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**DATE:** February 8, 2012

**TO:** Medicare Advantage Organizations  
Prescription Drug Sponsors

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

**SUBJECT:** Issuance for Public Comment of Draft Compliance Program Guidelines that will be published as Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual

CMS is pleased to announce the release of draft Compliance Program Guidelines for public comment. These guidelines will ultimately be published as Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. Chapters 9 and 21 will be identical.

These Compliance Program Guidelines apply to Advantage (MA) organizations (MAOs) and Prescription Drug Plan (PDP) sponsors. These Compliance Program Guidelines are being published in both the Prescription Drug Benefit Manual and in the Managed Care Manual to allow organizations offering both Medicare Advantage and Prescription Drug Plans to reference one document for guidance on their compliance program.

CMS is releasing this draft to obtain public comment for consideration before finalizing the Compliance Program Guidelines later this spring. The draft can be accessed at:  
[http://www.cms.gov/PrescriptionDrugCovContra/12\\_PartDManuals.asp](http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp).

CMS published regulations that provided more detailed regulatory requirements on each of the seven compliance program elements, which became effective January 1, 2011. In keeping with CMS' continuing efforts to update and clarify compliance program requirements, this draft provides guidance to enhance the operation of both the MA and Part D programs. Please note that certain sections of Chapter 9 are renumbered.

Chapter 9 of the Prescription Drug Benefit Manual previously focused solely on the prevention of fraud, waste, and abuse (FWA) in Medicare Part D. This draft includes interpretive guidance to prevent, detect, and correct Medicare Parts C and D program noncompliance and FWA.

You may compare this draft with the Prescription Manual - Chapter 9 that is currently in effect. The current version of Chapter 9 is available on the CMS website at:  
[http://www.cms.gov/PrescriptionDrugCovContra/12\\_PartDManuals.asp](http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp).

To ensure consideration, please provide your comments electronically using the attached form to [Parts C and D CP Guidelines@cms.hhs.gov](mailto:Parts_C_and_D_CP_Guidelines@cms.hhs.gov) by March 16, 2012, 5pm EST. Please enter your organization name in the subject line of the email. Thank you in advance for your careful review and comments on these Compliance Program Guidelines.