DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

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TO: Pharmaceutical Manufacturers

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SUBJECT: Medicare Coverage Gap Discount Program Guidance

The purpose of this memorandum is to clarify operational guidance for pharmaceutical manufacturers participating in the Medicare Coverage Gap Discount Program (CGDP). This document incorporates use of the Health Plan Management System (HPMS) Manufacturer Module, which automated many of the administrative functions specified in the initial guidance[1], and also further clarifies current deadlines for labeler code changes.

HPMS Access

The HPMS Manufacturer Module provides a vital link between CMS, manufacturers, and the Third Party Administrator (TPA). Manufacturers are responsible for maintaining their own points of contact and updating and verifying labeler code information through HPMS, (accessible at https://hpms.cms.gov/app/login.aspx). Therefore each manufacturer must designate individuals to maintain HPMS content for their organization. Manufacturers who signed CGDP agreements after2011 can also view and download their signed agreements through HPMS.

In order to gain access to HPMS, the individual must complete a CMS User ID Access form. The following link includes a summary of the User ID Process and the CMS User ID EUA Access Form application: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html. On the EUA Access form, Section 3, Manufacturers need to insert the P number in place of the contract number requested.

[1] See *Medicare Coverage Gap Discount Program Guidance,* dated December 17, 2010.

Manufacturer Contact Information

All manufacturers participating in the CGDP are required to provide CMS with Primary, Signatory TPA Liaison and CGDP Payment contact types, and are encouraged to use the optional Secondary Contact and Secondary Signatory Contact fields as well. Small or start-up manufacturers may have a single individual serve as several contact types. Descriptions of all manufacturer contact roles are provided within the HPMS Manufacturer Management Module.[2] Manufacturers should note that the TPA's Liaison Contact listed within the CGDP Portal must match the CMS' TPA Liaison Contact listed within HPMS in order for that individual to have access to invoicing information.

Each manufacturer is responsible for immediately updating HPMS with any changes to its contacts. Instructions to complete updates to contact information are included in the Drug Manufacturer Module User Guide within the HPMS' Drug Manufacturer Management module, under Documentation.[3] Failure to provide up-to-date contacts will jeopardize the manufacturer's knowledge of, and thus compliance with, key program requirements and deadlines. CMS will not waive any CGDP requirements to accommodate missed communications due to outdated contact information. HPMS contact information can be changed at any time. Newly assigned points of contact must complete and submit a CMS User ID Access form in order to be able to access data in HPMS.

Labeler Codes Covered by a Manufacturer Agreement

Manufacturers must provide CMS with all FDA-assigned labeler codes for the manufacturer's Applicable drugs[4] and are responsible for updating their labeler codes on an ongoing basis. HPMS must be used to request labeler code additions, deletions or transfers. Instructions to complete labeler code updates are included in the Drug Manufacturer Module User Manual within HPMS' Drug Manufacturer Management module, under Documentation. Please note the following:

Addition of New Labeler Codes:

New labeler codes are those that are either newly FDA-assigned or have not been previously specified by the manufacturer. A manufacturer must add any new labeler codes through HPMS as soon as the codes are assigned by the FDA, in advance of FDA drug approval. A new Applicable drug product, even if FDA approved for sale, is not eligible for coverage under the Medicare Part D program unless the labeler code is covered under a Manufacturer Agreement.

[2] Available via the following path: HPMS>Main Menu> Contract Management>Drug Manufacturer Data>Documentation>Drug Manufacturer Module User Manual.

[3] Available via the following path: HPMS>Main Menu>Contract Management>Drug Manufacturer Data>Documentation>Drug Manufacturer Module User Manual

[4] See 42 CFR 423.2315

In the event that a manufacturer has drugs associated with a new labeler code, the manufacturer should do the following to make sure that their drugs are eligible for coverage under Part D as soon as possible:

- List National Drug Codes (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.

- Add the labeler code into HPMS before database vendors, such as First DataBank and Medi-Span, receive NDCs associated with the new codes.

Timing: Requests to add the codes must be submitted into HPMS at least five business days prior to the month's end to be included in the following month's web posting of Coverage Gap Participating Labeler Codes.

Removal of Labeler Codes from the Agreement:

A manufacturer may request deletion of a labeler code from its contract through HPMS. CMS will approve the request only if the FDA NSDE file reflects retrospective last lot expiration dates for all Applicable Drugs (as defined in 42 CFR § 423.100) associated with the code.

While the request to delete a code must be submitted through HPMS,[5] the manufacturer must attest that there is no intention to use or add products under that labeler code by sending email to CGDP&manufacturers@cms.hhs.gov.

Timing: HPMS requests to delete codes along with the accompanying attestation must be received at least five business days prior to the month's end in order to become effective the following month. Consistent with the CGDP agreement, manufacturers will be invoiced for residual discounts after the codes are deleted.

Transfer of Labeler Codes between Manufacturers:

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 participate in the transfer process through HPMS; one manufacturer must request that the code be deleted from its record and the other manufacturer must request an addition to its record. Instructions for each function can be found in the User's manual within the Drug Manufacturer Module.

- After both manufacturers submit labeler code change requests through HPMS, CMS must approve each request. Transfers are not considered complete until both manufacturer requests have been approved. Each manufacturer's Primary Contact is notified via HPMS email when its request has been approved. The labeler code owner of record remains liable for payment of all discounts until the transfer becomes effective. Please see the Labeler Code Update Calendar for key dates in the transfer process on the TPA's

[5] Instructions for labeler code changes can be found in the Drug Manufacturer User Manual accessible at HPMS>Main Menu>Contract Management>Drug Manufacturer Data>Documentation>Drug Manufacturer Module User Manual.

website[6] or CMS' Part D Information for Pharmaceutical Manufacturers page.[7]

- The transfer of labeler codes includes all NDCs associated with that labeler code.

Timing. Please refer to the Labeler Code Update Calendar on the CMS and TPA websites.

Invoicing Policies and the Transfer of Labeler Codes:

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

- Manufacturer invoices are distributed according to the CGDP Calendar posted on the TPA's website.[8]
- Manufacturer invoices include discount amounts by labeler code for the entire quarter. This means that the manufacturer that assumes liability for a labeler code effective the second or third month within a quarter will be billed for all PDE activities for all three months (first, second, and third).
- The new labeler code owner receives the quarterly invoice if a transfer becomes effective by the third month of the quarter. Please see Labeler Code Update Calendar referenced above. For example,
    - If a labeler code transfer request is approved in February and becomes effective on March 1st, the Q1 invoice will be delivered to the new labeler code owner.
    - If a labeler code transfer request is approved in March and becomes effective on April 1st, the Q1 invoice will be delivered to the prior labeler code owner.
- Invoices are based upon all Prescription Drug Event (PDE) activity received by CMS during the quarter; 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 is billed for any residual discounts from dates of service that occurred prior to the transfer of the labeler code but were received by CMS after the transfer of the labeler code.
- The Invoice Reporting Period for Quarter 17 (Q17) ends on January 31 of each year. Although the invoice for this quarter is delivered on April 30, it only includes PDEs reporting gap discount amounts for that benefit year's Q17 submitted by January 31. For this reason, if there is a new labeler code owner to be invoiced for Q17, any changes must be submitted within 5 business days of the end of December to be included in January's posting of Coverage Gap Participating Labeler Codes. If submitted in January, the prior labeler code owner still receives the invoice for Q17.

[6] http://tpadministrator.com >CGDP Calendar
[7] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Pharma.html
[8] http://tpadministrator.com > CGDP Calendar

In the event that business needs do not coincide with the timing of the transfers, manufacturers are expected to reconcile any CGDP payments among themselves without CMS involvement. CMS holds the HPMS owner of record responsible for making discount payments until both manufacturers submit labeler code change requests through HPMS and until the quarter in which the transfer takes effect.

Changes in Manufacturer's Corporate Ownership or Company Name

Below, CMS outlines the process for reporting changes in manufacturer's corporate ownership or asset ownership and company names. The purpose of this guidance is to help manufacturers ensure products remain covered under a Manufacturer Agreement, without interruption, to promote the timely processing and payment of CGDP invoices.

1) Processes for Ownership Changes

The following situations describe typical types of ownership changes and the process to be followed:

a. Sale or Transfer of a Product(s) only

CMS does not normally need to be notified of asset sales. However, manufacturers should keep in mind that CMS administers the CGDP based on labeler codes. This means that:

- CMS invoices manufacturers for all Applicable Drugs within a labeler code. If individual drug products within a labeler code are sold, the manufacturer who owns the code is invoiced for all products within the code.

- If an Applicable Drug is covered under an agreement and is then sold to a non-contracted manufacturer that re-labels the drug such that it no longer is covered under a Discount Agreement, the drug can no longer be covered under Part D.

b. Corporate Sales or Mergers

- Contracted Manufacturer to Contracted Manufacturer Purchases: This includes the merger or acquisition of a corporate entity that holds a CGDP Agreement into another corporate entity that also holds a CGDP Agreement. The parent organization involved in these transactions must comply with the Notification Requirements listed in item "2" below.

- Contracted Manufacturer to Non-contracted Manufacturer Purchases: This involves the acquisition of a contracted manufacturer by a non-contracted manufacturer. The CGDP Manufacturer's Agreement states that the Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect.

2) Notification Requirements for Changes in Ownership and Company Name Changes

All organizations considering a change of corporate ownership must notify CMS at least 60 days prior to the anticipated effective date of change. If a manufacturer fails to notify CMS of a change in ownership, the entity risks delayed notification of invoices due, and will be liable for any resulting civil monetary penalties. The notice to CMS regarding a change of ownership, above, must contain the following information:

- Name and P number(s) of the manufacturers involved in the ownership change, and the anticipated role of each party.
- The anticipated date of the change.
- A statement of which corporate entity will be responsible for processing and paying the invoices after the corporate change.
- A statement indicating all changes in contacts and when these changes will be requested within HPMS and through the TPA.

All organizations that make a corporate name change must notify CMS immediately and submit a Certificate of Amendment within 30 days of the effective date of change. All required notifications as described above should be sent to CMS via email at: CGDP&manufacturers@cms.hhs.gov.

Maintenance of FDA Records

CMS relies on FDA listings to identify applicable drugs in the CGDP. 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 Directory. Accurate NDC listings 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 outdated NDC be removed from the Directory, in order to show that it was not a result of manufacturer non- compliance with the CGDP 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 document and provide appropriate advance notice to electronic database vendors may result in the manufacturer being responsible for discounts for drugs dispensed after the last-lot expiration date.

Please submit any questions about this memorandum to CGDP&manufacturers@cms.hhs.gov or call Sonia Eaddy at 410-786-5459.