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

CENTER FOR MEDICARE

DATE: August 3, 2010

TO: Pharmaceutical Manufacturers, Relabelers, Repackagers, and Distributors

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—Manufacturer Agreements

The Centers for Medicare & Medicaid Services (CMS) has finalized the model Manufacturer Agreement and model Third Party Administrator (TPA) Agreement for participation in the Medicare Coverage Gap Discount Program. Thank you for providing your contact information so that we can forward these documents, along with instructions and the labeler code spreadsheet, for your signature and completion. **The deadline for returning the signed agreements and labeler code spreadsheet is September 1, 2010.** We look forward to working with you on the successful implementation of this program.

The following summarizes the development of the model agreements and the signature process required for 2011:

Model Manufacturer and Third Part Administrator Agreements

Beginning in 2011, the Affordable Care Act of 2010 establishes the Medicare Coverage Gap Discount Program (CGDP). The CGDP will make manufacturer discounts available to applicable Medicare beneficiaries enrolled in Medicare Part D that are receiving applicable drugs (i.e. brand drugs or biologics) while in the coverage gap.

The Affordable Care Act required CMS to establish a Model Manufacturer Agreement, in consultation with manufacturers and allowing for public comment, which all manufacturers must sign to participate in the CGDP. Only applicable drugs covered by a signed manufacturer agreement may be covered under the Medicare Part D beginning in 2011. In addition, all participating manufacturers must sign an agreement with a third party administrator (TPA) contracted with CMS to administer certain requirements established by the Secretary necessary to implement the CGDP.

CMS issued a draft Model Manufacturer Agreement for public comment on May 21, 2010 and draft Third Party Administrator (TPA) and Data Use Agreements for public comment on July 9, 2010. CMS met on site with the Pharmaceutical Research and Manufacturers of America (PhRMA) on 5/14/10 and the Biotechnology Industry Organization (BIO) on 5/17/10. In addition, CMS held a

public meeting in Baltimore, MD on June 1, 2010 where we discussed the draft Model Manufacturer Agreement and received feedback from manufacturers, Part D sponsors, PBMs, beneficiary advocates and other members of the public.

Summary of comments received on Draft Model Manufacturer Agreement published in the Federal Register on May 21, 2010:

The main issues raised by manufacturers on the draft Model Manufacturer Agreement were:

1) The requirement for manufacturers to pay quarterly invoices within 14 days of receipt— Manufacturers commented that this period would not provide sufficient time to appropriately review and evaluate the invoices to ensure accurate payments.

   CMS Response: CMS revised the payment timeframe to be 38 calendar days from receipt of invoice. This timeframe is consistent with the Medicaid Drug Rebate Program's payment timeframe.

2) The requirement that manufacturers pay invoices even when amounts are in dispute, and receive refunds if the dispute demonstrates that funds were erroneously paid — Manufacturers commented that they should not be required to pay amounts that are clearly erroneous or disputed in good faith.

   CMS Response: CMS maintains this requirement in the revised agreement (with one exception for drugs not subject to the manufacturer agreement) because PDE data has been subject to numerous controls prior to being submitted to the government and because CMS will be performing extensive editing on the data prior to invoicing manufacturers. Moreover, unlike rebates these discounts will have already been provided at point-of-sale unlike rebate agreements and CMS seeks to minimize taxpayer expense.

3) The level of detail for the information that would be provided to the manufacturers to support the discount payments— the draft Model Agreement stated that manufacturers would receive only summary-level data. Manufacturers commented that claim-level data is necessary to allow them to check for duplicate claims and perform reasonableness checks on quantities dispensed and applicable discount amounts.

   CMS Response: CMS revised the level of data that will be provided to manufacturers along with the invoice to be claim-level utilization information and, in addition will upon audit only, provide PDE cost elements for a statistically significant sample size to allow manufacturers to validate discount calculations. ***CMS will not provide any beneficiary identifiable information, even upon audit.***

Summary of comments received on Draft TPA and Data Use Agreements shared with manufacturers on July 9, 2010:

- The data use requirement that manufacturers meet federal data security standards that are required for federal government agencies — Manufacturers raised concerns that this requirement was overly burdensome and would require them to overhaul their existing security programs solely for participation in the CGDP. They noted the TRICARE retail pharmacy program administered by the Department of Defense provides manufacturers with similar data but does not require manufacturers to meet the level and scope of the security standards applicable to federal agencies.

  CMS Response: CMS revised this specific requirement because CMS will not be releasing PHI to manufacturers. The Agreement maintains requirements for manufacturers to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use of or access to it.

- The data use requirement that manufacturers are not to sell, rent, lease, loan, or otherwise grant access to the data covered by the Agreement— Manufacturers asked CMS to clarify that manufacturers may grant access to data to contracted third parties for purposes of assisting the manufacturer in evaluating the accuracy of claims discounts, resolving disputes and otherwise exercising its rights and responsibilities under the Agreement.

  CMS Response: CMS clarified in the revised Agreement that such access is allowable.

- The language in the TPA Agreement suggesting that manufacturers would be bound by the contractual arrangement between CMS and the TPA — Manufacturers raised concerns that CMS is obligating them to comply with unknown provisions in CMS's agreement with the TPA.

  CMS Response: CMS clarified in the revised version that only the TPA is governed by the contractual arrangement between CMS and the TPA.

The final Model Manufacturer Agreement and Model Third Party Administrator Agreement are now posted on the CMS Part D manufacturer webpage:

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

The Agreements became final when they were posted on the CMS website on August 2, 2010, commencing the 30-day signing period. CMS is distributing official copies of enumerated Agreements to manufacturers following the process outlined below. The deadline for signing the Agreements to participate in the CGDP for 2011 is September 1, 2010.

The 2011 Agreement signing process and deadline for manufacturers that have submitted their contact information:

- On August 3, 2010, CMS will distribute the official copy of the model Manufacturer Agreement, model TPA Agreement and Labeler Code Submission Spreadsheet to the primary contact person identified by the manufacturer. Technical instructions for completing each of these documents will be provided. All required information must be completed.

- CMS encourages all manufacturers, including all labelers, relabelers, repackagers and distributors with their own FDA assigned labeler codes, of prescription drugs products that are covered under Part D to sign the agreement even if your company does not believe any of its products are applicable drugs. If it turns out that your company does not have any applicable drugs, signing the Agreement does not impose any discount requirements. However, if you fail to sign the Agreement and later determine that some of your products are indeed applicable drugs, your company will not have another opportunity to sign an Agreement for 2011 and any such products cannot be covered under Part D until 2012 at the earliest.

- Manufacturers that do not currently market any products may still sign the Agreement. Such manufacturers must designate on the labeler code spreadsheet that no labeler codes are currently available. Such manufacturers will be allowed to update their labeler code spreadsheet at a later date when products become available as long as the manufacturer has a signed Agreement in place before the deadline.

- All Manufacturers must complete and return the signed agreements and completed labeler code spreadsheet by 11:59 p.m. Eastern Time on September 1, 2010. **CMS cannot extend this deadline for participation in the CGDP for 2011.**

- CMS will post the manufacturers that have signed agreements on the CMS Part D manufacturer webpage as soon as we receive and process these agreements.

- CMS will return a signed copy to the manufacturers during the month of October 2010.

The 2011 Agreement signing process and deadline for manufacturers that have NOT submitted their contact information:

- Manufacturers intending to participate in the CGDP must submit their contact information as instructed on the CMS Part D manufacturer webpage:

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

  Any remaining manufacturers intending to participate should submit this information as soon as possible to ensure that they receive an official copy of the Manufacturer Agreement prior to the deadline.

- Once CMS has received the contact information, CMS will distribute a copy of the model Manufacturer Agreement, model TPA Agreement and Labeler Code Submission Spreadsheet to the primary contact person identified by the manufacture. Technical instructions for completing each of these documents will be provided. All required information must be completed.

- CMS encourages all manufacturers, including all labelers, relabelers, repackagers and distributors with their own FDA assigned labeler codes, of prescription drugs products that are covered under Part D to sign the agreement even if your company does not believe any of its

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- All Manufacturers must complete and return the signed agreements and completed labeler code spreadsheet by 11:59 p.m. Eastern Time on September 1, 2010. **CMS cannot extend this deadline for participation in the CGDP for 2011.**

- CMS will post the manufacturers that have signed agreements on the CMS Part D manufacturer webpage as soon as we receive and process these agreements.

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