



**PLAN OVERSIGHT & ACCOUNTABILITY GROUP**

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**DATE:** November 13, 2006

**TO:** Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PD) Sponsors

**FROM:** Cynthia E. Moreno /s/  
Director

**SUBJECT:** Final MA-PD and PDP Part D Audit Guides for Part D Program Audits

The Centers for Medicare & Medicaid Services (CMS) is preparing to begin regularly scheduled desk and onsite program audits of Part D sponsors to assess their compliance with the Part D regulations found at 42 CFR 423 and other appropriate CMS standards. These audits will encompass randomized chapters of the final versions of the “Medicare Advantage Prescription Drug Plan Sponsors Part D Audit Guide” and the “Prescription Drug Plan Sponsors Part D Audit Guide.” These guides can be downloaded at the following website address: [http://www.cms.hhs.gov/PrescriptionDrugCovContra/08\\_RxContracting\\_ReportingOversight.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage). As indicated in the May 9, 2006 memo “Part D Audit Guide – Response to Industry Comments,” we are hereby providing industry with general guidance regarding the Part D audit process provided below.

**Audit Contractor:** CMS has entered a contract with Advanced Pharmacy Concepts / Booz Allen Hamilton (APC/BAH) to assist the Agency with its Medicare managed care audit work. This contractor will assist CMS in a variety of ways—including conducting comprehensive audits, conducting focused audits, and by providing staff assistance to CMS audits teams.

**Audit Scheduling:** Approximately 9 weeks prior to each scheduled audit, CMS will contact the Part D sponsor to determine an acceptable date for the audit and to discuss audit logistics. This call will be followed by written notification 3 weeks later, which will (1) inform the Sponsor of the Audit Guide chapter(s) that the audit will cover and (2) include the initial request for documentation. We expect many of the Part D audits to be conducted as desk audits (not at the Sponsors’ site), with the entrance conference, interviews, and exit conference to be held via conference call. We estimate that desk audits, from the date of the entrance conference to the date of the exit conference, will take no more than one month to complete. Onsite audits usually last no more than one week. Sponsors are expected to have key staff responsible for compliance and operations in the area(s) selected for audit available during that time.

**Required Audit Documentation:** One of the critical components of the audit process is the Part D sponsor's ability to provide CMS Audit Teams with appropriate documentation to demonstrate its compliance with CMS requirements. Therefore, CMS will provide Part D sponsors with a list of audit documentation required from the Sponsor for CMS scheduled desk or onsite audits at the time CMS informs the sponsor that it has been selected for audit. It is the Part D sponsor's responsibility to prepare and provide this documentation, when requested by CMS, in order to demonstrate compliance with each element in the audited chapters. Each Sponsor must be able to track and produce each universe indicated and retrieve the necessary documentation for each sample selected by CMS from each universe. Written notification of the audit will provide the exact requirements for each universe requested.

**Delegated Entities:** Unlike Part C, Part D sponsors are responsible for obtaining universes and samples from each of its contracted entities that are delegated to perform functions on behalf of the Sponsor, if applicable. Part D sponsors must combine their own universes with any universes they request and receive from their delegated entities prior to submitting them to CMS.

**Submitting Universes:** Universes or other documentation that contains individually identifiable beneficiary information should not be sent via e-mail or fax in order to ensure they are kept secure and confidential. The Part D sponsor must mail this documentation to CMS using a secure method that will reasonably ensure the security of the information (e.g., saving files on a password-protected CD and sending the CD to CMS via a common carrier with a tracking system).

**Deeming:** While the Part D regulations allow for deeming for Part D, standards and thresholds need to be established before any elements can be deemed. Therefore there are no deemed elements at this time. We expect that deemed elements will be identified in the future.

**Performance Assessment Exemptions:** Performance Assessment exemptions for Part D may be developed in the future as each Sponsor establishes a performance track record. MA-PDs' Performance Assessment exemptions for Part C do not apply to Part D. For now, CMS will use a risk assessment process to select Part D sponsors and audit elements that will be audited.

**Coordination with Part C Audits:** It is CMS' goal to coordinate the timing of audits and the selection of audit elements as much as possible between Part C and Part D, especially for Sponsors who have the same staff involved in any particular function scheduled for audit. This will be a challenge given that each Sponsor conducts business somewhat differently, and we welcome your feedback on this aspect of the process.

Please direct questions concerning the Part D audit guide to Trish Axt at [trish.axt@cms.hhs.gov](mailto:trish.axt@cms.hhs.gov) .