

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: April 20, 2012

TO: Pharmaceutical Manufacturers

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

SUBJECT: Medicare Coverage Gap Discount Program Basics

Section II (f) of the Coverage Gap Discount Program (Discount Program) manufacturer agreement requires that manufacturers comply with CMS' administrative requirements in order for their drugs to continue to be eligible for coverage under Medicare Part D. The purpose of this memorandum is to provide manufacturers that are new to the Discount Program with some general information about program operations to help them fulfill their obligations under the agreement.

At a minimum, we recommend that participating manufacturers become familiar with the following:

Manufacturer Web page
Systems Connectivity
Discount Program Calendar
Manufacturer Resources
Disputes and Appeals

Manufacturer Web Page

CMS' manufacturer page includes items of particular interest to manufacturers participating in the Discount Program. The page is updated at least monthly and includes an archive of CMS guidance documents. It can be found at

http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage.

Systems Connectivity

Manufacturers must have access to two distinct systems in order to fulfill their obligations under the Discount Program. CMS' Health Plan Management System (HPMS) serves as the system of record for manufacturer contracts and the Third Party Administrator (TPA)'s system performs invoice-related functions. Both systems identify each manufacturer by "P" number, the unique identifier assigned to each manufacturer during the contracting process.

HPMS Each manufacturer must gain access to HPMS in order to maintain accurate contact information, request labeler code changes and perform other administrative tasks. Instructions for requesting access to HPMS are attached to this memo.

CMS uses HPMS points of contact to disseminate relevant information to manufacturers. It is critical that each manufacturer maintain up-to-date HPMS contact information and immediately update the information whenever changes occur. Failure to meet deadlines will not be excused for reasons of incorrect contact information on file.

Manufacturers should contact CMS about how name changes, mergers, acquisition or other corporate changes can be entered into HPMS. Once such changes are in HPMS they are then conveyed to the TPA for assimilation into that data base.

Manufacturers also must request additions or deletions of their labeler codes through HPMS. The effective dates for requesting labeler code changes can be found in the CMS December 17, 2010 guidance posted on the manufacturer web page.

Beginning with 2013 agreements, HPMS also has electronic signatory capability. Each manufacturer should make sure that its signatory's information is accurately reflected within HPMS and that the designated signatory has access to HPMS. (Instructions for requesting that electronic signature capability be added to the signatory's HPMS access will be forthcoming.)

TPA: By this time each manufacturer contracted for the 2012 contract year has established connectivity with the TPA. We encourage manufacturers to thoroughly review the CSSC website, www.csscooperations.com, for file formats to be used for invoices, invoice reports, confirmation files and disputes submissions.

Discount Program Calendar

CMS has developed a Discount Program calendar which can be found on the Manufacturer Page. Please note that the first invoices with 2012 dates of service will be posted to manufacturers' mailboxes on April 30, 2012. In order to allow sufficient time to process payments due by June 8, 2012, we recommend that manufacturers access their invoices as soon after April 30 as possible.

Manufacturers are responsible for downloading invoice files and submitting confirmation files by the deadlines specified. ***In addition, the TPA will not accept disputes after the designated filing deadlines.***

Other Manufacturer Resources

User Group Calls.

CMS conducts periodic manufacturer user group calls. The site to register for the calls is <http://www.msccginc.com/registration/pm.cfm>. Individuals must know their company's P number in order to register. Please contact Winsome Higgins at 410-786-1835 with any questions about the user group calls.

Email and Phone Inquiries

There are a number of resources available to answer individual manufacturer questions. Please consult the following table to determine the right resource for your question based upon the nature of the inquiry.

Topic	Email Address	Phone Number
Policy, Agreement or Administrative Related	CGDPandmanufacturers@cms.hhs.gov	410-786-3694
Invoice or Disputes Submission Process	csscooperations@palmettogba.com	877-534-2772
HPMS Password Resets	CMS_IT_service_desk@cms.hhs.gov	410-786-2580
HPMS Non-password Related Access Assistance	HPMS_access@cms.hhs.gov	Not Available
HPMS Help Desk for Non-access Technical Assistance	HPMS@cms.hhs.gov	1-800-220-2028

Disputes and Appeals

Manufacturers must pay all amounts invoiced by the TPA but may dispute the accuracy of the invoices. Per the Discount Program Agreement, the manufacturer cannot withhold payment pending resolution of a dispute or appeal.

The dispute process includes three levels of review. First, manufacturers may ask the TPA to review the accuracy of the invoice submitted. If the manufacturer receives an unfavorable determination from the TPA or the TPA fails to make a determination within 60 days, the manufacturer may appeal to the independent review entity (IRE). Finally, if the manufacturer receives an unfavorable determination from the IRE, the manufacturer may appeal the IRE's decision to the CMS Administrator.

CMS has issued guidance documents pertaining to disputes and appeals that are posted on the manufacturer's page. Manufacturers need to familiarize themselves with these guidance documents prior to submitting disputes.

We look forward to working with you and appreciate your participation in the Coverage Gap Discount Program. Please contact Shelly Winston at 410-786-3694 if you have any questions about this document.

Attachment – Requesting HPMS Access

- Download the *Application for Access to CMS Computer System* form from <http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf>
- Complete the form as follows:
 - Section 1- Check “New” as the type of request unless you have a CMS user ID. (If you have a CMS user ID you may file it in on the top right and check “connect/reconnect”).
 - Section 2 – Check “Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – **Using HPMS Only**” and complete the other data entry fields, where applicable.
 - Section 3 – Enter the P# ____ (s) for which you need access.
 - 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_CommlUser".
 - Section 5 – State briefly that you require HPMS.
 - Section 6 – Leave blank.
 - 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 ensuring the successful processing of your request.
- Submit the original (not a copy) user access for to CMS via traceable carrier to:

ATTENTION: Adam Foltz
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.
- Once access has been granted you will receive an email from HPMS with your user name and ID.