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

Medicare Part C and D Oversight and Enforcement Group

<Insert Date>

EMAIL: <Insert CEO email address>

CEO NAME,
ADDRESS OF SPONSOR & CONTACT INFO

Re: 2013 CMS Program Audit – Medicare Advantage and Prescription Drug Plan Contract;
<Insert Contract Number(s)>:
HPMS Audit ID:

Dear **<Insert SO CEO name>:**

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 (FA)
- Part D Coverage Determinations, Appeals & Grievances (CDAG)
- Part C Organization Determinations, Appeals & Grievances, (ODAG)
- Part C and Part D Compliance Program Effectiveness (CPE)
- Special Need Plans – Model of Care (SNP-MOC)
- Outbound Enrollment Verification (OEV)

The audit will be conducted over a two week period beginning **<Insert Date>.** The first week the audit will be conducted virtually via webinar and will cover all program areas except Part C and Part D Compliance Program Effectiveness. The Part C and Part D Compliance Program Effectiveness area will be conducted the second week either virtually or onsite. We will conduct an entrance conference at **10:00 a.m. EST on Monday, <Insert Date>, a pre-exit summary conference at 10:00 am EST on Friday, <Insert Date> and final exit conference at 10:00 am EST on Friday, <Insert Date>. All of these conferences will be conducted 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, 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, and X-A contain the templates for your organization to submit the requested data.

Attachments I-B, III-A, IX-B contains 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.

CMS is requesting that your organization provide a list (using Attachment VI) of previously self-disclosed and self-identified issues of non-compliance that may be found in the data universes requested by CMS. **If these issues of non-compliance were corrected prior to receiving the audit start notice and CMS is able to verify their correction, this may prevent these issues from negatively impacting your audit score. Any non-compliant issues that have been corrected and are not disclosed on this list or were corrected after the audit start notice will be counted against your organization in the event the audit team detects the issue.**

Method and Deadline for Submissions:

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

Please note that the HPMS Audit Module will require CEO-level attestation for all data uploaded into the system. **Please validate all data (and documentation) submissions before they are provided to CMS. The sponsor validation process must include ensuring that the data is 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 the CMS audit lead. CMS expects that your 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 system should have the appropriate staff available to facilitate the webinars during the time of the audit.

On-Site Audit

As previously stated, the compliance audit may be onsite the second week of the audit. If it is onsite, 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 during the first week of the audit. Your audit lead will have more details for you regarding the compliance audit.

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.

Please ensure that your CEO logs on to the HPMS Audit module to attest that you received this notice within two (2) business days of this notice.

In the meantime, if questions arise regarding the audit, this letter, or the data we are requesting, please contact your CMS audit lead at **<Insert AL name>** at **<Insert AL phone #>** or **<Insert AL email address>** .

We look forward to your cooperation.

Sincerely,

/s/

Tawanda Holmes
Director, Division of Audit Operations
Medicare Part C and D Oversight and Enforcement Group

cc:
Michelle Turano, CMS/CM/MOEG
Michael Dibella, CMS/CM/MOEG
Jonathan Blanar, CMS/CM/MOEG
Doreen Gagliano, CMS/CM/MOEG
<Insert AL name>, Audit Lead, CMS/CM/MOEG
<Insert AM name>, Account Manager, CMS/ **<Insert Region>**
<Insert Branch Manager name>, Branch Manager, CMS/ **<Insert Region>**
<Insert Sponsor's Chief Financial Officer(s) name>, <Insert Sponsor's Org name>, <Insert Sponsor's email address>
<Insert Sponsor's Medicare Compliance Officer name>, <Insert Sponsor's Org name>, <Insert Sponsor's email address>

The following documentation is available for download in the HPMS Audit module by navigating to the Submission Materials page. Additional instructional documentation with regards to the audit process may be found under the Documentation section.
Files are available in both .xlsx and .txt formats.

Attachment I – FA Audit Process and Universe Request
Attachment I-A – FA Universe Template
Attachment I-B – Sample Case Minimum Documentation Required
Attachment II – CDAG Audit Process and Universe Request
Attachment II-A – CDAG Universe Template
Attachment III – CPE Data and Documentation Request
Attachment III-A – CPE Sample Case Minimum Documentation Required
Attachment III-B – CPE Compliance Program Contacts
Attachment IV – CPE Organizational Structure and Governance PowerPoint Presentation Template
Attachment V – CPE Self-Assessment Questionnaire
Attachment VI –Self Disclosure Report
Attachment VII – ODAG Audit Process and Universe Request
Attachment VII-A – ODAG Universe Template

Attachment VIII – 2013 Audit Process Document

Attachment IX – SNP MOC Audit Process and Universe Request – *(if applicable)*

Attachment IX – A – SNP MOC Universe Template *(if applicable)*

Attachment IX- B – SNP MOC Sample Case Minimum Documentation Required *(if applicable)*

Attachment X – OEV Protocol Audit Process and Universe Request

Attachment X – A – OEV Universe Template