Attachment VIII

Medicare Advantage & Prescription Drug Program Audit Process

Center for Medicare

Medicare Part C & Part D Oversight and Enforcement Group

Division of Audit Operations

Contents

INTRODUCTION

The Centers for Medicare & Medicaid Services (CMS) Medicare Part C and Part D Oversight and Enforcement Group (MOEG) conducts program audits of Prescription Drug Plan (PDP) and Medicare Advantage Organization (MAO) Sponsoring Organizations (SO)[1] who enter into contracts with the Center for Medicare (CM). CMS updates the program audit process annually based on comments received from the industry via email, conference events, industry listening sessions, and the post audit questionnaire distributed at the conclusion of each audit.

AUDIT MISSION, VISION AND GOALS

Mission: To evaluate sponsors' performance in core program areas that directly affect drugs and other care.

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

Goals:
1) Utilize a data driven process to select sponsors for audit
2) Audit performance areas related to beneficiary access
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 a continuous process of improvement (i.e. survey sponsors, track audit team performance, etc.).

HOW SPONSORS ARE SELECTED FOR AUDIT

MOEG conducts a Risk Assessment to assign a risk score to each sponsoring organization. In accordance with the above stated mission, both the program audit scope and the risk assessment utilized to identify sponsors for audit is focused on evaluation of beneficiaries' ability to access care and prescription drugs. As such, sponsors that present a higher risk to beneficiaries' ability to access care were selected for audit. Additionally, sponsors identified as being low risk were selected for audit to further MOEG's goal of enhancing its data driven approach to select sponsor for audit. At the conclusion of the audit year, the correlation between better audit scores and lower risk sponsors, and vice versa, will be analyzed. The results of this analysis will be utilized to enhance the predictive value of the risk assessment.

Sponsors from the following categories will be selected for audit:

[1] Please note that the term "sponsoring organization" is used to refer to both PDPs and MAOs, and Section 1876 Cost Plans.

1. **Routine Audits - Routine audits are scheduled throughout the year**
    a. High Risk Plans (Risk Assessment Results)
        - Sponsors identified as having a high risk score as per MOEG's Risk Assessment are included in this audit category. The majority of the audited sponsors will be selected from this category.
    b. Lower Risk Plans
        - Sponsors identified as being low risk will be selected for audit for purposes of testing the level of correlation between audit results and the risk assessment.
    c. Low Performing Icons (LPI)
        - All contracts with less than 3 stars for their Part C or D summary star rating for at least 3 years and not recently audited will be selected for audit.
    d. Sponsors not audited in last 4 years and don't meet audit categories a-c above.
    e. Regional Office Referrals
        - Sponsors referred for audit by the regional office due to identified regional office concerns (i.e. High increase in enrollment, CTM outlier, etc.) are included in this category.

2. **Ad Hoc Audits**
    a. Ad hoc audits are not scheduled like a routine audit. Ad hoc audits are an oversight tool that allows MOEG to promptly act when there is reason to believe that a sponsor is non-compliant with CMS policy.

PLANNING AND PREPARATION

Pre-Audit Activities

- **Start Notice/Engagement Letter –** The Audit Lead (AL) contacts the SO's compliance officer via phone and then sends an audit engagement letter including protocols (see Appendix A and B of the HPMS memo) 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 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 of the HPMS memo). The schedule will be broken down per audit area and days of the week.

WEBINAR & ON-SITE AUDIT ACTIVITIES (10 DAYS)

The first week of audit will be kicked off by an entrance conference, and the audit of all applicable operational areas (Part D Formulary Administration (FA); Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organization Determinations, Appeals, and Grievances (ODAG); and Special Need Plans – Model of Care (SNP)) will be conducted virtually via webinar[2]. During the second week, the audit lead and the Part C and Part D Compliance Program Effectiveness team will arrive on-site to conduct the audit of your compliance program effectiveness. This will allow the compliance officer to be actively engaged during the audit of all operational areas and it will allow the audit team to deliver more focused results in a timely manner.

- **Entrance Conference** – The audit starts with an entrance conference held the morning of the first day facilitated by the 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 week #1 – operational areas via webinar**[2] – 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 findings in real time (although some determinations may be pending 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.

  CMS conducts the audits virtually through the use of secure webinar technology[2]. The 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. Findings are usually determined in real time as CMS and the SO discuss each sample case.

[2] Not all audits are conducted virtually. CMS reserves the right to conduct the audit onsite if needed.

- **Preliminary Exit Conference – occurs at the end of week #1 –** CMS will discuss the operational findings identified during the operational audit.

- **Conducting the audit week #2 - 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. Findings for compliance elements are communicated as soon as CMS comes to a determination. CMS will consider the results of the operational audit in week #1 during the evaluation of the compliance audit. This portion of the audit will generally last 3-4 days.

- **Final Exit Conference – conducted at the end of week #2 -** On the last day of the visit, the 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 60 days of the conclusion of the audit). The SO has 10 business days to respond to the report with comments to CMS. CMS will review the SO's 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 (72 hours for immediate corrective actions). SO may request more time if needed. Depending on the results of the audits, SOs may be subject to an enforcement action (i.e., civil money penalty (CMP), sanction, etc.).

    - **Immediate Corrective Action Required (ICAR) -** If CMS identifies systemic deficiencies during an audit that have the potential to cause significant beneficiary harm (whether medical or financial) in the areas of FA, CDAG, or ODAG, the plan will be notified that it needs to take immediate corrective action. Significant beneficiary harm exists if the identified deficiency resulted in the plan's failure to provide medical services or prescription drugs, causing financial distress, or posing a threat to enrollee health and safety due to non-existent or inadequate policies & procedures, systems, operations or staffing. The SO has 72 hours to

provide a corrective action submission to CMS and CMS will begin validation immediately to ensure resolution.

- **Corrective Action Required** – Sponsor will be afforded a total of seven (7) calendar days from the issuance of the final audit report to submit a corrective action plan for all conditions with a "corrective action required (CAR)" in appendix A. Sponsor should include a brief summary describing the process and give a timeframe for correction. Once submitted, CMS will review the corrective action plans. Once accepted by CMS, the sponsor will have 90 calendar days from the date of acceptance of the corrective action plan to correct the conditions noted in the report and to conduct internal testing to evaluate the effectiveness of the corrective action. At or before the expiration of this period, CMS expects sponsor to provide CMS with the attestation in Appendix B of the audit report that these conditions have been corrected and are not likely to recur or inform CMS that the corrective actions were not effective for specific conditions and that additional time is needed (sponsor shall specify what additional time is needed and for which conditions). After sponsor has implemented corrective actions and internally tested them for effectiveness, CMS will validate that correction has indeed occurred. The regional office account manager is responsible for overseeing validation activities. Validating correction of the CAR conditions will be completed by a variety of methods, including but not limited to; (1) relying on the corrective action plan submitted by the sponsor, (2) leveraging results from other CMS reviews/monitoring activities, (3) conducting a virtual walkthrough of the sponsor's systems, processes, and procedures, (4) conducting a virtual walkthrough of sponsor's own internal testing results, (5) testing samples from sponsor submitted universes, and (6) reviewing CDAG/ODAG timeliness (effectuation and notices) through sponsor universe submissions. CMS will use its discretion in determining the validation method for each condition resulting in a CAR. This is the validation process for 2013 audits and is subject to change for future audit years.

- **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.).