

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
Cheri Rice, Acting Director, Medicare Plan Payment Group

SUBJECT: Medicare Coverage Gap Discount Program Guidance

DATE: December 17, 2010

The purpose of this memorandum is to provide pharmaceutical manufacturers with operational guidance necessary for participating in the Medicare Coverage Gap Discount Program (Discount Program) and fulfilling the obligations required under the Medicare Coverage Gap Discount Program Agreement (Manufacturer Agreement). The Discount Program becomes effective January 1, 2011.

CMS relies on correct and timely manufacturer information for the production of accurate Discount Program invoices. Manufacturers that fail to update their information per the timeframes below and, as a result, are billed for discounts based on incorrect information, must pay the amounts billed, and CMS will not consider such failure to be grounds for successful dispute of invoiced amounts. This memorandum provides manufacturers with required timeframes and processes for reporting to CMS changes in points of contact, labeler codes, and ownership.

Requirements include:

- Completion of the CMS User ID Access form in preparation for the automation of routine communication and reporting functions associated with the Discount Program. Manufacturers are required to submit documentation to CMS no later than **January 21, 2011**. (Section 1)
- Maintenance of contact information (Section 2)
- Submission of all labeler codes and updates to the list of codes when new codes become available (Section 3)
- Submission of changes in corporate ownership (Section 4)

- Maintenance of up-to-date electronic FDA registrations and listings of all national drug codes (NDCs), including the timely removal of discontinued NDCs from the FDA NDC Directory (Section 5)

Section 1. HPMS Access

CMS is in the process of modifying the existing Health Plan Management System, (HPMS) software in order to support the Discount Program. This change will result in creation of a manufacturer module that will automate many routine communication and reporting functions associated with the Discount Program.

Once this system is available manufacturers will utilize the HPMS module for Discount Program administration. The module will provide a vital link between contracted manufactures and CMS. Manufacturers will maintain and update their own points of contact, update and verify labeler code information, and view the Discount Agreement on line through HPMS.

We expect that the first release of the HPMS manufacturer module will be available for use in March 2011. In preparation for this automation, all points of contact (see section 2) within the manufacturer's organization must complete a CMS User ID Access form before they will be able to access the data. The form can be located by clicking on the following link: <http://www.cms.hhs.gov/AccessstoDataApplication/>. Completed CMS User ID forms must be returned to CMS no later than **January 21, 2011** to ensure timely processing. Instructions to complete the User ID form are provided in Attachment 1. Manufacturers must include their P #____ on the CMS User ID form. Return the completed CMS User ID forms to:

ATTENTION: Gregory Buglio
Centers for Medicare & Medicaid Services
Re: HPMS Access for Manufacturers
7500 Security Boulevard
Mail Stop: C4-18-13
Baltimore, MD 21244

Section 2. Manufacturer Contact Information

During the contracting process, each manufacturer participating in the Discount Program was required to provide CMS with a primary contact, a signatory contact, and a third-party submitter contact (if applicable). CMS used this information during the process of securing Manufacturer Agreements and has continued to communicate Discount Program information to contracted manufacturers' designated points of contacts.

Each manufacturer is responsible on an ongoing basis for communicating any changes in contact information to CMS¹. Failure to do so will jeopardize the manufacturer's knowledge of, and thus compliance with, key program requirements and deadlines. CMS will not waive any Discount Program requirements to accommodate missed communication due to outdated contact information.

¹ Medicare Coverage Gap Discount Program Agreement, Section II(f) and Section IX(a)3.

Manufacturers may now add more individuals as points of contact to make sure that their organizations stay updated on Discount Program developments. Please make all point-of-contact changes using the following process:

- Use the contact information form that is available on the CMS Part D manufacturer's webpage at http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage.
- Submit the completed form with updated information via email to CGDPandmanufacturers@cms.hhs.gov.
- Enter "Updated Contact Spreadsheet for P #____" in the subject line of the email. Each manufacturer has been assigned a P number, which must be included in all correspondence to CMS.

Section 3. Labeler Codes Covered by a Manufacturer Agreement

Along with their signed Manufacturer Agreements, manufacturers submitted Labeler Code Spreadsheets to indicate the labeler codes covered by their agreements. Manufacturers are responsible for keeping the lists of labeler codes current on an ongoing basis and must provide all of their FDA-assigned labeler codes to CMS². Manufacturers that fail to update their labeler codes per the timeframes specified below are responsible for paying the amounts invoiced and will be unable to successfully appeal the amounts invoiced on the grounds that the labeler code data is incorrect.

Manufacturers must use the following process to update labeler codes:

- Use the Labeler Code Spreadsheet template found at http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage
- Submit labeler code changes via email to CGDPandmanufacturers@cms.hhs.gov.
 - a. For the Addition of New Codes:**
 - New labeler codes are those that are either newly FDA-assigned or have not been previously specified by the manufacturer.
 - Submit the new code(s) to CMS as soon as possible but no later than 3 business days after having received written notification of the codes from the FDA.
 - Enter "Labeler Code Addition for P#____" in the subject line of the email.
 - Submit any new labeler code(s) to CMS in advance of providing database vendors, such as First DataBank and Medispan, with any NDCs associated with the new codes.

² Medicare Coverage Gap Discount Program Agreement, Section II (c).

- List the NDCs with the FDA in advance of commercial distribution of the product so that CMS and Part D sponsors can accurately identify applicable drugs once they are provided to pharmacies for distribution to patients.

CMS will add new code(s) to the manufacturer's record and the CMS web posting of Coverage Gap Participating Labeler Codes the first business day of the month following the request as long as the manufacturer's request to add the code is submitted at least 5 business days prior to month's end.

b. For the Transfer of Labeler Codes:

- Manufacturers' business needs may call for transfer of existing labeler code(s) from one manufacturer to another. In these cases CMS requires that both manufacturers take part in the transfer process.
- Submit a transfer request 45 days prior to an invoice date in order for the change to be included in that invoice. Transfer requests received after that time will be effectuated the subsequent quarter. The labeler code owner of record remains liable for payment of all discounts until the transfer is complete.
- The labeler code owner of record must submit a request to CGDPandmanufacturers@cms.hhs.gov for the labeler deletion indicating the company that will assume ownership of the code and the proposed effective date for code transfer.
- Enter "Transfer of Labeler Code for P #____" in the subject line of the email.
- CMS will confirm the code transfer with the proposed new owner of the code.
- If both manufacturers are in accord with the transfer, CMS records the transfer and associated transactions will become effective at the beginning of the next quarter. The existing labeler owner of record will be responsible for paying discount amounts until both companies receive a notice from CMS that the code has been transferred to the new owner.
- The transfer of labeler codes must include all NDCs associated with that labeler code. CMS will not transfer individual NDCs.

Manufacturers should be aware of the following regarding invoice production and processing of labeler code transfers:

- Manufacturers' quarterly invoices will be billed on the last business day of the month following that quarter.
- Invoices will be based upon all Prescription Drug Event (PDE) activity received by CMS during the quarter; as the year progresses invoices may include claims from prior quarters' dates of service. This means that once a manufacturer assumes liability for discounts associated with a labeler

code, that company will be billed for any residual discounts from dates-of-service that occurred prior to the transfer of the labeler code.

- Manufacturer invoices will include discount amounts by labeler code for the entire quarter. Labeler code activity will not be billed in time increments smaller than a quarter.

In the event that business needs do not coincide with the timing of the transfers, manufacturers are expected to reconcile any Discount Program payments among themselves without CMS involvement. CMS will hold the owner of record responsible for making discount payments until the CMS-designated transfer date.

c. For the Deletion of Labeler Codes:

Routine Requests-Manufacturers will have an opportunity to remove obsolete labeler codes from their listings of approved codes during an annual confirmation process to be established by CMS. Further guidance on the validation of existing labeler codes for the upcoming contract year will be forthcoming.

Section 4. Changes in Manufacturer's Corporate Ownership

Manufacturers must notify CMS of a change in ownership within 30 days after the manufacturers execute a legal obligation for such an arrangement and no later than 45 days prior to the change in ownership taking effect.

In the event of a transfer in manufacturer ownership, the Discount Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect. In the event of an acquisition, CMS will bill, and the acquiring entity shall pay, all applicable discounts for the acquired company³. In the event that CMS was not notified of an ownership change per the timeframe specified then the original manufacturer will be invoiced and payment will have to be reconciled between the manufacturers involved in the transaction. CMS will not consider untimely notice of changes of ownership to be grounds for manufacturers to successfully dispute the invoiced amount.

Section 5. Maintenance of FDA Records

CMS relies on the FDA to identify applicable drugs in the Discount Program.

Manufacturers must ensure that all of their drug products (i.e. national drug codes (NDCs)) are properly listed on the FDA NDC Directory. Manufacturers must electronically list and maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory⁴. Accurate NDC listings will enable CMS and Part D sponsors to accurately identify applicable drugs and, accordingly, updates to the FDA NDC Directory must precede NDC additions made to commercial electronic databases used for pharmacy claims processing. Manufacturers will not be able to successfully appeal invoiced amounts based on inaccurate or out-of-date FDA NDC Directory listings without documentation that the manufacturer notified the FDA of an error, or requested that an out-dated NDC be

³ Medicare Coverage Gap Discount Program Agreement, Section IX (b).

⁴ Medicare Coverage Gap Discount Program Agreement, Section II(k).

removed from the Directory, in order to show that it was not a result of manufacturer non-compliance with the Discount Program requirement.

In addition, CMS expects manufacturers to maintain up-to-date listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Only the manufacturers know the last-lot expiration dates for their NDCs and therefore, the manufacturers are responsible for ensuring that these electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market. A manufacturer's failure to provide appropriate advance notice to electronic database vendors may result in the manufacturer's being responsible for discounts after the last-lot expiration date unless the manufacturer can document that it provided such appropriate advance notice to the database vendors, or the manufacturer has provided advance notice to the FDA of the marketing end date⁵.

Please submit any questions about this memorandum to CGDPandmanufacturers@cms.hhs.gov or call Shelly Winston at 410-786-3694.

⁵ Medicare Coverage Gap Discount Program Agreement, Section II(g).

Attachment 1

Requesting HPMS Access for New Users

- If your organization does not have HPMS access, please download a copy of the Application for Access to CMS Computer Systems form at:

<http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf>

- Complete the form as follows:

- o Section 1 – Check “New” as the type of request.
- o Section 2 – Check “Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – Using HPMS Only”. Complete the other data entry fields, as appropriate.
- o Section 3 – Enter the P# ___ for which you need access.
- o Section 4 – Check the first row beneath the "Default Non-CMS Employee" row (i.e., place a check in the Connect box of the third row). On the blank line beside your check mark, write "HPMS_P_CommUser".
- o Section 5 – State briefly that you require HPMS.
- o Section 6 – Leave blank.
- o Sign and date the Privacy Act Statement on page 3 of the form. Also enter your name and Social Security Number at the top of page 3. This step is critical to ensuring the successful processing of your request.

- Send the completed form to the attention of Gregory Buglio via an expedited mail service by June 11, 2010:

ATTENTION: Gregory Buglio
Centers for Medicare & Medicaid Services
Re: HPMS Access for Manufacturers
7500 Security Boulevard
Mail Stop: C4-18-13
Baltimore, MD 21244

- On each individual’s form, please ensure that it includes an original signature/date, social security number, and the contract number(s) for which the user needs HPMS access.

Your request will **not** be processed without completing these steps.

Please send any questions regarding HPMS access to gregory.buglio@cms.hhs.gov. Thank you for your prompt attention.