

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

TO: Pharmaceutical Manufacturers

FROM: Cheri Rice, Director, Medicare Plan Payment Group
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DATE: January 27, 2015

RE: Updates to the Medicare Coverage Gap Discount Program Manufacturer Dispute and Appeals Submission Process

The Centers for Medicare & Medicaid Services (CMS) is announcing updates to the codes in the manufacturer dispute and appeal processes for manufacturer disputes associated with the Coverage Gap Discount Program (CGDP). These updates are intended to streamline the manufacturer dispute process, align dispute and appeal codes, and provide manufacturers with reason codes that if upheld are more likely to provide meaningful invoicing updates. Manufacturers must use the following codes beginning with disputes and appeals of fourth quarter 2014 invoiced amounts:

Reason for Manufacturer Dispute	Dispute Code	Appeal Code
Duplicate Invoice Item	D01	A01
Closed Pharmacy	D02	A02
Not Part D Covered Drug	D03	A03
Aberrant Quantity/Invalid Days Supply	D04	A04
High Price of Drug	D06	A06
Last Lot Expiration Date-NDC not on the market	D07	A07
Marketing category is not NDA or BLA	D09	A09
PDE improperly invoiced beyond manufacturer agreement Invoice period	D11	A11
Excessive Gap Discount Gap Discount for Single PDE- disputed PDE exceeds maximum discount amount for a PDE	D13	A13
Excessive Gap Discount Gap Discount for Multiple PDEs- total accumulated gap discounts for a single beneficiary exceed cumulative maximum discount	D14	A14
Other	D99	A99

As part of this change the following dispute reason codes will no longer be available for use in submitting manufacturer disputes effective February 8, 2015: Invalid Days' Supply (D05), Early Fill (D08), Date of Service is Prior to 01/01/2011 (D10), and Invalid Prescription Service Reference Number (D12). The rationale for deactivating these dispute reason codes is as follows:

Invalid Days' Supply (D05)

When a dispute is submitted on the basis of invalid days' supply, the dispute should demonstrate that the days' supply is inconsistent with the packaging of the product or that it represents a days' supply that is unlikely in the Medicare population. The Third Party Administrator (TPA) generally will deny a dispute filed on the basis that the days' supply is not a medically appropriate variation in dosing as the dispute process is not intended to be used as a retrospective utilization management review.

CMS has found that when manufacturers have disputed a gap discount amount reported on the Prescription Drug Event (PDE) record on the basis of days' supply, the rationale provided most often by the manufacturers is that the days' supply reported is inconsistent with the packaging of the product, i.e. the quantity dispensed. This same rationale is also most often the basis for disputes submitted under D04 Excessive Quantity. For this reason, we believe that manufacturers who wish to submit on the basis of days' supply should submit these disputes under reason code D04 Excessive Quantity if the manufacturer believes that the days' supply is inconsistent with the quantity submitted. In limited instances, manufacturers have cited that they believe the days' supply is inconsistent with the price of the drug. In these instances, D06 High Price of the Drug should be used. Manufacturers should continue to use the D04 and D06 reason codes as described in our March 5, 2012 guidance released through HPMS titled, "Medicare Coverage Gap Discount Program—Dispute Resolution."

Early Fill (D08)

To date, the TPA has received very few disputes citing this reason as the basis. Because there are many situations in which a beneficiary may receive an early fill of a prescription such as a vacation supply, replacement for lost or damaged medications, or another clinically appropriate temporary removal of pharmacy refill too soon edits, CMS is deactivating this dispute reason code.

Date of Service Prior to 01/01/2011 (D10) and Invalid Prescription Service Reference Number (D12)

The TPA has received no disputes on the basis that the date of service for the dispensing event was prior to 1/1/2011 and very few disputes on the basis that the Prescription Service Reference Number is invalid. Gap discount PDEs accepted from Part D sponsors are saved after a rigorous set of data edits are applied. In addition to the extensive editing process, PDEs with coverage gap amounts are subjected to additional data analysis by CMS before they are used to generate invoices to the manufacturers for the CGDP. For example, the editing process prevents the invoicing of gap discount amounts reported prior to the start of the Coverage Gap Discount Program by rejecting any PDEs reporting gap discount amounts with dates of service prior to 1/1/2011. Because the PDE editing process rejects PDEs with the conditions that these dispute reasons address, CMS is deactivating these dispute codes.

Dispute Submission File Edit Updates

Any disputes submitted with the deactivated reason codes after February 8, 2015, will receive new reject edit E126 stating that the dispute reason code can no longer be used:

E126: "Dispute reason code is no longer valid."

The new reject edit E126 will return this message when triggered by the submission of any of the deactivated dispute reason codes (D05, D08, D10, or D12) if the code is submitted after February 8, 2015. Manufacturer dispute submission file edits associated with the aforementioned dispute reason codes will also be deactivated after February 8, 2015:

E250: "For dispute reason code D05. Additional Information field is blank. Additional information is required."

E280: "For dispute reason code D08. Supporting Detail Reference Number is missing. The Detail Reference Number of the previous fill is required."

E281: "For dispute reason code D08 - Additional Information field is blank. Additional Information is required."

If a manufacturer should find a reason to submit a dispute for any of the above reasons, the dispute reason code of Other (D99) should be used. When using the D99 dispute reason code, manufacturers should populate the Additional Information field with a description of the basis of the dispute and include any supporting dates or detail reference numbers in the appropriate fields.

Updated versions of the Dispute Submission File, Dispute Return File, and Dispute Resolution File layouts and the Dispute Reason Code and Dispute Submission File Edit spreadsheets have been posted to the TPA website.

Please direct any questions regarding this guidance to the Third Party Administrator at tpaoperations@tpadministrator.com or 1-877-534-2772.