

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



**CENTER FOR MEDICARE**

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DATE: October 1, 2010

TO: All Part D Sponsors

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

SUBJECT: Medicare Coverage Gap Discount Program—Manufacturer Labeler Codes Posted on CMS Part D Manufacturer Webpage

Last week the Centers for Medicare & Medicaid Services (CMS) announced that the nation's pharmaceutical manufacturers will provide 50 percent discounts on the cost of covered brand-name prescription drugs for beneficiaries in the Medicare Part D coverage gap, or donut hole, starting in 2011. The purpose of this memorandum is to notify Part D sponsors that the labeler codes for these manufacturers of applicable drugs are now posted on the CMS Part D Manufacturer Webpage:

[http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp#TopOfPage](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage). This is the complete list of applicable drug labeler codes for the 2011 calendar year as of October 1, 2010. While we do not anticipate many changes during 2011, it is possible that a manufacturer could add new labeler codes that currently are not marketed or currently are marketed by another manufacturer. CMS will promptly notify Part D sponsors of any such changes to the labeler code list.

CMS reminds Part D sponsors that beginning January 1, 2011; all applicable Part D drugs (i.e. Part D drugs approved under new drug applications (NDAs) or licensed under biologics license applications (BLAs)) may be covered under Part D **ONLY** if they are marketed under labeler codes specified on the CMS labeler code list referenced above. CMS has made no exceptions to this requirement. All other covered Part D drugs (e.g. Part D drugs approved under abbreviated new drug applications (ANDAs), supplies associated with the injection of insulin) are not affected by this requirement and may continue to be covered.

Part D sponsors are responsible for determining which Part D drugs are applicable drugs. CMS is still working with the FDA to make more complete and reliable information available to assist with these determinations and also has begun working with manufacturers to update their FDA NDC Directory listings. In the meantime, for missing or conflicting NDC information, Part D sponsors need to contact the FDA and the manufacturers involved to assist with getting all NDCs properly listed on the FDA NDC Directory by notifying the FDA and manufacturers involved which NDCs are missing and which NDCs are listed more than once.

Finally, CMS is sending the attached communication to pharmacies to alert them about the implementation of the Medicare Coverage Gap Discount Program and the effect it could have on their business. CMS believes Part D sponsors must do more than simply use the labeler code list to establish new point-of-sale edits and pharmacy messaging for January 1, 2011. We expect Part D sponsors to communicate with their network pharmacies and pharmacy benefit managers (PBMs) so that the pharmacies and PBMs also can take steps to prepare for any changes, including working with suppliers, to ensure applicable Part D drug products remain available to Medicare beneficiaries.

If you have any questions regarding this guidance, please contact Craig Miner at 410-786-7937 or [craig.miner@cms.hhs.gov](mailto:craig.miner@cms.hhs.gov).

ATTACHMENT -- Medicare Information for Pharmacists

Medicare Coverage Gap Discount Program beginning January 1, 2011

CMS has signed discount agreements with manufacturers that cover all brand name and biologic Part D drug products needed under the Part D program. We are sending this email to pharmacies to notify you that the labeler codes for these manufacturers are now available on the CMS Part D Manufacturer Webpage:

[http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp#TopOfPage](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage).

Beginning January 1, 2011; all applicable Part D drugs (i.e. Part D drugs approved under new drug applications (NDAs) or licensed under biologics license applications (BLAs)) may be covered under Part D **ONLY** if they are marketed under labeler codes from the manufacturers specified on the CMS labeler code list referenced above. CMS has made no exceptions to this requirement. All other covered Part D drugs (e.g. Part D drug approved under abbreviated new drug applications (ANDA), supplies associated with the injection of insulin) are not affected by this requirement and may continue to be covered.

Pharmacies should review the list of labeler codes on the CMS website to determine if their inventories have applicable Part D drugs with the labeler codes that will be covered under Medicare Part D in 2011 and determine if the exclusion of other applicable Part D drugs with other labeler codes will affect them. The CMS list can be used to ensure purchases in the upcoming months include applicable Part D drugs that will continue to be covered under Medicare Part D in 2011.

Please submit NDC specific Part D drug questions that relate to the Medicare Coverage Gap Discount Program to [partD\\_NDC@cms.hhs.gov](mailto:partD_NDC@cms.hhs.gov).