

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



CENTER FOR MEDICARE

DATE: November 3, 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—Prospective Beneficiary Notice of Formulary Changes

In the May 21, 2010 Medicare Coverage Gap Discount Program (Discount Program) guidance, the Centers for Medicare & Medicaid Services (CMS) stated that Part D sponsors must provide prospective notice to affected Part D enrollees (as defined in 42 CFR 423.100) if those members were affected by failure of a manufacturer to sign a discount agreement. Although CMS collected discount agreements from manufacturers that cover all necessary applicable Part D drugs, it is still possible that a beneficiary may need to switch from their specific non-covered brand to a covered alternative. Part D sponsors will also need to remove any affected formulary drugs from their marketing materials by immediately updating formularies on their website and ensuring that future printings of formulary materials do not include these drugs. Part D sponsors should remove affected drugs from their CMS approved formulary at the time of their next formulary submission to CMS.

If a Part D sponsor determines that any beneficiaries are affected by a manufacturer's failure to sign an agreement, the sponsor should send notification to all affected enrollees as soon as possible but no later than November 30, 2010. CMS anticipates that only a limited number of these notifications will be necessary based upon our analysis of PDEs and, therefore, considers this notification to represent an ad hoc enrollee communication as defined in section 20 of chapter 3 of the Prescription Drug Benefit Manual. These ad hoc enrollee communications must be submitted to CMS in accordance with section 90.2.2 of this chapter and must include the following language:

A change in the law requires companies that make brand-name prescription drugs to give a discount on those drugs to Medicare. Beginning January 1, 2011, prescription drugs made and sold by companies that have not agreed to give a discount to Medicare can no longer be covered (paid for) by Medicare Prescription Drug Plans.

We are writing to you because you are taking <drug name>, <drug name>, <drug name>. Starting in January this <these> prescription drug<s> will not be covered by Medicare. This is because the company <companies> that make<s> this <these> prescription drug<s> did not agree to give a discount to Medicare. No Medicare Prescription Drug Plans including <Plan name>, can cover (pay for) this <these> prescription drug<s> at all, or give an exception.

You can continue to pay for this <these> prescription drug<s> yourself, but <Plan Name> covers many other prescription medications that may be right for your health condition. If you continue to pay for this <these> prescription drug<s> yourself, the costs will not count towards your Medicare Prescription Drug Coverage out-of-pocket spending.

Please talk to your doctor about using another prescription drug<s> on <Plan Name's> list of covered drugs (formulary.) You can get a copy of the formulary on our website <website URL> or by calling our Member <Customer> Service Department at <Telephone number and TTY number.>

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