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

CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

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

Jeffrey Kelman, M.D., Chief Medical Officer

DATE: June 2, 2010

SUBJECT: Early Refill Edits on Topical Ophthalmic Products

The Centers for Medicare & Medicaid Services (CMS) is re-issuing this guidance based on complaints we have received regarding the application of early refill edits (i.e. refill-too-soon edits) to topical ophthalmic products. CMS recognizes that early refill edits are an important utilization management tool used to promote compliance and prevent waste. However, it is equally important that Part D sponsors implement such edits in a manner that does not unreasonably put beneficiaries at risk of interruptions in drug therapy that potentially have serious consequences.

Part D sponsors need to take into consideration differences that some dosage forms, such as topical ophthalmics, present when establishing early refill edits. Edits based on an algorithm that is appropriate for tablets and capsules are not necessarily appropriate for other dosage forms for which administration is not as easily measured and controlled. This is not to say that Part D sponsors should not implement early refill edits for such medications, especially given that these edits can identify inappropriate use, but it does mean that such edits need to reasonably accommodate waste that can be anticipated given the nature of these products and their self-administration among the Medicare patient population. Part D sponsors also should be prepared to allow overrides of these edits on a case-by-case basis when appropriate and necessary to prevent unintended interruptions in drug therapy.

To assist Part D sponsors in determining proper edits to protect beneficiary access CMS recommends that sponsors allow the following for topical ophthalmic products:

- Permit refills at 70% of the predicted days of use. By way of an example, for a prescribed medication with an expected duration of 30 days of use, the refills would be permitted at day 21.
- Ensure that the refill allowances are the same regardless of purchase through retail or mail-order sources.

- Permit physicians to authorize earlier refills than 70% days of use for particular beneficiaries who continue to have difficulty with inadvertent wastage.

If you have any questions regarding this guidance, please contact Keely Ireland at 410-786-7160 or keely.ireland@cms.hhs.gov.