

Appendix A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard, Mail Stop C1-22-06
Baltimore, Maryland 21244-1850



PROGRAM COMPLIANCE AND OVERSIGHT GROUP

<Insert Date>

EMAIL:

ADDRESS OF SPONSOR

Re: 2012 CMS Program Audit – Medicare Advantage and Prescription Drug Plan Contract;
Contract Number(s):

Dear:

This letter is to notify you that your organization has been selected for a program audit by the Centers for Medicare & Medicaid Services (CMS) for the above-listed Medicare Advantage and Prescription Drug Plan contracts. We will review the following areas:

- Prescription Drug (Part D) Formulary Administration
- Part D Coverage Determinations and Appeals
- Part D Grievances
- Part C Organization Determinations and Appeals
- Part C Grievances
- Part C Access to Care
- Part C and Part D Compliance Program Effectiveness
- Part C and Part D Agent Broker Oversight (Licensure, Appointment, Testing, Training, OEV and Complaints)
- Part C and D Enrollment/Disenrollment
- Part D Late Enrollment Penalty (LEP)

The audit will be conducted from **<insert date>**. This audit will be conducted virtually via webinar, except the Part C and Part D compliance program effectiveness audit, which will be conducted onsite. The audit lead will also be onsite. We will conduct an entrance conference at **10:00 a.m. EST on Monday, <Insert Date> at (Address of Sponsor) and via conference call.**

Access to Facilities and Records

In order for CMS to conduct these audits effectively, we will require access to your facilities, records, and office staff and leadership.

Information to be Provided Prior to the Audit

Universe Data and Associated Documentation:

As part of the audit, CMS is requesting universes for each of the above-mentioned performance areas. These documents also contain requests for data universes (and associated documentation as necessary). Attachments I-A, II-A, IV-VI, VII-A, IX-A, X-A and XI-A contain the templates for your organization to submit the requested data.

Attachments I-B, III-A, and IX-B contain the sample case file minimum documentation required once we start the audit and provide you with sample requests. Please pay particular attention to these documents as this is the evidence CMS will be auditing to determine compliance with CMS requirements. We expect most if not all of this data and documentation to be available to the auditors electronically from your information systems during the audit but will confirm these details with your organization prior to the audit.

In an effort to select appropriate samples that do not cause a sponsor to fail due to a previously reported issue, CMS is requesting that the sponsor provide a listing of Previously Self-Disclosed items that impact the universes. Self-disclosed items should be specific, at the beneficiary level, to ensure that the case is not selected as a sample. Organizations should use Attachment XII to report their self-disclosed items.

Method and Deadline for Submissions:

All of the above-requested data and documentation submissions must be submitted electronically via Secure File Transfer Protocol (SFTP) within 10 business days (**by 5p.m. EST on <Insert Date>**). In order to use the SFTP facility, CMS needs your organization to provide us with the contact information for two users (or 1 generic user) who will be responsible for the SFTP electronic submittal process. Please submit this information **by 12 noon EST Thursday, <Insert Date>**. CMS will then forward an SFTP user guide and login instructions to these designated users.

Please validate all data (and documentation) submissions before they are provided to CMS. The sponsor validation process must include ensuring that the data are readable, complete (e.g., contain data from all contracts and plan benefit packages within contracts), and contain all data (or documentation) responsive to the request.

Specific Requirements For Webinar Capability

CMS will use its webinar capability to conduct this audit. In advance of the start date, CMS will conduct a test with your organization to ensure our webinar capability is fully functional with your information technology. If technological issues arise, CMS will work with your organization to handle them accordingly. If your organization has secure webinar capability and you prefer to use it, please discuss that with your contact below. CMS expects that your

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organization will have the appropriate staff available during the webinar to answer any questions raised.

Please note that webinar audits may run concurrently for each audit area. Organizations that prefer to use their webinar should have the appropriate staff available to facilitate the webinars during the time of the audit.

On-Site Audit

As previously stated, please expect the audit lead and compliance team to be onsite for the audit. We request that your organization provide a conference room for CMS staff that can accommodate approximately 5 people, has a conference phone, and has a projector to display information on the wall. The other audit areas will be conducted virtually.

Access to Key Personnel and Systems Requirements During Audit

CMS expects your organization to have key personnel available to the CMS auditors from any of your operational areas or delegated entities that perform functions related to the areas of audit identified above (e.g., pharmacy benefit manager). You also need to ensure that the reviewers have the ability to access any electronic information systems and electronic records (regardless of whether these systems or records are housed remotely or with delegated entities) related to the above-listed performance areas, including, but not limited to, those systems and records related to formulary administration, pharmacy claims and adjudication, coverage determinations, appeals and grievances, and any systems and records related to the operations.

Key personnel in each of the areas selected for audit should be at a minimum prepared to explain your internal policies and procedures, how your systems operate and be familiar with CMS requirements and how these requirements have been operationalized in your organization. Personnel should also be able to maneuver through the necessary systems (i.e., formulary claims, coverage determinations and appeals, etc.) while the review is being conducted.

In order to clarify our audit process requirements and respond to any initial questions you may have about the information requested or the audit process, we will be contacting your organization immediately to set up a conference call within two (2) days of the date of this notice.

In the meantime, if questions arise regarding the audit, this letter, or the data we are requesting, please contact CMS at (Phone) or (email).

We look forward to your cooperation.

Sincerely,

/s/

CEO

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Tawanda Holmes
Director, Division of Compliance Policy & Operations
Program Compliance and Oversight Group

cc:

Mr. Gerard J. Mulcahy, CMS/CM/POCG

Ms. Michelle Turano, CMS/CM/PCOG

Audit Lead, CMS/CM/PCOG

Account Manager

Branch Manager

Associate Regional Administrator

Center for Program Integrity

Attachment I – Formulary and Benefit Administration Audit Process and Universe Request 2012

Attachment I-A – Formulary and Benefit Administration Universe Template 2012

Attachment I-B – Sample Case Minimum Documentation Required 2012

Attachment II – Part D Coverage Determinations, Appeals and Grievances Audit Process and Universe Request 2012

Attachment II-A – Part D Coverage Determinations, Appeals and Grievances Universe Template 2012

Attachment III – Compliance Program Data and Documentation Request 2012

Attachment III-A – Compliance Program Sample Case Minimum Documentation Required 2012

Attachment IV – Organizational Structure and Governance PowerPoint Presentation Template 2012

Attachment V – Compliance Program Effectiveness Self-Assessment Questionnaire 2012

Attachment VI – Self Disclosure Report

Attachment VII - Part C Organizational Determinations, Appeals and Grievances Audit Process and Universe Request 2012

Attachment VII-A - Part C Organizational Determinations, Appeals and Grievances Universe Template 2012

Attachment VIII – 2012 Audit Process

Attachment IX Agent/ Broker Oversight Audit Process and Universe Request for 2012

Attachment IX- A Agent/ Broker Oversight Universe Template 2012

Attachment IX-B Sample Case Minimum Documentation Required 2012

Attachment X Enrollment/Disenrollment Audit Process and Universe Request for 2012

Attachment X-A Enrollment/Disenrollment Universe Template 2012

Attachment XI LEP Audit Process and Universe Request for 2012

Attachment XI-A LEP Universe Template