DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-16-16
Baltimore, Maryland 21244-1850

**MEMORANDUM**

TO:         All Part D Sponsors

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

RE:         Medicare Prescription Drug Benefit Manual – Chapter 7

DATE:      May 25, 2007

CMS is pleased to release the final version of Chapter 7 of the Prescription Drug Benefit Manual (Medication Therapy Management and Quality Improvement Program). In drafting this final chapter, CMS considered all comments received on the draft of Chapters 7 released for public comment on December 1, 2006.

Chapter 7 contains information about Part D sponsor requirements specific to the following areas:
- Quality Assurance
- Medication Therapy Management
- E-prescribing
- Drug Utilization Management

Included with this memorandum is a summary of changes from the draft to the final version of Chapter 7.

If you have any questions regarding Chapter 7, please contact Greg Dill at (312) 353-1754 or gregory.dill@cms.hhs.gov. This chapter will also be posted at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage.

**Chapter 7**
**Summary of Changes from the Draft Chapter**

In order to balance different viewpoints from various stakeholders, we made a number of modifications from the draft chapter. Since most modifications were intended to clarify (but not change) existing policy, we provide a summary only of the major changes made to the final version of Chapter 7 below.

**Changes to Final Version of Chapter 7**

- 20.3 – Retrospective Drug Utilization Review

  o Addressed comments related to notification or discovery of an allegation of fraud or abuse.

- 30.5 – MTMP Application
  o Added language regarding MTMP applications and MA-PFFS plans.

- 30.6 – MTMP Approval Considerations
  o Addressed issue of gaps in MTM services between plan years.

- 30.10 – Coordination with Care Management Plans
  o Expanded the discussion on Part D Sponsor coordination with Medicare Health Support Organizations

- 60.1 – Over-the-Counter (OTC) Drugs as Part of Utilization Management Programs
  o Clarified our expectations for the offering of OTCs drugs offered outside of step-therapy protocols.