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DATE: July 27, 2012

TO: All Medicare Advantage, Prescription Drug Plan, Cost Organizations, and PACE plans

FROM: Gerard J. Mulcahy, Acting Director  
Program Compliance & Oversight Group

SUBJECT: Issuance of the Final Compliance Program Guidelines, Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual

The Centers for Medicare & Medicaid Services (CMS) is pleased to announce the release of the final Compliance Program Guidelines for Medicare Advantage (MA) organizations (MAOs) and Prescription Drug Plan (PDP) sponsors. The final guidelines are posted on the CMS website and attached to this email. These guidelines are being issued as both Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. The content of these Chapters is identical and apply equally to the MA and Part D programs.

On February 8, 2012, we solicited public comment on the draft Compliance Program Guidelines. In response to our request, we received comments from 68 separately identified entities. We received comments from a broad spectrum of stakeholders, including MAOs, PDP sponsors, cost-based contractors, consumer advocacy groups, pharmacy associations, and health plan associations. After careful review of the comments received, we have incorporated a number of revisions and clarifications to the final policy guidance. Attachment A contains a summary of significant changes made between the draft and final versions of the program guidelines. We have also made editorial and minor changes throughout the document.

Finally, on May 11, 2012 via HPMS, we released the 2012 Program Audit Process and Protocols, which includes sections on how CMS will evaluate Sponsors' compliance programs during an audit. We encourage all Sponsors to use the Compliance Program Guidelines in conjunction with the audit protocols in the oversight of their organizations' compliance program oversight.

If you have questions regarding the Compliance Program Guidelines, please contact your Account Manager or submit your inquiry to [CMSParts\\_C\\_and\\_D\\_CP\\_Guidelines@cms.hhs.gov](mailto:CMSParts_C_and_D_CP_Guidelines@cms.hhs.gov).