

MCS HEALTHCARE HOLDINGS, LLC

Procedure No: CA-COMP-039

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Department: Compliance	Effective Date: June 16, 2010
Unit: Audit and Monitoring	Most Recent Revision Date: 10/21/2020
Procedure Title: Delegation Oversight	Applies to: <input checked="" type="checkbox"/> MCS Advantage, Inc.
Approved by: Corporate Compliance Committee	

PURPOSE

To establish a standardized process for evaluating and managing pre-delegation audits, audits and monitoring efforts of the entities to which MCS Advantage, Inc. (MCS) delegates core operations and/or functions. MCS ensures that each entity fulfills the terms and conditions of its delegated functions with MCS and that each entity is in compliance with all applicable Federal and commonwealth laws, and internal policies and procedures.

PROCEDURES**I. Pre-Delegation Audit:****A. Planning Phase**

1. MCS Operational Area/Business Owner notifies in advance to the Compliance Department of contracting vendor services for a potential delegation of services.
2. The Operational Area/Business Owner provides to the Compliance Department the following documents: scope of services to be delegated, copy of the response to the Request for Proposal (RFP), and drafted Delegation Agreement.
3. The Compliance Department will identify the scope of services to be provided by the First Tier Entity to determine if core functions will be delegated.
4. If based on the results of the analysis, the entity is potentially considered as a First Tier Entity to which core functions will be delegated, the Compliance Department presents the entity to the Corporate Compliance Committee (CCC).
5. The Compliance Department, with the support of the Operational Area/Business Owner, will schedule a pre-delegation audit.
6. Once a potential First Tier Entity has been identified and scheduled for a pre-delegation audit, a preliminary review is performed to obtain an understanding of the respective operations. During the preliminary review, the Compliance Department gathers relevant information, including applicable policies and procedures, about the processes that will be performed in order to obtain a general understanding of the operations.
7. A Pre-Delegation Audit Notification Letter is sent by the Compliance Department to the potential First Tier Entity. This letter indicates the audit's objective, scope, timeline and initial request. The scope of the pre-delegation audit must include the compliance program evaluation and testing of

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its delegated functions, including policies and procedures.

8. The potential First Tier Entity will be afforded ten (10) business days to submit the information requested.
9. The Compliance Department conducts an entrance meeting with the potential First Tier Entity. The purpose of this meeting is to clarify any doubts and/or issues with the audit scope and timeframe of the pre-delegation audit.

B. Audit Fieldwork Phase:

1. The Compliance Department performs the pre-delegation audit procedures to test the potential delegated entity's compliance program effectiveness and, with the help of the Operational Area, review the core operations that could be delegated. These procedures may be performed using, but not limited to, the following techniques: interviews, observation, inspection, and review of systems or methodology to ensure compliance.
2. All findings cited in the pre-delegation audit report must be corrected prior to the delegation.

C. Issuance of the Pre-delegation audit report

1. After concluding the pre-delegation audit, the Compliance Department discusses the preliminary audit findings, if any and request any corrective actions, if applicable. Preliminary findings are shared with the CCO and Senior Management, or delegated, as applicable.
2. The Compliance Department prepares a draft report detailing the audit objective, scope and methodology, conditions and corrective action plans required to address the issues identified, and overall conclusion.
3. The Compliance Department shares the report with the Operational Area/Potential First Tier Entity in order to review and submit their comments. After review, comments these are discussed and addressed, as applicable.
4. The pre-delegation draft report is completed after receiving the review comments from the Operational Area and potential First Tier Entity.
5. After its approval, the pre-delegation final report is completed. The final report is signed by the Compliance AVP, Director or Supervisor in charge of the oversight process and the CCO.
6. The results of the pre-delegation assessment are presented at the CCC meeting. The final pre-delegation report is issued to the potential First Tier Entity and to the Operational Area.
7. An exit meeting is conducted with the potential First Tier Entity and Operational Area. In the meeting, the Compliance Department discusses the findings noted during the review, the corrective actions required (if any), next steps and compliance expectations.

D. Management of Non-Compliance

1. If the audited entity is contracted by MCS, and a condition is cited, the Compliance Department requires the First Tier Entity to provide a corrective action plan (CAP) and its implementation

timeline prior to the delegation of the core functions that were found non-compliant.

2. Management of Non-Compliance is performed in accordance to procedure CA-COMP-040 Compliance Auditing and Monitoring.

E. Validation of Corrective Action Plans

Validation Audit is performed in accordance to procedure CA-COMP-040 Compliance Auditing and Monitoring.

F. Safeguarding of Audit and Monitoring Documentation

The Audit and Monitoring Team records in TeamMate the accumulated evidence (e.g. print screens, attendance sheets, policies and procedures reviewed during the audit, etc.) and the results of the pre delegation audit and procedures performed including RCA, IA and CAP and documentation of departures from regulatory requirements and/or policies and procedures.

G. Pre Delegation Audit Updates

At the end of the working week the auditors send to all of the parties involved in the pre-delegation audit, including the CCO and Senior Management the status of the pre-delegation audit discussed in the Entrance Meeting, as applicable.

H. Escalation

Whenever there is an issue with the timeframes established for the delivering of documentation such as supporting documents, RCA, CAPs, IA; or issues related to any other aspect of the pre-delegation audit process these are escalated promptly to the CCO or designee. Also, extensions of the required timeframe are escalated, evaluated and granted by the CCO, or designee.

II. Post Delegation Audit

1. MCS remains responsible for the lawful and compliant administration of the Medicare Part C and Part D benefits under its contracts with CMS, and with local regulations regardless of whether MCS delegated some of those duties to other entities. For that reason, MCS developed a strategy to monitor and audit on a risk basis its First Tier Entities, to ensure that they are in compliance with all applicable laws and regulations. This strategy is documented in MCS's Compliance Risk Assessment Policy and Procedure - CA-COMP-008 and the annual audit and monitoring work plan.
2. Post Delegation Audit or Monitoring is performed in accordance to procedure CA-COMP-040 Compliance Auditing and Monitoring.

DEFINITIONS

1. Activity Start Date: Date when the delegation audit notification is sent to the auditee(s). This date will be used to populate the Activity Start Date Column from CPE universes. The Workplans' status column will be "In Progress".
2. Activity Completion Date: The Activity Completion Date is the date the pre-delegation or delegation audit activity was completed as demonstrated in the following examples:
 - If an audit took place from January 15, 2018 to January 31, 2018 but the final report was

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issued in March of 2018, the date that would be used would be January 31, 2018.

- If the sponsoring organization completed monitoring a function of the PBM to ensure it properly implemented its transition policy for new enrollees on February 28, 2018, that is the date that would be used for the date the monitoring activity was completed.

When the activity is completed, the Workplans' status column will be changed to "Fieldwork Completed".

3. Date of Report Issuance: Date when the final report is sent to the auditee(s) and Senior Management team, as applicable. When the final report is issued without conditions/findings, the Workplans' status column will be changed to "Closed". If the final report is issued with conditions/findings and corrective actions plans is requested the Workplans' status column will be changed to "Pending CAP Validation".
4. Validation Start Date: Date when the CAP Validation Audit Notice is issued or sent to the auditee(s). When this happens the Workplans' status column is changed to "Validating".
5. Date CAP Validation Audit Report Issuance: The date when the CAP Validation Audit and Closure Letter is issued and sent to the auditee(s). When this happens the Workplans' status column is changed to "Closed".
6. Audit: An Audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.
7. Business Owner: The individual responsible for leading the relationship between MCS and the First Tier Entity. The Business Owner monitors the operational performance and reports results to the Compliance Department.
8. Corrective Action Plan (CAP): A step by step plan of action that the organization develops to achieve targeted outcomes for resolution of identified non-compliance instances or conditions.
9. Corrective Action Required (CAR): Systemic deficiency that must be corrected, but the correction is not immediate. While this deficiency may affect beneficiaries, they are not such a severe nature that beneficiaries' immediate health and safety is affected. Generally, involve deficiencies with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations, or staffing.
10. Delegation Agreement: A legal agreement between MCS and the First Tier Entity, which expresses the terms and conditions consistent with MCS regulatory agencies' requirements.
11. First Tier Entity: Any party that enters into a written arrangement, acceptable to CMS, with an Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program.
12. Immediate Corrective Action Required (ICAR): Systemic deficiency so severe that requires immediate correction. Identified issues of this nature would be limited to situations where the issue resulted in a beneficiary's lack of access to medications and/or services or posed an immediate threat to beneficiary health and safety.
13. Invalid Data Submission (IDS): Invalid Data Submission conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts.

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14. Monitoring: Regular reviews performed as part of normal operations. Monitoring activities may occur to ensure corrective actions are undertaken or when no specific problems have been identified to confirm ongoing compliance.
15. TeamMate: Audit Management Software System that integrates paperless strategies for managing the complete audit process.

ATTACHMENT(S)

N/A

Related MCS Policies and/or Procedures

MCS-Policy-006 Effective System for Routine Monitoring and Auditing

MCS-Policy-007 Prompt Response to Compliance Issues

CA-COMP-008 Risk Assessment and Auditing and Monitoring Work Plans

CA-COMP-040 Compliance Auditing and Monitoring

PROCEDURE REVISIONS:

DATE	CHANGE(S)	REASONS
4/23/2012	Change in the procedures of overseeing delegated entities.	Transfer the ownership of delegated entities to the Business Owner.
10/19/2012	Change the process of determination of a FDR. Incorporate MCS Delegation Oversight Program and Quarterly Delegated Entities Compliance Attestation.	Update policy according to revised MA Chapter 21 and PD Chapter 9 – July 27, 2012
7/1/2013	Update the policy and procedure in accordance with the revised Compliance Program. Incorporate the use of Team Mate and Team Central auditing tools. Eliminate the Compliance Requirements section as these are distributed through other Compliance P&P's. Reduce the submission period for the final Audit Report from 60 to 45 business days. Incorporate the FDR Analysis Tool.	Annual review of P&P
7/30/2014	To separate Policy from procedure. To incorporate Compliance Audit and Monitoring Methodology, CMS Program Audit Process and Protocols. To clarify the process after discussing changes with the MCO.	Annual review of P&P
12/18/2014	Update Procedure based on Compliance Program Effectiveness Audit recommendation and 2015 CMS Readiness Checklist.	Ad hoc Review of Procedure
8/25/2015	Update Procedure based on CMS' 2015 Audit of MCS' Compliance Program Effectiveness recommendations and/or findings.	Annual Review of P&P
8/17/2016	Typographical errors and change in holding company.	Annual revision to comply with CA-COMP-001.
12/20/2017	Update audit and monitoring steps in relation to the review of policies and procedure.	Processes were changed to reflect changes in the Compliance Program
7/25/2018	Typographical errors and update audit and monitoring steps in relation to the review of policies and procedure.	Ad hoc Review of Procedure

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DATE	CHANGE(S)	REASONS
7/22/2020	Eliminate Post Delegation auditing and monitoring procedure as it was consolidated into procedure CA-COMP-040 Part C and D Auditing and Monitoring. Added definitions and clarify processes for safeguarding of documentation and escalation.	Annual Revision
10/21/2020	To eliminate the Delegation Oversight Committee	Annual Revision