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TO: Pharmaceutical Manufacturers

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

SUBJECT: Medicare Coverage Gap Discount Program -- Verification of 2012 Labeler Codes

DATE: July 20, 2011

The purpose of this memorandum is to provide pharmaceutical manufacturers with operational guidance necessary to validate labeler codes for participating in the Medicare Coverage Gap Discount Program (Discount Program) for the 2012 benefit year.

In March 2011, CMS released the Drug Manufacturer Module in the Health Plan Management System (HPMS). The module stores the manufacturer points of contact, labeler codes and Manufacturer Agreements. In order to ensure that CMS has an accurate list of labeler codes for the 2012 benefit year, manufacturers must verify their labeler codes within HPMS no later than **August 12, 2011**. CMS will continue to hold manufacturers responsible for the payment of discounts associated with existing labeler codes in HPMS that manufacturers fail to verify for the 2012 benefit year in accordance with the following instructions.

Instructions to Verify Labeler Codes

- Use the following navigation path in HPMS to verify labeler code information: HPMS Homepage>Contract Management>Drug Manufacturer Start Page>choose Select Contract Number>Labeler Concur Data.
- On the Edit Labeler Concur Data page, select “Yes” or “No” in the Concur column for each labeler code. If “No” is selected, use the dropdown box in the Non-Concur Reason column to select one of the reasons provided. Organizations may also provide additional text in the Notes field.
- Once you have answered yes or no respectively for each labeler code, click Next.
- On the Confirm Labeler Concur Data page, select Submit.
- Once the data has been submitted, the data can be viewed by selecting View Labeler Concur Data.

CMS will investigate any labeler codes submitted to CMS with a non-concur status. Upon confirmation that either: 1) all NDCs under the labeler code have passed their last lot expiration date, or 2) the labeler code was transferred to another manufacturer in 2012, CMS will initiate

the deletion of the labeler code effective January 1, 2012 and your organization's primary contact will automatically receive an email notification.

CMS intends to post the initial list of covered labeler codes for the 2012 benefit year to the CMS website in the early Fall. The list will be posted at http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage. This initial list represents a point in time and will be updated on a monthly basis beginning January 2012 to reflect any additions or deletions to labeler codes.

Please submit any questions about this memorandum to cgdpandmanufacturers@cms.hhs.gov or call Shelly Winston at 410-786-3695.