DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: Medicare Advantage – Prescription Drug Organizations
Prescription Drug Plan Sponsors

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

SUBJECT: Medicare Prescription Drug Benefit Manual – Chapters 6 & 7

DATE: March 3, 2010

CMS is pleased to release the updated Chapter 6 (Part D Drugs and Formulary Requirements) and Chapter 7 (Quality Improvement and Medication Therapy Management) of the Medicare Prescription Drug Benefit Manual. The revisions to Chapters 6 and 7 contain changes previously released in the 2010 Call Letter and HPMS memoranda. Specifically, CMS made the following revisions:

Chapter 6;

- Added new section clarifying best practices for sponsors to consider the proper listing of a drug product with the FDA as a prerequisite for making a drug coverage determination.
- Clarified that the bundling of services under Part C must be available to enrollees in LTC facilities.
- Added language indicating that CMS will review home infusion drug files to ensure only home infusion drugs are included under a supplemental benefit under Part C, if elected.
- Added a section that includes a waiver of the definition of Part D drug with respect to home infusion drugs covered as part of a bundled benefit under Part C.
- Added language based on the removal of a drug based on long term shortage and market availability.
- Added a section permitting Part D sponsors the option of sending transition fill notices to network LTC pharmacies in addition to sending notice to enrollees residing in LTC facilities.
- Clarified transition requirements applying to both drugs removed from a sponsor's formulary as well as drugs that remain on the formulary but now require new prior utilization or step therapy restrictions.
- Added language indicating that beneficiaries must be permitted to have a full outpatient supply available under Part D to continue therapy once their limited Part A supply is exhausted.
- Updated the drug list in Appendix A and Appendix D of Chapter 6.

Chapter 7;

- Added definitions of both "Immediate Need" and "Urgent Complaint" to the definition section.
- Expanded the guidance to Part D sponsors to maintain written policies and procedures explaining the level of concurrent drug utilization review checks, system logic, established thresholds and accompanying pharmacy messaging.
- Clarified that sponsors should maintain a written retrospective drug utilization review policy with clear objectives and identify the relevant claims data for review under these objectives.
- Added a section suggesting a periodic evaluation of medication errors be completed to look for trends and patterns that require the sponsor's attention.
- Updated the Part D Medication Therapy Management Program (MTMP) instructions for enrollment methods, targeting procedures and MTM services.
- Clarified MTMP reporting requirements.
- Added a section requiring Part D sponsors to obtain the Prescription Origin Code and report on their PDE submissions for new prescriptions.
- Added language to clarify the monitoring and recording of grievances separate of CTM under the sponsor's Part D Reporting Requirements.
- Clarified how long an "urgent need" complaint should take to be resolved.
- Edited language to reflect CMS' right to classify any complaint as "immediate" or "urgent" if it doesn't meet the standard guidelines for types of complaints and what determines whether a complaint is egregious or not.

The revised manuals will be posted at
http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp.

Any questions regarding this manual chapter may be directed to Keely Ireland on (410) 786-7160, or via email at keely.ireland@cms.hhs.gov.