DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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

DATE: May 31, 2011

This memorandum provides manufacturers with the revised guidance for appealing invoiced discount payments under the Medicare Coverage Gap Discount Program (Discount Program). CMS issued the draft guidance on April 7, 2011 for public comment. We reviewed all of the timely comments received and are making a number of changes and clarifications in this guidance. However, not all of the comments are addressed in this guidance because they were beyond its scope. We will consider addressing other comments, such as those pertaining to our low-volume cell policy, in future guidance or rulemaking.

CMS is implementing an 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) of the Act requires us to provide a reasonable mechanism to resolve manufacturer disputes involving the discounts provided under the Discount Program and section V of the Agreement specifies the rights and obligations of both 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 specifies the standard that manufacturer appeals must satisfy in order for the independent review entity (IRE) to further review and validate a disputed discount payment. This guidance also clarifies what facts manufacturers must demonstrate, at a minimum, to satisfy this standard. The standard is necessary to help ensure that the appeals process efficiently and effectively addresses potential gap discount payment errors in accordance with statutory and contractual requirements while discouraging the submission of appeals based primarily upon unfounded bases. We will evaluate the implementation of the appeals process, and revise this guidance in the future, if necessary, to address issues that might emerge.

Bases for Appeals under the Medicare Coverage Gap Discount Program

Overview

Manufacturers receive quarterly Manufacturer Invoice and Data reports from Palmetto GBA, LLC., the third party administrator (TPA), detailing their liability for the coverage 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 CMS Part D Information for Pharmaceutical Manufacturers webpage.

Manufacturers have the right to dispute invoiced discount payments based on the Medicare Part D Discount Information on the Manufacturer Data Report. 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 TPA confirms that the gap discount is correct, the manufacturer may appeal to the IRE, Provider Resources, Inc. Manufacturers may only appeal disputes that 1) were initially submitted to the TPA and have received a timely unfavorable determination from the TPA or, 2) were not resolved by the TPA within 60 days of submission. CMS will oversee the IRE to ensure it makes determinations in accordance with statutory, regulatory, and CMS requirements but we cannot otherwise intervene in specific IRE determinations. If the manufacturer receives an unfavorable determination by the IRE, the manufacturer may request review of the IRE determination 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. However, CMS believes the vast majority of disputes will be resolved during the initial dispute process with the TPA based on confirmation of prescription drug event (PDE) data. Therefore, manufacturer appeals must demonstrate why the disputed discount payment likely is in error in order for the IRE to further review and validate a disputed discount payment. A discount payment is in error only if it is not accurately calculated or if it is not calculated based upon accurate data that represents the dispensing event that occurred. It is not an error if the discount payment is accurately calculated based upon accurate data for dispensing events that actually occurred, even if the amount calculated appears to indicate that the dispensing event may not have been clinically appropriate. [In other words, the appeals process is not intended to "look behind" or second guess the clinical decision making of the prescriber or Part D plan.]

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 likely 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, and manufacturers will

not receive additional information from CMS. In making the decision to appeal, manufacturers also 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. The IRE may take into consideration such previous CMS analysis and validations performed before or during the resolution of the initial dispute when making an appeal determination.

Based upon industry research, we believe there are several primary dispute reasons that may reasonably be appealed and the following sections are intended to clarify what we expect manufacturers to demonstrate on these appeals to justify further review and validation by the IRE. While manufacturers are not precluded from appealing other unfavorable dispute determinations, manufacturers need to determine that the information it provided with the original dispute meets the standard for appeal.

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 and validate "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). We remind 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

A quantity is considered aberrant if it represents a clearly excessive quantity for a given days' supply or is inconsistent with packaging of the product. Legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling. Therefore, appeals should be based on quantities that likely represent errors and not medically appropriate variation in dosing.

Generally, the IRE will further review and validate appeals based on the manufacturer's representation that the quantities represent greater than three times the maximum FDA labeled daily dose. To justify further review and validation by the IRE, manufacturers that appeal quantities that represent doses less than three times the maximum FDA labeled daily dose, or for any quantity-related appeal if there is no maximum FDA labeled daily dose, will need to demonstrate that the dose represents a severe threat to the health of beneficiaries, is inconsistent with the packaging of the product, or otherwise represents an unlikely dose in the Medicare population.

Not Part D Covered Drug--Part B Drug 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 patient and/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. Conversely, other drug products, such as oral anticancer drugs or IVIG, may be covered under Medicare Part B or Part D when dispensed by a pharmacy depending upon the indication and/or patient setting.

Manufacturers that appeal a discount payment on the basis that the drug product is covered under Medicare Part B must specify which Medicare Part B coverage category is the basis for their appeal to justify further review and validation by the IRE. If the appeal is based upon an injectible drug product being covered under Medicare Part B when provided incident to a physician's service, the Service Provider indicated on the detailed Manufacturer Data Report cannot be a pharmacy because pharmacies do not provide drugs in this Medicare Part B benefit category. If the appeal is based upon a Medicare Part B benefit category that may be dispensed from a pharmacy, the manufacturer must demonstrate that the claim likely should have been covered under Medicare Part B. The IRE may use Part D sponsors' previous B vs. D coverage determinations as the basis for determining these appeals. 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 manufacturers will need to provide other reliable information to demonstrate that the gap discount amount is excessive and likely in error to support further review and validation by the IRE.

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. A link to the IRE can be found on the CMS manufacturer's page at http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage under "Related Links Outside CMS". This link will take the manufacturer to the IRE's website where an account must be created (if one has not already been established). In order to set up a new account, the manufacturer must provide the manufacturer name, an email address and create a password. After creating the account, the manufacturer will be able to submit new appeals and track existing appeals in the future. Submission of the appeal requires completion of an online Appeal Request Form; a hard-copy version of the form is provided in Attachment One of this document. An automated email response will be sent to the manufacturer to confirm receipt of the appeal.

As the IRE considers the appeal the manufacturer may receive a request for additional information. Failure to comply with this request within the time frame specified may result in a denial of the appeal. 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 electronically 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 appeal. The IRE will include a reason and explanation for each of its determinations on the appeal reply document.

Administrator's Review

A manufacturer that has received an unfavorable 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 determination.

The Administrator will notify the manufacturer's contact of record and CMS staff of his or her determination. All determinations by the Administrator will be final and binding.

Attachment One
Coverage Gap Discount Program Appeal Request Web-Based Form

Instructions: Complete the information below and click the "Submit" button to send your appeal. You will receive an automated email response indicating the submission has been successfully received. Questions regarding the completion of this form may be submitted to cgdpappeals@provider-resources.com.

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	**Date Dispute Submitted to TPA**	**Date of TPA Decision**	**Dispute Resolution Code (if applicable)**	**Reason Code for IRE Appeal**	**Explanation for IRE Review Request**	**Amount Invoiced**	**Amount Appealed**
						$ -	$ -
						$ -	$ -
						$ -	$ -
						$ -	$ -

Appeal Detail Data Dictionary	
Field Name	**Definition**
Report ID	Year/quarter item that was placed on manufacturer invoice. Format is YYYYQQ.
Detail Reference Number	The unique coverage gap reference number for this coverage gap discount found on the manufacturer invoice.
Date Dispute Submitted	Date manufacturer sent dispute to TPA per the manufacturer dispute submission.
Date of TPA Decision	Date TPA dispute decision was rendered and manufacturer was notified.
Dispute Resolution Code (if applicable)	Drop down menu from the TPA'S decision for the manufacturers dispute : 1) Upheld 2) Denied 3) Denied/Rejected on error 4) Denied/Received after 60 days
Reason for Appeal	Drop down menu for the reason the manufacturer is appealing the TPA decision to the IRE: 1) NDC Not on Market 2) Aberrant Quantity 3) Not Part D Covered Drug (i.e., Part B Drug Ineligible for Discount) 4) High Price of the Drug/Excessive Gap Discount 5) Other
Reason for IRE Review Request	Text field for manufacturer to provide a detailed explanation for submitting an appeal request to IRE
Amount Invoiced	Net payment amount reported on invoice.
Amount Appealed	Invoice amount appealed.