

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

TO: Pharmaceutical Manufacturers

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DATE: March 25, 2011

SUBJECT: Release of the Health Plan Management System (HPMS) Drug Manufacturer Module

CMS is pleased to announce the release of the HPMS Drug Manufacturer Module. To access the module, pharmaceutical manufacturers should use the following navigation path: HPMS Homepage>Contract Management>Drug Manufacturer Data.

The Drug Manufacturer Module is pre-populated with baseline information and pdf versions of the Manufacturer and Third Party Administrator Agreements provided to CMS during the contracting process for the Coverage Gap Discount Program (Discount Program). The Module enables manufacturers to make routine changes to their company's data. This guidance revises and supersedes the December 17th guidance for maintaining contact and labeler code information.

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 CMS will not waive any Discount Program requirements to accommodate missed communication due to outdated contact information.

CMS will no longer accept updated contact information through email.

Manufacturers must use the following process to make all point-of-contact changes:

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

- Use the following navigation path in HPMS to update contact information: HPMS Homepage>Contract Management>Drug Manufacturer Start Page>choose Select Contract Number>Contact Data.
- Manufacturers now may add more individuals as points-of-contact to make sure that their organizations stay updated on Discount Program developments.

Labeler Codes Covered by a Manufacturer Agreement

Along with their signed Manufacturer Agreements, manufacturers submitted labeler code Spreadsheets to indicate the labeler codes that are 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.

CMS will no longer accept updated labeler code information through email.

Manufacturers must use the following process to update labeler codes:

- Use the following navigation path in HPMS to update labeler code information: HPMS Homepage>Contract Management>Drug Manufacturer Start Page>choose Select Contract Number>Labeler Data.
 - a. **For the Addition of New Codes:**
 - New labeler codes are those codes that are newly FDA-assigned and have not been previously used by any 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.
 - The primary contact and secondary contact (if available) identified in HPMS will receive an email indicating that the request to add a labeler code has been received. After the approval/denial of the additional labeler code, the primary and secondary contact (if available) identified in HPMS will receive an email indicating the approval and effective date or the denial.
 - 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.
 - 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.

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

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 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 through HPMS for the labeler deletion indicating the company that will assume ownership of the code and the proposed effective date for code transfer.
- The primary contact and secondary contact (if available) identified in HPMS will receive an email indicating that the request to transfer (add/delete) a labeler code has been received. After the approval/denial of the transfer (adding/deleting) for labeler code, the primary and secondary contact (if available) identified in HPMS will receive an email indicating the approval and effective date of the transfer or the denial.
- 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 the email notice from CMS with the effective date that the code is 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, the 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 through HPMS. Further guidance on the validation of existing labeler codes for the upcoming contract year will be forthcoming.

For more information on how to use the Drug Manufacturer Module, click on the “User Guide” link on the Drug Manufacturer Module Start Page in HPMS.

Questions concerning this memorandum may be sent in an email to CGDPandmanufacturers@cms.hhs.gov or call Shelly Winston at 410-786-3694.

If you require technical assistance, please contact the HPMS Help Desk at hpms@cms.hhs.gov or 1-800-220-2028.