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

CENTER FOR MEDICARE

DATE: December 27, 2010

TO: All Part D Sponsors

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

SUBJECT: Unapproved Colchicine Products

CMS has received a number of questions related to unapproved colchicine products. The purpose of this email is to clarify CMS' expectations regarding Part D coverage of these products.

FDA recently issued an announcement about the marketing of unapproved single-ingredient oral colchicines. (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227796.htm). Based upon information available within this announcement, CMS will no longer accept PDEs for unapproved colchicine products after June 30, 2011. Sponsors must ensure that they continue to provide formulary coverage of approved colchicine.

Unapproved colchicine may still be available on pharmacy shelves. Sponsors must make the determination whether or not to continue to cover these products. CMS is providing the following options depending upon the determination that is made by the Part D sponsor:

1. Continue coverage while pharmacy supplies last or June 30, 2011. However, Part D sponsors should notify affected beneficiaries that this product is being discontinued and only the approved version(s) of colchicine will be available in the near future.

2. Discontinue coverage of unapproved colchicines following appropriate beneficiary and CMS notifications. Sponsors choosing this option must comply with beneficiary protections relating to formulary changes and provide 60 days notice to affected beneficiaries and other entities, as described in Chapter 6 of the Prescription Drug Benefit Manual, sections 30.3.4.1 and 30.3.4.2.

Although this memorandum directly addresses unapproved colchicine products, CMS acknowledges that some Part D sponsors might currently cover other unapproved products that the sponsors reasonably believe are Part D drugs based upon a lack of currently available public information to the contrary. If new information becomes available or a sponsor now otherwise determines that any such products are not Part D drugs, CMS expects sponsors to discontinue

coverage and follow the same process specified in option 2 above. Since these unapproved products are not included on the Formulary Reference File (FRF), sponsors must submit these formulary deletions to CMS using the attached coverage discontinuation template for unapproved drugs to PartDFormularies@cms.hhs.gov at least 60 days before the effective date of the deletion.

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