS at pdejan2011@cms.hhs.gov.

¹ For more information on the Warning Report and the subsequent Part D Exclusion from Reconciliation Report ("Exclusion Report"), see the HPMS memoranda, *Reconciliation PDE Exclusion Process*, January 6, 2014, and *Updates to the Reconciliation Prescription Drug Event (PDE) Exclusion Process*, April 16, 2014.

² See the HPMS memorandum, Revision to Previous Guidance Titled "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs," October 6, 2011.

The following categories of flagged PDEs that could appear on a Warning Report:

	Category	Notes
Enrollment	Beneficiaries retro-actively disenrolled (no enrollment in any Part D plan on the date of service (DOS)), or DOS on the PDE is greater than 32 days after beneficiary date of death	Currently, the only category that could carry over to the Exclusion Report.
Low Income Status	Retroactive Low Income (LI) Status or change in LI Copay Levels for the DOS after the PDE was accepted - Beneficiaries awarded Low Income (LI) Status retro-actively Beneficiaries with a loss of LI eligibility after the PDE was accepted	
Prescriber Identifier	Prescription Drug Event (PDE) data with non- National Provider Identifiers (NPIs) in the Prescriber ID field	Only applies to benefit year 2013 since an edit was subsequently implemented to address this category.
Sanctioned Providers	Prescriber listed on OIG LEIE and is not assigned an active sanctioned provider waiver Prescriber listed on OIG LEIE with active sanctioned provider waiver. Verify if waiver applicable Service Provider listed on OIG LEIE and is not assigned an active sanctioned provider waiver Service Provider listed on OIG LEIE with active sanctioned provider waiver. Verify waiver applicable	This Warning Report category identifies PDEs that did not receive edit 789, 790, 793 or 794 due to retroactive notification of sanctioned provider status.
Invoiced Outliers	Beneficiary lost Low Income eligibility for the Date of Service after the PDE was accepted Beneficiary was retroactively disenrolled or the DOS is more than 32 days after date of death. (subset of PDEs identified in the Enrollment category above) PDE with DOS beyond pharmacy NCPDP close date Total Reported Gap Discount Amount for the beneficiary exceeds gap discount threshold (PLRO = 0) Reported Gap Discount Amount on PDE exceeds gap discount threshold Total Reported Gap Discount Amount for the beneficiary exceeds Out-of-Pocket threshold	PDEs that meet the criteria for an outlier are included in the Warning Report when another PDE in the same PDE family has been invoiced already.
Outliers Past Q17 (for non- invoiced benefit years only)	Beneficiary lost Low Income eligibility for the Date of Service after the PDE was accepted Beneficiary was retroactively disenrolled or the DOS is more than 32 days after date of death. (subset set of PDEs identified in the Enrollment category above) PDE with DOS beyond pharmacy NCPDP close date Total Reported Gap Discount Amount for the beneficiary exceeds gap discount threshold (PLRO = 0) Reported Gap Discount Amount on PDE exceeds gap discount threshold Total Reported Gap Discount Amount for the beneficiary exceeds Out-of-Pocket threshold	This includes PDEs that met the criteria for an outlier in Q17. These PDEs are posted to the PDE Analysis website in Q17 and are included on the Warning Report until they are resolved.