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

CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: All Part D sponsors

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

SUBJECT: Change in the Definition of a "Medically Accepted Indication"

DATE: December 9, 2008

This memorandum provides additional guidance to Part D sponsors on the implementation of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 182 of MIPPA affects the definition of a Part D drug by amending section 1860D-2(e)(1) of the Act to revise the definition of the term "medically accepted indication" for Part D drugs used in anti-cancer chemotherapeutic regimens. This provision takes effect on January 1, 2009.

Beginning January 1, 2009, Part D sponsors will be required to apply the Part B definition of a medically accepted indication to those anti-cancer chemotherapeutic drug claims that are not covered by Part B and are therefore Part D covered drugs. To accurately adjudicate these claims, Part D sponsors will be required to thoroughly understand and apply Part B's definition of an anti-cancer chemotherapeutic regimen, utilize Part B compendia (found at http://www.cms.hhs.gov/CoverageGenInfo02_compendia.asp), and consider peer reviewed medical literature when necessary. Section 50.4.5 of Chapter 15 of the Medicare Benefit Policy Manual (http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf) will be the authoritative guidance for Part D sponsors in their consideration of medically accepted indications for off-label Part D anti-cancer chemotherapeutic claims.

CMS understands that actual implementation of this new provision may be complicated for prospective or concurrent drug utilization review (DUR) programs by the prohibition on the use of prior authorization under our existing six classes of clinical concern policy for anti-neoplastics. While Part D sponsors may apply prior authorization to establish appropriate payment under Medicare Part B or Part D for anti-neoplastics, this exception does not currently permit extension of prior authorization to facilitate collection of information necessary to consider the revised definition of a medically accepted indication for Part D anti-cancer chemotherapeutic drugs. Consistent with our six classes of clinical concern policy, once a Part D sponsor establishes that Part D is responsible for payment, the sponsor must remove any drug utilization management tools and provide access to anti-neoplastics for those enrollees currently taking the drugs. However, Part D sponsors may perform retrospective reviews (see section 10.6.1 of Chapter 6 of the Prescription Drug Benefit Manual) to establish that the presence of a medically accepted indication for an anti-chemotherapeutic drug regimen has been satisfied.

We also expect that this provision would be considered during the coverage determinations and appeals process.

If you have any questions on section 182 of MIPPA and how this provision affects the definition of a Part D drug, you may contact CDR Greg Dill at Gregory.Dill@cms.hhs.gov or (312) 353-1754.