DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Beneficiary Choices

MEMORANDUM

TO: All Part D Sponsors

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

RE: Clarification of June 1, 2007 "Mid-Year Formulary Reference File Proxy NDC Changes" Memorandum

DATE: July 23, 2007

Following issuance of the June 1st memorandum, CMS has received a number of requests to clarify the specific national drug codes (NDCs) correlating with the March update proxy deletions for which CMS will establish prescription drug event (PDE) edits to reject PDE submissions with dates of service after May 31, 2007.

We will not be establishing PDE edits for NDCs for which the formulary reference file continues to include a proxy code from any labeler (brand or generic) for the same active ingredient, strength, dosage form, and route of administration as the proxy code deleted during the March update, unless new information from the Food and Drug Administration (FDA) becomes publicly available.

CMS continues to expect Part D sponsors to evaluate the Part D drug status of individual drug products that were represented by deleted proxy codes and continue to cover, in accordance with their formulary and plan terms, those drug products with NDCs that it determines satisfy the definition of a Part D drug. However, we also recognize that information needed to confirm FDA status of NDCs is not always readily available, especially when both approved and unapproved versions of a drug may be on the market. For this reason, a Part D sponsor may consider drug products to be Part D drugs so long as the best publicly available information does not provide an objective and reasonable basis for concluding that specific drug products (i.e., those represented by specific NDCs) are not Part D drugs, and information available from the FDA or CMS does not indicate otherwise.