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

CENTER FOR BENEFICIARY CHOICES

DATE**:** February 3, 2006

TO: Medicare Part D Plans

FROM: Abby Block, Director, Center for Beneficiary Choices

SUBJECT: Prescription Niacin products

There has been significant confusion among Part D plans and Medicare beneficiaries whether Niaspan® is included or excluded from the Medicare Prescription Drug Benefit. Several unique factors, including the mention of Niacin (nicotinic acid) as a USP "Formulary Key Drug Type" for 2006, likely contributed to this confusion. The Centers for Medicare & Medicaid Services (CMS) has not issued formal guidance clarifying the status of Niaspan®, although many plans either inquired about the status of these products or concluded that since these are not Part D drugs, they should not be on their basic formularies.

CMS has determined that prescription Niacin products (e.g. Niaspan®, Niacor®) are prescription vitamins and, therefore, excluded from the definition of a Part D drug in accordance with statutory requirements. The effective date of this decision is June 1, 2006 due to the ambiguity and unique circumstances surrounding prescription Niacin products, and the previously authorized delay in issuance of EOB notices[1]. Prior to this effective date, Part D plans may treat prescription Niacin products as either excluded prescription vitamins or as Part D drugs. After May 31, 2006, prescription Niacin products will be universally excluded from the definition of a Part D drug.

Part D plans that currently have prescription Niacin products on their formularies should remove the drug using the standard negative change template request. This request should be submitted to PartDformularies@cms.hhs.gov at least 60 days prior to removal of the drug. All of these change requests must be submitted to CMS no later than April 1, 2006. Removal of the drug from the HPMS formulary files and the Medicare Prescription Drug Plan Finder formulary files should follow the standard process after submission of the negative change request.

[1] On January 27, 2006, CMS notified Part D plans that they could wait until March to send the first Explanation of Benefits (EOB) document to members. A plan choosing to send the first EOB to members during the month of March must ensure that the EOB reflects any activity for the months of January and February. In addition, plans must send an EOB extension notice during the month of February for all members who utilized the prescription drug benefit during the month of January.

In the interest of full disclosure, plans that currently identify prescription Niacin products on their formularies should take steps to alert potential enrollees of this impending change, and must notify affected enrollees in one of the following ways:

- By providing direct written notice to affected enrollees at least 60 days prior to the effective date of the change; or

- By providing the enrollee with a 60-day supply of the Part D drug at the time an affected enrollee requests a refill of the Part D drug under the same terms as previously allowed and provide written notice of the formulary change. [Note: This method will not be available for prescription Niacin products under any circumstances after May 31, 2006]

Part D plans must provide written notice of these changes to affected enrollees through a member formulary medication change notice and/or the Explanation of Benefits (EOB). These documents are considered marketing materials and must comply with CMS marketing guideline requirements. In addition, notice of the formulary change must be posted on the Part D plan's Web site, in accordance with the marketing guideline requirements. The actual written notice document does not need to be posted.