Attachment VIII

2012 Program Audit Process

Center for Medicare
Program Compliance & Oversight Group
Division of Compliance Policy and Operations

INTRODUCTION

The Centers for Medicare & Medicaid Services (CMS) Program Compliance and Oversight Group (PCOG) conducts program audits of Prescription Drug Plan (PDP) and Medicare Advantage Organization (MAO) Sponsoring Organizations who enter into contracts with the Center for Medicare (CM). Please note that the term "sponsoring organization" (SO) is used to refer to both PDPs and MAOs. Section 1876 and 1833 Cost Plan Sponsors will not be audited in 2012; however CMS will consider these plans for 2013.

AUDIT MISSION, VISION AND GOALS

Mission: To evaluate sponsors performance to ensure beneficiaries have access to care.

Vision: To drive the industry toward improvements in the delivery of health care services in the Medicare Advantage and Prescription Drug program.

Goals:

1) Utilize a data driven process to select sponsors for audit
2) Audit performance areas related to beneficiary access
   - Part C Access to Care,
   - Part D Formulary,
   - Part C and D Organizational/Coverage Determinations, Appeals, and Grievances (ODAG/CDAG),
   - Part C and Part D Enrollment/Disenrollment,
   - Late Enrollment Penalties (LEP),
   - Part C and Part D Compliance Program,
   - Part C and Part D Agent/Broker Oversight
3) Conduct outcome based audits and ensure non-compliant issues are corrected.
4) Conduct industry-wide outreach and education on lessons learned from the audits.
5) Engage in continuous process of improvement (i.e. survey sponsors, track audit team performance, etc.).

HOW SPONSORS ARE SELECTED FOR AUDIT

In 2012, sponsors will be selected for audit based on at least one of the following categories:

A. Good performers[1] - 6 sponsors
B. Poor stars performers (<3 stars for > 3 years) – 4 sponsors
C. Worst performers[2] (PCOG Risk Assessment) – 20 sponsors

[1] In 2012, CMS reviewed six 5-star Medicare Advantage Organizations (MAOs)

[2] PCOG will utilize existing CMS data (plan performance reviews, star ratings, etc) in conducting a risk assessment.

D. Middling performers (average Risk Assessment risk scores, but trending downward) - 5 sponsors
E. 5-year cycle sponsors (plans that have not been audited within a 5-year period) or referrals from the ROs – 5 sponsors
F. Sponsors selected for Ad Hoc audits – 5 sponsors

PLANNING AND PREPARATION

Pre-Audit Activities

- **Start Notice/Engagement Letter –** The PCOG Audit Lead (AL) sends an audit engagement letter including protocols (see Appendices A, B, and D) to the SO four weeks prior to the first day of the audit. This communication notifies the SO that they have been selected for audit. It specifies the areas for audit under consideration. The letter also states when and where the audit will take place as well as CMS requirements with regard to facility/records access, information needed prior to the audit, on-site space requirements, key personnel and system requirements.

- **Follow-Up Call** – The PCOG AL conducts a follow-up call with the SO and the audit team 1-2 days after the date of the engagement letter. The purpose of this call is to review the audit process, timelines, and CMS expectations and address any questions the SO may have regarding the audit process. Other details are covered regarding CMS requirements mentioned in the engagement letter.

- **Universe Submission to CMS from the SO** – Within 10 business days of receiving the engagement letter the SO uploads all requested data to a Secure File Transfer Protocol (SFTP) per instructions provided by the AL.

- **Send SO Audit Schedule** – CMS will send the SO a schedule of audit activities for the week of the webinar and onsite audit (see Appendix C). The schedule will be broken down per audit area and days of the week.

Webinar & On-Site Audit Activities (5 – 10 days)

- **Entrance Conference** – The audit starts with an entrance conference held the morning of the first day facilitated by the PCOG AL. The purpose of this conference is to make introductions, review the CMS audit approach and expectations, answer questions, and allow the SO to make a presentation on their behalf regarding their company.

- **Conducting the audit** – Team Leads (TL) conduct the audit using audit protocols and record audit results as declared by the TL. TLs will review sample cases live in the SOs system and determine pass/fail in real time (although some

determinations may pend depending on additional data requests). This allows CMS to be transparent with potential audit failures. In addition, the SO is expected to provide any supporting documentation as requested by CMS personnel.

- **Audit Process for On-Site Compliance** – The compliance team will conduct management, board of directors, and staff interviews, operations and system walk-throughs, as well as review samples. The logistics for these activities are discussed prior to the on-site visit. Pass and fail compliance elements are communicated as soon as CMS comes to a determination.

- **Audit Process for Webinar (all areas except compliance)**[3] – CMS conducts the audits virtually through the use of secure webinar technology. The PCOG AL is responsible for ensuring that all necessary technology, including webinar rooms, conference lines, and physical rooms for team members are set up appropriately. Webinar technology is tested prior to the start of the audit. Expectations of staffing are the same for both physical and virtual audits. Pass and failed cases are usually determined in real time as CMS and the SO discuss each sample case.

- **Exit Conference –** On the last day of the visit the PCOG AL conducts an exit conference with the SO to provide audit results and next steps. The SO is afforded the opportunity to ask questions about the results and audit findings and provide any follow-up information as appropriate. The goal during the audit is to be transparent so there are no surprises at the exit conference.

Post Audit Activities

- **Draft Audit Report Preparation and Issuance to SO** – At the conclusion of the audit, CMS prepares and issues a draft audit report (goal is within 30 days of the conclusion of the audit). The SO has 5 business days to respond to the report with comments to CMS. CMS will review the SOs comments and determine if the comments warrant a change to the report. CMS may disagree or agree with the SOs comments. CMS has the final decision in making changes to the final report.

- **Issuing the Final Audit report and Corrective Action Requirement(s)** – CMS issues the final report (the goal is within 10 days from receiving the SO comments) and provides the SO 90 days to correct any deficiencies. SO may request more time if needed. Depending on the results of the audits, SOs could expect a compliance action (i.e., notice of noncompliance, warning letter, etc.)

- **Corrective Action Monitoring and Validation** – Once the time period given to the SO to correct any deficiencies has expended (or when the SO claims all deficiencies have been corrected, whichever is earlier), the SO submits a

[3] Note: Not all audits are conducted virtually. CMS reserves the right to conduct the audit on site at the SOs physical location.

corrective action summary and CEO attestation to PCOG and their Account Manager (AM). The AM is responsible for overseeing validation activities. Using the same protocols, the AM will request a new universe and selects samples for review (via desk review or webinar). If the review is via desk review, the samples will be provided in advance to the SO. If the review is via webinar, the samples will be provided the day of the webinar to review live in the system.

- **Closing the Audit** – Once it is determined that all deficiencies have been corrected, the SO will receive a close out letter. If issues remain, the AM decides next steps (i.e. escalating compliance actions from original audit, etc.).