DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-16-16
Baltimore, Maryland 21244-1850

Center for Beneficiary Choices

MEMORANDUM

TO: All Part D Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

RE: Generic Drug Adjudication for Copayments Fixed by Statute

DATE: July 6, 2007

We want to take this opportunity to remind Part D sponsors of the definition of generic drugs and how to ensure that you are properly administering generic copayments fixed by statute. Specifically, 42 CFR 423.4 defines generic drugs as those drug products for which there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)). In other words, for purposes of Part D, what determines whether a drug is a generic drug is the type of application on file for that drug product with the Food and Drug Administration (FDA). If a drug product approval is based upon an abbreviated new drug application (ANDA), that drug is therefore a generic drug.

This definition applies regardless of whether the brand-name drug is no longer manufactured and there is only one remaining ANDA-approved drug product on the market, whether the sponsor's formulary includes the drug on the its generic cost-sharing tier or on a higher tier, or how a particular drug product is identified by the major drug listing services. Consequently, when sponsors by statute are required to apply specific copayments for generic drugs (that is, for generic drugs obtained by low-income subsidy eligible enrollees and enrollees with spending above the out-of-pocket threshold), they must ensure that the appropriate cost-sharing is applied to the generic drug as defined under our regulations.

For example, in accordance with 42 CFR 423.782(a)(2)(iii)(A), in 2007 non-institutionalized full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty level for their family size will pay no more than $1.00 for generic drugs. Consequently, the sponsor must ensure that these individuals pay no more than a $1.00 copayment for generic drugs, including ANDA approved drug products, even if a Part D sponsor places an ANDA approved drug product in its preferred brand cost-sharing tier rather than its generic cost-sharing tier.

Thank you for your attention to this matter. If you have any questions, please contact LCDR Greg Dill at Gregory.Dill@cms.hhs.gov or 312-353-1754.