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MEDICARE PLAN PAYMENT GROUP

TO: All Part D Plan Sponsors

FROM: Cheri Rice, Director
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SUBJECT: Drug Data Processing system announcements regarding 2011 PDE rejects,
                Reopening of the 2011 Part D payment reconciliation, and PDE data analysis findings

DATE: April 23, 2013

On June 7, 2012, CMS released a Health Plan Management System (HPMS) memo titled, "Cleanup strategy for rejected Prescription Drug Events (PDEs) impacting the 2011 reconciliation". The memo identified several reject edit codes that required further analysis that could not be completed in time for the 2011 Part D payment reconciliation. The analytic work performed found a mixture of compliance issues, system edit issues, and the need for additional guidance. This memo will summarize the findings of our analysis, explain any necessary adjustments to edits, and highlight some of the plan reporting issues that are causing the edits to generate. This memo will also discuss reopening priorities and how the 2011 reopening fits into that schedule. Finally, this memo will discuss requirements for the claim adjudication began timestamp field based upon feedback received from our request for comments in the January 4, 2013, HPMS memo titled, "Prescription Drug Event (PDE) data analysis findings" and will discuss the issue of inappropriately reporting Covered D Plan Paid (CPP) amounts in the coverage gap (Enhanced Alternative (EA) Mapping Rule 3) for low income beneficiaries.

Edit 671

CMS made adjustments to the editing logic for edit code 671 in February 2012. After this fix, CMS has seen a significant reduction in edit code 671 and the edit occurs infrequently. However, CMS has received emails on two situations which are triggering edit code 671.

In the first scenario, the beneficiary purchases a Part D drug that results in a straddle claim from the coverage gap to the catastrophic phase based upon the Part D sponsor's benefit. After the sponsor calculates the PDE, it is determined that the beneficiary has Other Health Insurance (OHI). Based upon the other payer, the beneficiary would not have moved from the coverage gap to the catastrophic coverage phase, yet the Part D sponsor submits the PDE as if the beneficiary has reached the catastrophic phase. Because the True Out-of-Pocket (TrOOP) accumulator plus the sum of the TrOOP eligible fields is less than the TrOOP threshold amount and Gross Drug Cost Above the Out-of-Pocket threshold (GDCA) is greater than zero, CMS is rejecting the PDE.

CMS has not released guidance on how to report PDEs that fall within this scenario. We will issue future guidance to address this scenario.

The second scenario involves non-Calendar Year (CY) Employer Group Waiver Plans (EGWPs). When the plan is a non-CY EGWP, PDEs are rejecting in error when the non-CY EGWP is using the TrOOP threshold amount from the prior benefit year in which their benefit began and CMS is editing the PDE using the TrOOP threshold for the current calendar year. For example, a non-CY EGWP runs from 7/1/2012 through 6/30/13 and uses $4,700.00 as the TrOOP threshold through 6/30/13. When a PDE is submitted in January 2013, the Drug Data Processing System (DDPS) is evaluating the PDE using the 2013 TrOOP threshold of $4,750.00 as opposed to $4,700.00.

The issue will also impact edit 670, which validates that Gross Drug Cost Below Out-of-Pocket Threshold (GDCB) must be greater than zero when the TrOOP Accumulator is less than the Out-of-Pocket (OOP) threshold.

CMS will correct edit codes 670 and 671 for non-CY EGWPs in November 2013 release of DDPS. We will release more information about these corrections when we issue guidance on the November DDPS updates.

Edit 738

When a PDE is submitted to the DDPS, the National Drug Code (NDC) on the PDE is evaluated and edit 738 is generated when the drug is a Part D non-coverable drug. CMS evaluated NDCs on PDEs that were potentially receiving edit 738 in error that were submitted for review through the PDEJan2011 mailbox. The majority of NDCs submitted were correctly receiving edit 738. A small number of NDCs that had an incorrect subcategory were corrected in the DDPS editing code to allow sponsors to resubmit the PDEs. In general, the updated NDCs were mainly in subcategories 212 (line flush) and 220 (NDC not on market). Sponsors are encouraged to first evaluate any PDEs receiving edit 738. If the sponsor believes edit 738 was generated in error, the sponsor may submit any issues related to edit 738 and the subcategory classification to PDEJan2011@cms.hhs.gov.

Edit 834

Edit 834 was implemented in January 2012 as a result of the requirement in the Advance Notice of Methodological Changes for Calendar Year 2012 for Medicare Advantage Capitation Rates, Part C and D Payment Policies and 2012 Call letter that all prescriber identifiers submitted on standard and non-standard format PDEs must be valid. The edit has not occurred frequently but CMS received feedback from the industry that some PDEs were rejecting in error. A fix is being put in the May 2013 release of DDPS to address false positive reject 834 edits. More details will be provided in our memorandum announcing changes to DDPS for May 2013.

Edit 867

Edit 867 is issued when a PDE with a coverage gap discount is not designated by the Food and Drug Administration (FDA) as New Drug Application (NDA) or Biologics License Application (BLA). It is also issued when a PDE with a coverage gap discount is designated by the FDA as NDA or BLA, but the date of service (DOS) does not fall within the marketing category start and end date on the date of PDE submission. CMS has continued to monitor this edit. We have not seen elevations in the volume of this edit. Due to fluctuations in NDC listing information with the FDA, we do see changes in the NDCs that are causing the edit to be issued.

If sponsors feel that the current marketing category is not listed correctly or the marketing category start and/or end date is not accurate, they should reach out to the manufacturer to notify them of the possible error so that manufacturers can make corrections to the FDA data. Plans can also notify CMS of the issue through the PDEJan2011 mailbox. However, please note that only the manufacturer can update the information with the FDA. CMS cannot make changes to this data and CMS must use this data source to verify the legitimacy of coverage gap discount PDEs.

Edit 870

CMS adjusted the editing logic for 870 and the new editing logic became effective on December 28, 2012. Refer to HPMS memo released on December 26, 2012 titled, "Correction to previous memo titled "Updates to the Drug Data Processing System for Edit 870". After the new editing logic was implemented, there has been a significant decline in the number of PDEs receiving edit 870. CMS has received additional questions regarding 870 even after the implementation of the fix in December 2012. Some of the issues are a result of plan error.

One plan sponsor failed to report CPP when drug costs fell within Enhanced Alternative (EA) mapping rule 4. This error resulted in a negative CMS calculated gap discount amount. The editing formulas are correct. However, if the plan populates the PDE incorrectly, it is possible that the CMS calculated gap discount amount is negative. The negative amount is incorrect but is only calculated in error as a result of plan error in populating the PDE. There was another issue in which the sponsor was not reporting a gap discount for PDEs determined to be gap discount eligible. It should not be assumed that because a brand drug or authorized generic is placed within a plan's generic tier that it will not be eligible for the coverage gap discount. Gap discount eligibility is based on the drug's status with the FDA not where it resides on a plan sponsor's formulary. Another sponsor was receiving edit 870 but the PDEs were being populated differently from what was submitted and approved in their bid. Most of the recent inquiries related to edit 870 have been a result of plan PDE reporting issues and the edit has appropriately rejected these PDEs.

The one issue that CMS needs to address regarding edit 870 is the PDE selection criteria for gap discount editing. PDEs are selected if they meet several criteria, including:

- Date of service >= 1/1/2011;
- NDC is listed at "BLA" or "NDA" by the FDA
- PDE is not a Medicare Secondary Payer (MSP) or Coordination of Benefits (COB) claim;
- PDE is not a compounded drug; and
- PDE must fall partially or completely in the coverage gap.

To determine if the PDE falls within the gap, there are several statements that may be true. One such statement indicates that the Total Gross Covered Drug Cost Accumulator > Initial Coverage Limit (ICL) and the TrOOP Accumulator + Patient Pay Amount + Other TrOOP Amount + Low Income cost-sharing Subsidy (LICS) + Reported Gap Discount <= OOP. The flaw with this statement is that it does not exclude PDEs in which the beneficiary is in the catastrophic coverage phase, all TrOOP eligible fields are zero, and PLRO is > zero. CMS will adjust the selection criteria for edit 870 so that only PDEs where Delta TrOOP >0 (sum of Patient Pay Amount, Other TrOOP Amount, LICS, and Reported Gap Discount) are selected for editing. CMS expects to have the selection criteria fixed and in production for DDPS by the end of June.

The editing logic implemented in December 2012 is working correctly. If sponsors receive edit 870, the first step in resolution should be to evaluate the PDE compared to the bid information submitted for the benefit year to ensure that the PDE is being populated according to the co-pays and coinsurance listed in the bid data. The next step is to ensure that the PDE is being populated according to the steps for populating coverage gap PDEs published in CMS guidance. If the sponsor has followed these two steps and believes that they have found a trend in which PDEs are consistently being rejected with edit 870, then the sponsor may want to submit a sample to CMS for review.

Edit 871

Edit 871 has not occurred frequently; however, CMS has received some inquiries related to this edit. The sample PDEs reviewed by CMS showed discrepancies between the cost-sharing structure provided in the bids versus what the plan was reporting on the PDE. This reporting discrepancy is causing the edit to reject the PDEs but this is expected since the sponsor is reporting the PDE differently from what was submitted in the bid. From our analysis of edit 871 PDEs, the edit is appropriately rejecting the PDEs. If a sponsor receives this edit, the sponsor should follow the steps outlined above under edit 870.

Data Stability and Reopening of Previous Payment Reconciliations

CMS reconciliation resources have not fundamentally changed since the beginning of the program. However, the volume and complexity of PDE and DIR data submissions has substantively increased over that time, especially with the introduction of the coverage gap discount program. This necessitates focus on the largest issues with material impact.

CMS has received numerous emails regarding the status of a 2011 Part D Payment Reconciliation. CMS intends to eventually perform a global reopening of 2011, but not until we see stability in the data for that year. For previous coverage years, we have observed substantive data movement due to audit and other post reconciliation oversight activity. The oversight cycle for 2011 has not even fully begun yet. Accordingly, CMS is not in the position to assess the stability of CY2011 PDEs and DIR at this time.

CMS has observed relative stability in the data for 2007 and 2008. Both years have had material changes necessitating a reopening. This has been requested by many plan sponsors. We plan on reopening benefit years 2007 and 2008 during the current calendar year. We will then assess benefit years 2009 and 2010 prior to making any plans to reopen 2011.

Claim Adjudication Began Timestamp

CMS released a HPMS memo on January 4, 2013, requesting feedback from sponsors regarding the Claim Adjudication Began timestamp. Based upon the responses, CMS would like to summarize its expectations for populating this field.

CMS will continue the requirements for this field that were stated in the July 9, 2010, HPMS memo titled, "Revised Guidance for Prescription Drug Event (PDE) Record Changes Required to Close the Coverage Gap". In that guidance, we state that when a sponsor submits an adjustment or a deletion/resubmission PDE, the Claim Adjudication Began Timestamp will change. CMS also expects the timestamp to be unique for each PDE. However, we are clarifying that CMS will not implement a requirement to populate the field to nanosecond level. Moreover, CMS will not implement reject edits to ensure that the field is unique or that it is being changed for adjustments or deletion/resubmission records. However, we will review the data and may perform outreach and/or compliance actions if the requirements are not being followed.

CPP on Coverage Gap PDEs for LICS beneficiaries

CMS found a significant number of PDEs in which the beneficiary falls completely in the coverage gap phase of the benefit (EA Mapping Rule 3, not Rule 4), the beneficiary is low income, and CPP is reported in error. This error was found in all plan types and is not limited to EA plans. The majority of commenters to this analysis indicated that CPP is allowed when the drug cost falls within Rule 4. Although this is true, the analysis was limited to Rule 3 PDEs. CMS expect sponsors to review their accepted PDE data for this potential reporting issue and make corrections to the PDEs in time for the 2012 Part D payment reconciliation. CMS will re-run the analysis prior to reconciliation and may issue compliance actions for any organization that has not corrected the PDEs.

Any questions regarding to issues addressed in this memo can be submitted to PDEJan2011@cms.hhs.gov.