Related Department: Compliance	Effective Date: 6/16/2010
Policy Title: Effective System for Routine Monitoring and Auditing	Most Recent Revision Date: 12/17/2019
Approved by: Corporate Compliance Committee	Applies to: ☑ MCS Advantage, Inc.

POLICY

MCS has established and implemented an effective system for routine monitoring and identification of compliance risks. The system includes internal monitoring and auditing and, as appropriate, external monitorings and audits, including FDRs' compliance with regulatory agency requirements, such as CMS, and the overall effectiveness of the Compliance Program. MCS develops a monitoring and auditing work plan that addresses regulatory risks, including but not limited to risks associated with the Medicare Parts C and D benefits.

A. Annual Risk Assessment
   1. MCS conducts an annual risk assessment of all MCS's operational areas and First Tier Entities in order to determine where MCS is at risk for potential non-compliance and identification of areas in which additional controls should be implemented. Through this process MCS assesses major compliance and fraud, waste, and abuse (FWA) risk areas.
      a. Annual risk assessment takes into account all Medicare business operational areas and core processes related to Medicare requirements. Each operational area must evaluate the applicable Medicare requirements and must assess them according to the types and levels of risks the area and/or process present to the Medicare program and to MCS. Factors that MCS considers in assessing the risks associated with each area and/or process include, but are not limited to:
         i. Financial / Dollar Impact terms of revenues or losses;
         ii. Reputation / Customer Satisfaction;
         iii. Legal / Regulatory;
         iv. Member Impact
         v. Previous Risk Experience;
         vi. Complexity of Operations;
         vii. Management Confidence; and,
         viii. System Capabilities
      b. Risks identified by the annual risk assessment determine which risk processes will have the greatest impact, and are used to prioritize the monitoring and auditing strategy accordingly.

B. Monitoring and Auditing Work Plans
   1. Once the risk assessments are completed, the Monitoring, and Auditing Work Plans (the Works Plans) are developed prioritizing the identified compliance and FWA risks. MCS uses the monitoring and auditing work plans as a guideline to assure all identified operational areas and First Tiers Entities are monitored and/or audited through the year and to allocate the available resources.
   2. The Work Plans include, but are not limited to:
      a. Audit or monitoring activity to be performed;
      b. First Tier Entity, Department(s) or operational area(s) impacted by activity;
      c. Scheduled time for the audit or monitoring activity to be started;
      d. Scheduled time for the audit or monitoring activity to be completed.

3. The Work Plans include a schedule that lists all of the intended monitoring and auditing activities for the calendar year for MCS operational areas and First Tier Entities. (For more information on the auditing and monitoring processes see the procedures: CA-COMP-039 Delegation Oversight and CA-COMP-040. Internal Compliance Audit and Monitoring.)
4. The Work Plans may be modified throughout the year as risks change and evolve with changes in laws, regulations, CMS, or other regulatory agencies requirements and operational matters.
5. The Work Plans are presented to the Chief Compliance Officer (CCO), Corporate Compliance Committee (CCC), Board Compliance Committee (BCC) and Board of Director for review and approval.
6. The CCO oversees auditing and monitoring activities and the status and effectiveness of corrective actions taken.
7. Results of auditing and monitoring activities, as well as action plan status and changes in the Work Plans, are discussed in the CCC and BCC meetings.
8. Corrective actions and follow-ups are overseen by the CCO and assisted by the Auditing and Monitoring Unit and Special Investigations Unit, and include actions such as reporting findings to CMS or to the I MEDICs, if necessary.
9. The Compliance Program effectiveness is independently audited on an annual basis. Less formal measures are also used to monitor the Compliance Program effectiveness. Results are shared with the CCC and BCC.

C. Monitoring and Auditing of First Tier Entities
1. MCS validates the First Tier Entities ability to perform the proposed Medicare delegated activities prior to delegation. The pre-delegation assessment focuses on determining whether a prospective delegate meets the applicable performance standards, fiscal stability requirements and regulatory mandates and is capable of performing the proposed delegated responsibilities.
2. MCS only delegates activities to First Tier Entities who demonstrate, prior to delegation, the ability to perform delegated duties adequately, and who have the mechanisms in place to document the activities and produce associated reports.
3. The reports are discussed with the Business Owner. The pre-delegation report is discussed with the CCO. Final reports including all corrective actions and/or recommendations are presented to the CCC and Delegation Oversight Committee.
4. Afterwards, on an annual basis, First Tier Entities are audited or monitored according to the results of the Corporate and FWA Risk Assessments.

D. Special Investigations Unit (SIU)
1. MCS has an effective program to control FWA and to identify and address FWA internally and with FDRs in the delivery of Parts C and D benefits. As part of the Compliance Department, the Special Investigations Unit (SIU) is responsible for:
    a. Conducting a FWA risk assessment to determine FWA risks areas that may impact the organization and prioritize the monitoring and annual investigation plan accordingly;
    b. Providing trainings and education to MCS employees, members of the Board of Directors, and FDRs to recognize FWA indicators or issues that may warrant additional investigation by the SIU;
    c. Referring potential cases of illegal activity, including drug diversion, to the I-MEDIC, and/or law enforcement agencies and conducting case development, and support activities for I-MEDIC and/or law enforcement investigations;
    d. Identifying beneficiaries with drug utilization problems;
    e. Identifying and recommending providers for exclusion, including physicians, pharmacists, PBMs and any FDRs who have defrauded or abused the system;
    f. Assisting law enforcement by providing information needed to develop successful prosecutions;

g. Analyzing information obtained from MCS's software and applications;
h. Reviewing documents related to identified providers or beneficiaries such as: history of claims (queries), medical policies, payment policies, provider contracts (as applicable), members' enrollment forms (as applicable), descriptions of procedure and diagnosis codes, etc., that help support or dismiss possible patterns, schemes, or tendencies presented;
i. Monitoring the monthly verification of MCS employees and FDRs against the federal exclusion lists;
j. Consulting with applicable MCS personnel and/or medical consultants to obtain needed information and counsel;
k. Visiting providers to obtain copies of medical records and interview providers' personnel;
l. Identifying patterns, schemes, or tendencies, with specific attention to the geographic areas identified by CMS as high-risk counties. For more information, see the procedure: CA-FWA-005 Data Analysis to Identify Patterns of Fraud, Waste, and/or Abuse in High-Risk Counties.

2. The SIU works directly with the CCO in the implementation of the FWA program and/or corrective actions resulting from compliance and/or FWA investigations. The SIU provides periodic reports to the CCO, as applicable of:

a. Compliance and FWA referrals;
b. Investigation Reports of cases in which potential compliance and/or FWA issues are identified and/or cases that should be referred to any regulatory and/or law enforcement agency, as applicable;
c. Periodic metrics and/or assessments made by the SIU regarding FWA and compliance investigated schemes;
d. Periodic metrics and/or reports of corrective actions resulting from compliance and/or FWA investigations;
e. Any other information that the SIU identified that may represent a compliance and/or FWA issue for the organization.

E. OIG/GSA Exclusion List

1. MCS reviews all individuals and entities excluded from participation in Federal Health Care Programs. This takes place through screening of new employees, temporary employees, consultants, members of the Board of Directors, and FDRs, prior to hire, appointment or execution of a contract and monthly thereafter before the exclusion effective date. Screening takes place against the Department of Health and Human Services Office of Inspector General (OIG), List of Excluded Individuals and Entities (LEIE), exclusion list and the General Services Administration (GSA) list. If an individual's or entity's name appears on either the OIG or GSA list, corrective actions are taken as detailed in our policies and procedures.

2. FDRs are responsible for ensuring a process is in place to screen both potential and actual employees, contracted and/or individual entities against the OIG and GSA exclusion lists and report to MCS on a periodic basis. As part of the annual auditing and monitoring process, MCS will confirm that First Tier Entities are conducting this screening.

F. Preclusion List

1. Beginning on April 1, 2019 MCS must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list. CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. If MCS does not comply with this requirement it may be subject to sanctions including termination of its contract with CMS.

2. MCS as well its FDRs are responsible for ensuring processes are in place to screen prior to contracting and monthly thereafter.

G. Data Analysis for Fraud, Waste, and Abuse Prevention and Detection
   1. MCS engages in a variety of monitoring and auditing activities focused proactively on identifying potential non-compliance and FWA among its operational areas and First Tier Entities. MCS revises and refines its monitoring activities aimed at potential non-compliance, and FWA as new schemes and methods are uncovered in the industry and on a risk basis. MCS conducts periodic meetings and maintains communication with First Tier Entities regarding processes and policies to prevent, identify and report potential or actual non-compliance and FWA.
   2. MCS through the Special Investigations Unit (SIU) performs effective monitoring in order to prevent and detect FWA, which rely primarily on data analysis to identify patterns of aberrant and potentially abusive utilization and other forms of FWA, are conducted by MCS and by First Tier entities, as required. Some of these activities include:
      a. Analysis of prescription data in order to identify outlier prescription claims that may be the result of fraudulent or abusive behaviors, for example:
         i. Abnormal number of prescriptions/prescription patterns within suspected classes;
         ii. Patients that use multiple pharmacies or physicians;
         iii. Controlled substances prescribing patterns;
         iv. Excessive prescribing of medications intended for acute use;
         v. High dollar claims utilization or high quantity dispensed;
         vi. Geographical areas of concern activity. Any unusual and/or high activity conducted by a member, provider, pharmacy, or physician in a high risk county as defined by federal and/or local agencies; and
         vii. Duplicate therapies. Beneficiaries who are receiving multiple prescriptions within a therapeutic class within the same time frame.
      b. Examination by MCS's contracted Pharmacy Benefits Manager (PBM) of utilization activity for specific clinical patterns.
      c. PBM desk and onsite audits of pharmacies to identify claims discrepancies and overpayments.
      d. Part D claims review by a contracted vendor to detect coding and billing errors.
      e. PBM attendance at quarterly MEDIC meetings to coordinate efforts with other Medicare Part D plan sponsors, the MEDIC, and HHS-OIG. All pharmacies identified in these meetings are added to the PBM investigative audit program for further evaluation.
      f. Analysis of claims (Part C and Part C) are evaluated through an automatic monitoring system.
      g. Analysis and evaluation of claims based on regulatory and/or law enforcement fraud alerts, such as:
         i. CMS Fraud Alerts;
         ii. CMS-Pharmacy Quarterly Risk Assessment;
         iii. CMS Fraud Handbook; and,
         iv. HHS-OIG Annual Plan.

H. MCS allows access to any auditor acting on behalf of the federal government or CMS to conduct an on-site audit. MCS and FDRs provide records to CMS or its designee and cooperate in allowing access as requested related to Part C and D Programs.

DEFINITIONS

1. Centers for Medicare and Medicaid Services (CMS): The Federal agency within the Department of Health and Human Services (DHHS) that administers the Medicare program.

2. FDRs: First Tier, Downstream and Related Entities

   - First Tier Entity: Any party that enters into a written arrangement, acceptable to CMS, with MCS to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.
   - Downstream Entity: Any party that enters into a written arrangement, acceptable to CMS, with MCS, below the level of the arrangement between MCS and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.
   - Related Entity: Any entity that is related to MCS by common ownership or control and (1) Performs some of MCS's functions under contract or delegation; (2) Furnishes services to Medicare enrollees under an oral or written agreement; or (3) Leases real property or sells materials to MCS at a cost of more than $2,500 during a contract period.

3. I-MEDIC: Medicare Part C and Part D program integrity contractor for the Centers for Medicare & Medicaid Services (CMS). The purpose of the I MEDIC is to detect and prevent fraud, waste and abuse in the Part C (Medicare Advantage) and Part D (Prescription Drug Coverage) programs on a national level.

REFERENCES

- Sentencing Guidelines, Chapter 8 – Sentencing for Organizations, Part B – Remedying Harm form Criminal Conduct, Effective Compliance and Ethics Program.
- Medicare Managed Care Manual Chapter 11- Medicare Advantage Application Procedures and Contract
- Prescription Drug Benefit Manual, Chapter 9 and Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines; Section 50.5 – Element V: Well-Publicized Disciplinary Standards and Section 50.6 – Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks.
- 42 C.F.R. § 422.222, 422.224 and 422.503€ and § 423.504 €

RELATED MCS PROCEDURE(S)

- CA-COMP-008 Risk Assessment and Auditing and Monitoring Workplans
- CA-COMP-039 Delegation Oversight
- CA-COMP-040 Internal Compliance Auditing and Monitoring
- CA-COMP-060 Screening of OIG/GSA
- CA-FWA-002 Data Analysis to Identify FWA Patterns
- CA-FWA-003 Request and Review Clinical records Files
- CA-FWA-006 Internal Procedure for the Review and Initiation of Investigations from Pharmacy FWA Reports
- CA-COMP-071 Medicare Compliance Dashboard
- CA-COMP-080 Handling of Regulatory Agencies Identified Deficiencies

POLICY REVISIONS:

DATE	CHANGE(S)	REASONS
7/30/2014	Segregation between policy and procedure	Annual Review
8/25/2015	Typographical errors and review of section A.1.a	Annual Review
8/17/2016	To change Holding company and add new subsidiary	Annual Review
11/8/2017	Annual review and incorporation of changes to align the process being done with policy	Annual Review

DATE	CHANGE(S)	REASONS
12/21/2018	Clarify language and add information regarding the SIU responsibilities and the preclusion list requirements effective 1/1/2019.	Annual Review
05/08/2019	Replace NBI MEDIC for I MEDIC as the new contractor of CMS for Integrity Program (FWA Investigations)	Ad hoc review based on HMPS Memo
12/17/2019	Clarify that OIG/GSA process is performed prior to hiring, appointment or execution of a contract.	Annual Review.