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

CENTER FOR MEDICARE

TO: Pharmaceutical Manufacturers

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Medicare Coverage Gap Discount Program Appeals Guidance – Request for Comment

DATE: April 7, 2011

The purpose of this memorandum is to obtain comments from manufacturers on the draft guidance on the bases for appeals under the Medicare Coverage Gap Discount Program (Discount Program). CMS is implementing this appeals process in accordance with section 1860D-14A(c)(1)(A)(vii) of the Affordable Care Act of 2010 and section V of the Medicare Coverage Gap Discount Program Agreement (the Agreement). Section 1860D-14A(c)(1)(A)(vii) requires CMS to provide a reasonable mechanism to resolve manufacturer disputes involving the discounts provided under the Discount Program. Section V of the Agreement specifies the rights and obligations of CMS and manufacturers for resolving such disputes. A copy of the Agreement can be found on the CMS website at: http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage. The guidance, which follows below, proposes policies for CMS and manufacturers to resolve invoice-related appeals in accordance with these statutory and contractual requirements. CMS is issuing this draft guidance for public comment through close of business April 23, 2011. Comments should be sent electronically to CGDPandManufacturers@cms.hhs.gov. CMS will issue final guidance after considering all public comments.

Draft Bases for Appeals under the Medicare Coverage Gap Discount Program

Overview

Manufacturers receive quarterly Manufacturer Invoice and Data reports from Palmetto, the third party administrator (TPA) that detail their liability for the gap discounts advanced to beneficiaries by Part D sponsors. Additional information regarding the determination and provision of these gap discounts by Part D sponsors may be found in the Discount Program guidance dated May 21, 2010 that is posted on the Part D Information for Pharmaceutical Manufacturers webpage.

Manufacturers have the right to contest information contained in the quarterly Medicare Part D Discount Information on the Manufacturer Data Report. The first level of review is the dispute

process which is adjudicated by the TPA. Within 60 days of receipt of the information that is the subject of the dispute, manufacturers must electronically submit all discount payment disputes using the Dispute Submission Report file format provided by the TPA. The Dispute Submission Report file format and instructions are located on the CSSC Operations TPA/Drug MFG Webpage under the "FileLayouts" link at: http://csscoperations.com/Internet/Cssc.nsf/docsCat/TPA%20Drug%20MFG~File%20Layouts?open.

If the manufacturer is not satisfied with the findings of the TPA, the second level of review is the appeal process, which is conducted by the independent review entity (IRE), Provider Resources Inc. The second level of review may only be initiated after a disposition of a dispute submission by the TPA or when the TPA does not issue a finding within 60 days. In those instances where the manufacturer disagrees with the IRE ruling, the third level of review is to request review by the CMS Administrator.

Bases for Appeals

Manufacturers may appeal an unfavorable dispute determination to the IRE if the manufacturer in good faith continues to believe that disputed discount payments are in error. CMS believes the vast majority of questions will be resolved based on confirmation of PDE data during the dispute process. Manufacturers should be aware that they will not receive additional information from CMS during the appeal and that the burden of proof that the submitted data is in error is on the manufacturer. To proceed to the appeal phase, manufacturers will need to explain why the unfavorable dispute determination was wrong and why the information provided with the original dispute demonstrates that a discount payment is in error. Supporting evidence on appeal is limited to that which was submitted with the original dispute unless additional information is requested by the IRE. In making the decision to appeal, manufacturers should consider that CMS already performs editing on PDE records and conducts outlier analysis that is checking for duplicates, applicable NDCs, and incorrect gap discount calculations, prior to invoicing. When making an appeal determination the IRE may take into consideration previous CMS analysis and validations performed before or during the resolution of the first level dispute.

CMS believes there are several reasons for appeal based upon industry research and the following sections are intended to clarify what CMS expects manufacturers to demonstrate on these appeals.

NDC Not on Market

An "NDC Not on Market" appeal means that the last lot for that NDC has expired. The IRE will further review "NDC Not on Market" appeals if the manufacturer demonstrates that the date of service postdates the last lot expiration date for the NDC and that the manufacturer had timely reported that expiration date to the Food and Drug Administration (FDA). CMS reminds manufacturers that they are required to maintain updated electronic FDA listing of all NDCs, including the timely removal of NDCs no longer on the market from the FDA NDC Directory. Manufacturers should refer to section 5 of the December 17, 2010 guidance for additional information on their responsibility to maintain up-to-date listings with both the FDA and electronic database vendors (e.g. First DataBank, Medispan) used for pharmacy claims processing.

Aberrant Quantity

CMS will consider a quantity to be aberrant if it represents a clearly excessive quantity for a given days supply. Legitimate variations in patient characteristics and the therapeutic characteristics of drugs may warrant appropriate dosing in excess of FDA Labeling. Therefore, CMS is focusing on situations that are most likely to represent Aberrant Quantity and not medically appropriate variation in dosing. Generally, we would consider appeals based on the manufacturer's determination that the quantities represent greater than three times the maximum FDA labeled daily dose to warrant further review and validation. Manufacturers who consider product dosages, whether more or less than three times the maximum FDA dosages, to be aberrant should be prepared to demonstrate to the satisfaction of the IRE that the dosage represents a severe threat to the health of beneficiaries.

Part B Drugs Ineligible for Discount

Many prescription drug products that are covered under Medicare Part B may also be covered under Medicare Part D depending upon the indication or provider setting. For example, an injectible drug product that is covered under Medicare Part B when provided in a physician office from the physician's stock might be covered under Medicare Part D when dispensed by a pharmacy. Generally, the IRE will further review Part-B-drug-ineligible-for-discount disputes if the manufacturer demonstrates that the applicable drug would not be covered under Part D because the Service Provider indicated on the detailed Manufacturer Data Report does not represent a pharmacy. Please refer to Section 20.2 and Appendix C of Chapter 6 of the Medicare Prescription Drug Benefit Manual for more information on Medicare Part B versus Medicare Part D coverage.

High Price of the Drug/Excessive Gap Discount

The maximum gap discount amount is 50% of the negotiated price (less supplemental gap benefits, dispensing fee, and vaccine administration fee) between the Part D sponsor and the pharmacy as documented in the September 24, 2010 guidance entitled "Prescription Drug Event Edit Guidance Effective January 1, 2011". CMS performs an outlier analysis on PDE records to validate gap discount amounts prior to invoicing. Considering that manufacturers do not have access to the actual negotiated price of a drug between a Part D sponsor and a pharmacy, the manufacturer will need to demonstrate that the gap discount amount is excessive and likely in error.

Appeals Process

Manufacturers may request an appeal to the IRE within the earlier of thirty (30) calendar days of an unfavorable determination by the TPA, or sixty (60) calendar days after the submission of the initial request for dispute if the manufacturer does not receive a timely determination by the TPA. The Appeals Request Form (see attachment one) and instructions for completing and submitting the Appeals Request Form will be found at http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp.

The manufacturer must ensure a complete submission of the Appeals Request Form to ensure consideration of their request. Incomplete forms will be returned to the manufacturer for

completion or may be subject to denial. The Appeals review will not begin until the IRE receives a complete submission. In addition to the information provided by the manufacturer, the IRE will base its decision on information received by CMS, the TPA, the Part D sponsor, and other databases compiled by CMS or other sources.

The IRE will issue a determination via email to the manufacturer's contact person of record, the individual submitting the Appeals Request Form (if this is not the same person), and appropriate CMS staff within 90 days of receiving the Appeals Request Form. The IRE will include a reason and explanation for each of its determinations on the Appeal Reply.

Administrator's Review

A manufacturer that has received an unsatisfactory determination of its appeal may request a final review by the Administrator within 30 calendar days of that determination. Instructions on how to submit an appeal to the Administrator will be included with the IRE decision.

The Administrator has the discretion to elect or decline to review the IRE decision, and will notify the manufacturer's contact of record and CMS staff of his or her determination regarding review of the IRE decision. If the Administrator declines to review the IRE decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the IRE is final. All determinations by the Administrator will be final and binding.

Attachment One
Coverage Gap Discount Program DRAFT Appeal Request Form

Instructions: Submit the completed electronic form along with all supporting documentation to cgdpappeals@cms.hhs.gov. You will receive an automated email response indicating that the submission has been successfully received. Incomplete submissions will result in a delay or denial of your appeal. Questions may be submitted to cgdpappeals@cms.hhs.gov.

Summary Information		
Dispute Reference Number		
Date Dispute submitted to TPA		
Date of TPA Decision (if applicable)		
Contact Information		
Manufacturer Name		
P Number		
Name of Individual Submitting Appeal		
Email Address		
Telephone Number		
Alternate Contact Name		
Email Address		
Telephone Number		
Appeal Detail		
Invoice Report ID (e.g. 201101)		

Detail Reference Number	**NDC(s) in dispute**	**Dispute Reason Code**	**Amount Invoiced**	**Amount in dispute**	**Supporting Data***
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	

***** List file names of accompanying data which support Appeal