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DATE: December 20, 2019

TO: All Part D Plan Sponsors

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

SUBJECT: Updates to the Part D Potential Exclusion Warning Report and Exclusion Report

The Centers for Medicare & Medicaid Services (CMS) is announcing an update to the categories included on the Part D Potential Exclusion Warning Report (Warning Report) and Part D Exclusion from Reconciliation Report (Exclusion Report)¹. CMS distributes the Warning reports in an effort to provide Part D sponsors with the opportunity to address these PDEs before they may be excluded from the reconciliation or reopening process in the Exclusion Report. We remind sponsors that Warning Reports identify issues that the Part D sponsors should already be identifying through their ongoing analysis. CMS provides this report as a courtesy. As of the date of this memorandum, only the Enrollment and Plan-to-Plan (P2P) Categories on the Warning Report may carry over to the Exclusion Report.

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.

The chart below is the current list of flagged prescription drug event (PDE) categories as of the publication date of this memorandum. Note that there is a new Plan-to-Plan (P2P) Category that is specific to reopenings. A PDE will be excluded from a reopening when the PDE was a P2P PDE at the time of the initial reconciliation and is not a P2P PDE at the time of the reopening. For these PDEs, the contract of record was updated after the initial reconciliation so that the

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 HPMS memoranda, *Revision to Previous Guidance Titled "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,"* October 6, 2011

submitting contract is now the contract of record. This contract of record change would result in CMS paying for the PDE twice in the subsequent reopening because the P2P report from the initial reconciliation is used for reopenings and the PDE will now also be listed on the non-P2P report used in the reopening. The overpayment would be attributed to the PDE amount on the reopening's non-P2P report for the updated contract of record, as this amount was previously remitted to the updated contract of record (original submitting contract) during the P2P process. Therefore, the PDE on the non-P2P report will be excluded on the Part D Exclusion from Reconciliation Report for a reopening reconciliation.

Information regarding additional categories or changes to the existing categories will be released in future HPMS memorandum. A list of flagged PDE categories found on the Reports prior to the publication of this memorandum may be found in the HPMS memorandum, *Updates to the Part D Potential Exclusion Warning Report as of the First Quarter of 2018*, January 12, 2018.

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

Thank you

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

Category		Notes
Enrollment	Beneficiaries retroactively disenrolled (no enrollment in any Part D plan on the date of service (DOS)), or the DOS on the PDE exceeds the beneficiary date of death by more than the allowed margin. For PDEs with a DOS prior to 7/1/2017, the allowed margin is 32 days. For PDEs with a DOS equal to or greater than 7/1/2017, if the pharmacy is a Community/Retail Pharmacy Service and the beneficiary lives at home, the margin is 14 days. Otherwise, the margin is 32 days.	May carry over to the Exclusion Report.
Plan-to-Plan	PDE is excluded from reopening when the PDE was a plan-to-plan (P2P) PDE at the time of the initial reconciliation and is not a P2P PDE at the time of the reopening. For these PDEs, the contract of record was updated after reconciliation so that the submitter is now the contract of record.	Exclusion Report category.
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 retroactively.	
	Beneficiaries with a loss of LI eligibility after the PDE was accepted.	
Outliers Past Q17	Retroactive Low Income (LI) Status – Beneficiaries awarded Low Income (LI) Status retroactively.	This includes PDE data 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 after Q17 if they remain unresolved.
	Beneficiaries retroactively disenrolled (no enrollment in any Part D plan on the date of service (DOS)), or the DOS on the PDE exceeds the beneficiary date of death by more than the allowed margin. For PDEs with a DOS prior to 7/1/2017, the allowed margin is 32 days. For PDEs with a DOS equal to or greater than 7/1/2017, if the pharmacy is a Community/Retail Pharmacy Service and the beneficiary lives at home, the margin is 14 days. Otherwise, the margin is 32 days. (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.	
	Gap Discount PDEs after max TrOOP threshold.	