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TO: Pharmaceutical Manufacturers

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

SUBJECT: Revised Coverage Gap Discount Program Agreement for 2014

DATE: October 19, 2012

The Centers for Medicare & Medicaid Services (CMS) published a notice of proposed rulemaking for public comment on October 11, 2011 (76 FR 63018) that included provisions pertaining to the Medicare Coverage Gap Discount Program (Discount Program). The final rule, published on April 12, 2012 (77 FR 22072), codifies the Discount Program requirements in 42 CFR 423. Accordingly, we have revised the 2014 Discount Program Agreement to reference and conform to the new regulations. All manufacturers participating in the Discount Program must electronically sign the revised Agreement.

The revised Discount Program Agreement is now available to view in its entirety on the CMS pharmaceutical manufacturer webpage at [http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp#TopOfPage](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage). The Agreement will be available for manufacturer signature from December 4, 2012 to January 30, 2013.

In preparation for the January signature timeframe, manufacturers should begin to ensure that the individuals with the authority to enter into contracts for their organization have the necessary HPMS credentials to sign the agreement. Only those individuals who are assigned in HPMS as the Signatory contact will be permitted to electronically sign the Discount Program Agreement. Consequently, all Signatory Contacts must have a CMS user ID with electronic signature access in HPMS. To access the electronic signature in HPMS, an individual must: a) obtain a CMS user ID with access to HPMS; and b) request that the electronic signature functionality be assigned to the CMS user ID.

The detailed instructions will depend upon the type of user seeking access:

User Type	Instructions
The individual does not have a CMS user ID.	<ul style="list-style-type: none"><li>• Complete the steps described in <b>Attachment A</b> in order to obtain a CMS user ID with access to HPMS.</li><li>• Following the issuance of the CMS user ID, complete the steps described in <b>Attachment B</b> in order to obtain electronic signature access in HPMS for CY 2012.</li></ul>

<p>The individual has an existing CMS user ID, but requires electronic signature access in HPMS.</p>	<ul style="list-style-type: none"> <li>• Complete the steps described in <b>Attachment B</b> in order to obtain electronic signature access in HPMS for CY 2012. <b>Note:</b> Signatories must establish their official role and contract associations with CMS by completing the steps in Attachment B.</li> </ul>
<p>The individual has an existing CMS user ID but requires technical assistance.</p>	<ul style="list-style-type: none"> <li>• If you do not recall your password please call 1-410-786-2580.</li> <li>• For all other HPMS assistance contact the HPMS Help Desk at CMS1-800-220-2028</li> </ul>

CMS strongly recommends that organizations submit the necessary materials to obtain electronic signature **no later than November 9, 2012.** For general questions related to HPMS user access please contact the HPMS User Access Team at [HPMS\\_Access@cms.hhs.gov](mailto:HPMS_Access@cms.hhs.gov).

As stated above, manufacturers will be able to view and electronically sign the revised 2014 Discount Program Agreements in HPMS from December 4, 2012 through January 30, 2013.

For general questions related to the revised 2014 Discount Program Agreement please send an email to [CGDPandManufacturers@cms.hhs.gov](mailto:CGDPandManufacturers@cms.hhs.gov).

## **Attachment A – Requesting HPMS Access for a New User**

If the Signatory does **not** have an active CMS user ID with access to HPMS, the user must follow these steps to obtain a CMS user ID:

- 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.
  - 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.

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

**Note:** If electronic signature access is required, the user must complete the steps described in Attachment B once the CMS user ID is established.

## **Attachment B – Requesting Electronic Signature Access in HPMS**

In addition to obtaining and maintaining a CMS user ID with access to HPMS, designated signatories must establish their official role and P number associations with CMS.

If the signatory **does** have an active CMS user ID with access to HPMS, the user must follow these steps to become a designated contracting official in the system for CY 2012.

- Please do NOT resubmit the user request form.
- Ensure that your CMS user ID is recertified when notified by CMS. Users will receive an email notification from [ess@cms.hhs.gov](mailto:ess@cms.hhs.gov) with the subject “*CMS Certification Due Date.*” Please follow these instructions closely to ensure you recertify and retain your current user ID. If you do not complete the certification in a timely manner, your CMS User ID will be **revoked** and you will have to reapply as a new HPMS user (see Attachment A).
- Submit an official letter that states the name, role, CMS user ID and P-number associations for the individual identified in HPMS. The letter must be provided on your organization’s official letterhead and signed by a senior official of the organization. CMS recommends the use of the following sample language:

*(Name of organization)* hereby requests that *(Name of Signatory, their role, and their CMS user ID)* be granted electronic signature access as a contracting official in HPMS for the following P numbers: *(list specific P numbers)*.

Note: Organizations may send one consolidated letter for their primary and secondary signatories or separate letters for each individual.

- Submit the official letter to Adam Foltz via either:
  - Email in scanned PDF format to [adam.foltz@cms.hhs.gov](mailto:adam.foltz@cms.hhs.gov). Please use the following subject line: HPMS Access for Signatories
  - 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