

MCS HEALTHCARE HOLDINGS, LLC

# 2018 MCS Compliance Program

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## MISSION AND VISION OF THIS PROGRAM

### MISSION

Promote and support the highest level of compliance and ethical behavior throughout MCS and among all employees, Board of Directors members and FDRs.

### VISION

To elevate corporate performance in all its relationships by upholding and supporting proper compliance and ethical conduct.

## COMPLIANCE PROGRAM OVERVIEW

### INTRODUCTION

MCS adopted and implemented a Compliance Program that includes measures to prevent, detect, and correct instances of non-compliance as well as potential fraud, waste, and abuse ("FWA"). This Compliance Program is tailored to MCS's operations and unique circumstances. It is reviewed and revised on an annual basis, or more frequently, as required. It may be modified or amended, as needed, upon approval of the members of the Board. This Compliance Program:

- Demonstrates to employees, members of the Board, beneficiaries, FDRs, and regulators our commitment to responsible corporate conduct.
- Creates and reinforces an environment that requires employees, FDRs, and beneficiaries to report potential or actual cases of non-compliance, including potential FWA, confidentially, anonymously and without fear of retaliation or intimidation.
- Establishes controls to monitor MCS's operational areas and FDRs to ensure compliance with applicable laws, regulations and guidelines.
- Designates a single department responsible for interpreting and distributing compliance requirements and responsibilities, while compelling all employees, members of the Board, FDRs and beneficiaries to take accountability for identifying and reporting suspected or actual compliance violations, including potential FWA.
- Provides a mechanism to keep the Corporate Compliance Committee, Senior Management, the Board Compliance Committee and the Board of Directors apprised of compliance matters on an ongoing basis.

The implementation of this Program cannot guarantee that improper conduct will be entirely eliminated. Nonetheless, MCS expects full compliance from all employees and FDRs (collectively, "Covered Persons") with policies and procedures established in support of the MCS Compliance Program and Code of Conduct. They outline the basic principles that should guide all of MCS's activities. At MCS, activities are conducted in accordance with MCS's corporate values:

- **Accountability:** You are accountable for fulfilling your obligations and assuming responsibility for the results.
- **Compliance:** All of your actions and decisions are driven by the highest ethical standards and in accordance with applicable laws and regulations.
- **Trust:** You create trust and long lasting relationship with MCS beneficiaries, employees, business partners, and the community, through the compliance with your commitments and goals.

The general guidelines of this Compliance Program, in combination with the Code of Conduct, the MCS Employee Handbook and MCS's policies and procedures guide us in the right direction and provide us with MCS' expectations regarding business dealings.

It is each employee's responsibility to be familiar with the Compliance Program and adhere to all applicable MCS policies and procedures and corporate standards. Violations of this Program, the MCS Code of Conduct, policies, procedures or applicable laws or regulations may result in employee disciplinary actions, up to and including employment termination and, with respect to contractors, in corrective actions, monetary penalties and/or contract termination. All corrective actions will be applied on a timely and consistent manner.

## WHY IS COMPLIANCE IMPORTANT?

Compliance is the act of adhering to established guidelines, requirements, and legislation. Compliance with requirements is extremely important. Failure to comply with requirements is costly and can have significant repercussions for an organization including fines, bad press, a tarnished business reputation, sanctions, and contract termination with the regulators. MCS is subject to adhering to laws, regulations, and guidance which include, but are not limited to the following:

- Title XVIII of the Social Security Act
- Code of Federal Regulations, specifically 42 CFR §§422, 423 and 438
- Federal Sentencing Guidelines
- Federal and State False Claims Acts
- Federal Criminal False Claim Statutes
- Stark Law (Physician Self-Referral Statute)
- Anti-Kickback Statute
- Civil Monetary Penalties and Exclusions
- The Beneficiary Inducement Statute
- Fraud Enforcement and Recovery Act of 2009 Whistleblower (qui tam) Protection Act
- Health Insurance Portability and Accountability Act (HIPAA)
- Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal government
- Health Information Technology for Economic & Clinical Health (HITECH)

- HPMS memos
- Medicare Managed Care Manual
- Prescription Drug Benefit Manual
- Medicare Improvements for Patients and Providers Act (MIPPA)
- Patient Protection and Affordable Care Act
- The U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) Work Annual Plan
- Puerto Rico Insurance Code
- Puerto Rico Health Insurance Code
- Medicare Advantage and Part D Fraud Handbook

## WHO IS RESPONSIBLE FOR COMPLIANCE?

Compliance is everyone’s responsibility. This includes members of the Board, officers, employees (including temporary), and FDRs. Everyone is responsible for understanding and abiding by the requirements that govern our business and conducting business in a compliant and ethical manner.

## COMPLIANCE PROGRAM DESCRIPTION

This Compliance Program includes the following core requirements:

- I. Written Policies, Procedures, and Code of Conduct;
- II. Compliance Officer, Compliance Committee and High Level Oversight;
- III. Effective Training and Education;
- IV. Effective Lines of Communication;
- V. Well Publicized Disciplinary Standards;
- VI. Effective System for Routine Monitoring and Identification of Compliance Risk; and,
- VII. Procedures and System for Prompt Response to Compliance Issues.

## I. WRITTEN POLICIES, PROCEDURES AND CODE OF CONDUCT

### CODE OF CONDUCT

MCS adopted and implemented a Code of Conduct to describe compliance expectations from all employees, members of the Board, and FDRs to conduct themselves in a compliant and ethical manner; that issues of non-compliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected. The MCS Code of Conduct is approved by the Board of Directors.

## COMPLIANCE POLICIES AND PROCEDURES

MCS has compliance policies and procedures that are detailed and specific, that describe and implement the operation of the MCS Compliance Program. MCS updates the policies and procedures to incorporate changes in applicable laws, regulations, and others requirements. New and/or revised compliance policies and procedures are presented to the Corporate Compliance Committee (“CCC”) for review and approval.

## DISTRIBUTION AND ACKNOWLEDGEMENT

MCS distributes the Code of Conduct, the Compliance Program, and compliance policies and procedures to employees within ninety (90) days of hire, when there are updates and annually thereafter. As a condition of employment with MCS, all employees are required to annually acknowledge in writing that they have received, read, and agree to comply with the Code and related policies and procedures. All documents are also well-publicized using electronic tools accessible to all employees and shared with FDRs. FDRs may utilize their own compliance policies and procedures and Code of Conduct as long as they are:

- Comparable to those used by MCS.
- Compliant with federal, local and other applicable laws, regulations, and guidance.

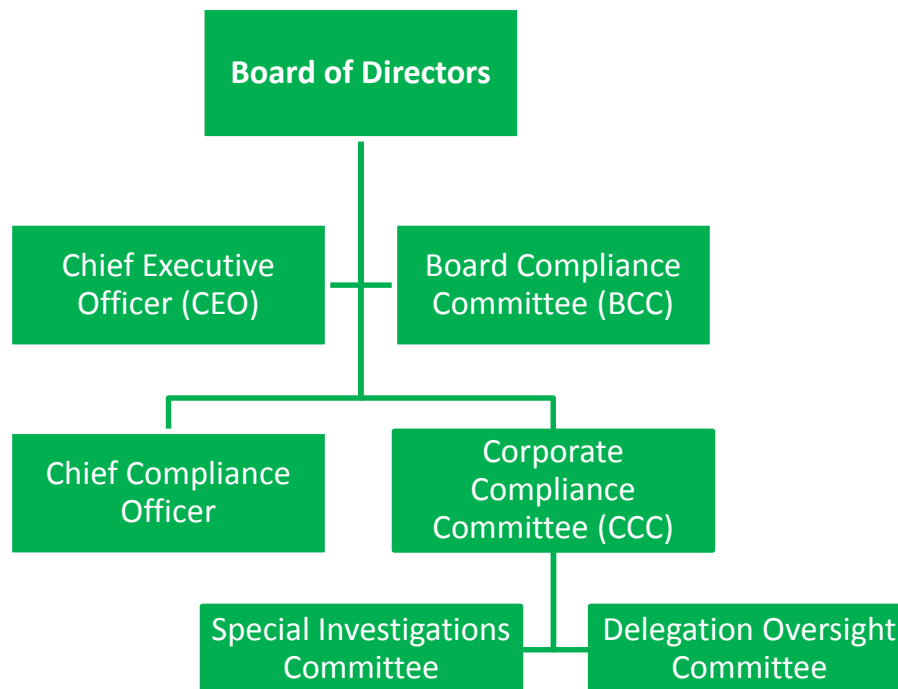
MCS uses a variety of mechanisms to ensure that the FDRs distribute the Code of Conduct and compliance policies and procedures to their employees and members of their board, including but not limited to including appropriate contract provisions in the First Tier’s contract and periodic monitoring of them.

For more information, refer to *MCS-Policy-001 Policies, Procedures, Code of Conduct and Compliance Program* and related procedure.

## II. COMPLIANCE OFFICER, COMPLIANCE COMMITTEE AND HIGH LEVEL OVERSIGHT

### COMPLIANCE ORGANIZATIONAL STRUCTURE

MCS has implemented a Compliance organizational structure that promotes a culture of compliance and ethical behavior, maintains open lines of communication, and provides effective oversight of the Compliance Program. For more information, refer to *MCS-Policy-002 Compliance Officer, Compliance Committee and High Level Oversight*.



The Board of Directors is a body of elected or appointed members who jointly oversee MCS activities. The Board of Directors appoints the Board Compliance Committee ("BCC") to assist it in overseeing the MCS Compliance Program, Code of Conduct, and compliance policies and procedures. The BCC is chaired by a member of the Board of Directors. The BCC is constituted of at least 3 members of the Board and the Chief Compliance Officer ("CCO").

The Board of Directors appoints the CCC to support the BCC in overseeing the MCS Compliance Program, Code of Conduct, and compliance policies and procedures. The CCC is chaired by the CCO. The members of the CCC include the Chief Executive Officer (CEO), a member of the BCC, and key members of MCS management. The Special Investigations and Delegation Oversight Committees provide support to the CCC.

The CCO reports to the Board of Directors but has a dotted line to the CEO. The CCO maintains open lines of communication with the Board of Directors by providing them with regular compliance updates and can report compliance matters directly to the Board of Directors without first going through any other layers of management.

## MCS BOARD OF DIRECTORS

The Board of Directors is responsible for providing ethical leadership and ensuring that resources are available to facilitate compliance and reduce risk of unlawful or improper actions. Members



of the Board are responsible for supporting and conveying an expectation of a corporate-wide culture of compliance and excellence in every phase of the operations. It is the responsibility of the Board of Directors to review, approve, support, and be knowledgeable about the contents and operation of the Compliance Program, Code of Conduct, and compliance policies and procedures. The Board of Directors is further responsible for exercising reasonable oversight with respect to the effectiveness of the Compliance Program and Code of Conduct. The members of the Board must demonstrate commitment to compliance with all applicable laws, regulations, and contractual obligations including, but not limited to, those with the Centers for Medicare and Medicaid Services ("CMS"), the Puerto Rico Health Insurance Administration ("ASES" by its Spanish acronym), the Office of the Commissioner of Insurance ("OCI"), and other regulatory entities. Finally, the members of the Board are ultimately responsible for overseeing compliance throughout the organization and among FDRs. Board oversight is critical to promote corporate governance that protects the mission of MCS and its beneficiaries. Reasonable oversight includes, but is not limited to:

- Approval of the Code of Conduct and Compliance Program;
- Approval of the annual risk assessment and annual compliance, FWA, and First Tiers' audit work plans;
- Understanding the compliance program structure;
- Remaining informed about the compliance program outcomes;
- Remaining informed about governmental compliance enforcement activity such as Notices of Non-Compliance, Warning Letters and/or more formal sanctions; and,
- Receiving regularly scheduled, periodic updates from the CCO

## BOARD COMPLIANCE COMMITTEE

The BCC is responsible for providing oversight of the structure and efficacy of the Compliance Program. The BCC meets regularly to oversee the implementation and effectiveness of the Compliance Program. They also receive and review periodic reports from the CCO. The BCC reports to and coordinates with the Audit Committee and/or Internal Audit Department regarding regulatory compliance matters that may affect the MCS business, financial statements, or compliance policies, including any material reports or inquiries from regulatory or governmental agencies. In addition, they also receive reports from, and coordinate with, the Audit Committee and/or Internal Audit Department regarding regulatory compliance issues arising as a result of the MCS internal audit function. Specific compliance oversight responsibilities include:

- Review and approval of the MCS Code of Conduct and Compliance Program;
- Review and approval of the Annual Risk Assessment and Annual Compliance, FWA and First Tier's Audit Work Plans.
- Remaining informed of outcomes from internal and external audits;
- Approve the appointment or removal of the CCO;
- Review and approval of performance goals for the CCO;
- Review results of performance and effectiveness assessments of the Compliance Program.

- Evaluate senior management team’s commitment to ethics and the Compliance Program;
- Review dashboards and other self-assessment tools that reveal compliance issues; and
- Provide oversight of the effectiveness of compliance monitoring, including the results of internal investigations and responses to instances of noncompliance and FWA;

## CORPORATE COMPLIANCE COMMITTEE

The CCC meets at least quarterly or more frequently, as necessary. The meeting is chaired by the CCO and includes key management from business units throughout MCS, as well as the CEO, General Counsel, Chief Medical Officer, Chief Audit Executive, Chief Operating Officer, Chief Financial Officer, and a member of the Board of Directors. The role of this Committee is to advise, report to, and support the BCC; take actions as needed to assist the BCC in performing its responsibilities; advise the CCO; and assist in the implementation and management of the Compliance Program. This Committee is responsible for:

- Reviewing and approving all new and revised compliance policies and procedures, developed and reviewed annually by senior management,
- Developing strategies to promote compliance and the detection of any potential violations;
- Reviewing and approving the Compliance Program, Code of Conduct and General Compliance, Privacy and FWA Trainings and ensuring they are appropriately completed;
- Assisting with the creation and implementation of the compliance risk assessment and of the compliance and FWA monitoring and auditing work plans;
- Reviewing and approving the Compliance, First Tier entities and FWA Annual Work Plans submitted by the CCO annually;
- Reviewing internal and external audit work plans and audit results;
- Reviewing corrective action plans resulting from external audits;
- Assisting in the implementation, and monitoring of effective corrective actions;
- Developing innovative ways to implement appropriate corrective and preventive actions;
- Reviewing effectiveness of the system of internal controls designed to ensure compliance with Medicare and Commercial regulations in daily operations;
- Supporting the CCO's needs for sufficient staff and resources to carry out his/her duties;
- Ensuring that MCS has appropriate, up-to-date compliance policies and procedures (including privacy and FWA);
- Ensuring that MCS has a system for employees and FDRs to ask compliance questions and report potential instances of non-compliance and potential FWA confidentially or anonymously (if desired) without fear of retaliation and/or intimidation;

- Ensuring that MCS has a method for beneficiaries to report issues of noncompliance and potential FWA;
- Reviewing and addressing reports of monitoring and auditing of areas in which MCS is at risk for program non-compliance or potential FWA, and ensuring that action plans are implemented and monitored for effectiveness; and
- Reviewing dashboards and other self-assessment tools that reveal compliance issues or privacy issues.

## SPECIAL INVESTIGATIONS COMMITTEE

The Special Investigations Committee (“SI Committee”) assists the CCC, Board of Directors and MCS in overseeing the Special Investigations Unit’s (“SIU”) cases of potential FWA. The main responsibility of the SI Committee is to provide feedback to the SIU regarding the administrative actions to be taken in the investigated cases of potential FWA. The SI Committee applies disciplinary guidelines enforced through the appropriate established internal or external entity. This includes, but is not limited to:

- Recommend the termination of an employee;
- Terminate the contract of an FDR;
- Implement administrative actions to a member in accordance with applicable regulations;
- Refer a case to Office of Inspector General U.S. Department of Health & Human Services (“HHS-OIG”), the National Benefit Integrity Medicare Drug Integrity Contractor (“NBI MEDIC”), the Office of the Commissioner of Insurance (“OCI”), or other local or federal agencies as appropriate;
- Develop strategies to promote FWA compliance;
- Assist with and oversee action plans to ensure they are implemented, documented, and communicated upon confirmation that a case of potential FWA has occurred;
- Approve and monitor the implementation of preventive actions.

## DELEGATION OVERSIGHT COMMITTEE

The Delegation Oversight Committee assists the CCC and is tasked with enforcing the Delegation Oversight Program at an operational level, including support to MCS operational areas. The main responsibility of the Committee is to provide feedback to the CCC regarding the functions delegated by MCS to different First Tier Entities to ensure compliance. The Committee’s task include but are not limited to:

- Quarterly review of the First Tier’s performance data;
- Recommendation of contractual penalties; assistance in the implementation of actions and penalties; etc.

The Delegation Oversight Program is available via internal application (*Compliance 360, Corporate Policies, Code of Conduct and Compliance Program Folder*) to all employees. First Tiers have access via hard copy or electronic versions of the program.

## CHIEF COMPLIANCE OFFICER

The CCO is a full-time employee of MCS that has overall responsibility for implementing and managing the Compliance Program and Code of Conduct, and for serving as a member of the executive leadership team and has direct access to the Chief Executive Officer (CEO) and Board of Directors in order to provide unfiltered, in-person reports to them, and is vested with the authority to ensure full compliance with the Compliance Program. The CCO also provides periodic reports to the CEO, CCC, BCC and the Board on the status and activities of the Compliance Program. Responsibilities include, but are not limited to the following:

- Administer, revise, manage, and provide information, at least quarterly or more frequently as necessary, to the CEO, CCC and BCC and the Board of Directors, on the status of the Compliance Program operations, the identification and resolution of potential or actual instances of non-compliance, and MCS's compliance oversight and audit activities;
- Oversee the planning, development, implementation, monitoring, and management of compliance initiatives, controls, and metrics to comply with applicable statutory and regulatory mandates, and ensure that operational units consistently achieve compliance with Federal and Puerto Rico mandates;
- Oversee the development, management, and revision of compliance policies and/or procedures to ensure that they are complete, accurate, and compliant with Federal and Puerto Rico mandates;
- Oversee the creation and coordination of General Compliance Trainings to ensure that all Board of Directors members, employees, and FDRs are knowledgeable about MCS's Compliance Program, Code of Conduct, and compliance policies and/or procedures, and all applicable statutory and regulatory requirements;
- Oversee the receipt, analysis, and dissemination of communications from CMS, ASES, OCI, and other regulatory agencies to appropriate MCS operational areas and/or FDRs, and track implementation of any required changes;
- Identify and communicate significant regulatory risks and recommendations for mitigation to executive leadership;
- Provide guidance to senior management to address, manage, and document compliant operations in respective business units;
- Communicate with senior management regarding compliance issues, status, initiatives, and risks;
- Monitor and communicate changes in laws, regulations, and governmental manuals and guidelines with probable impact on MCS operations;
- Promote full compliance with company policies and procedures, and local and federal laws and regulations applicable to our industry;
- Chair the CCC;
- Respond to reports of potential instances of FWA, including the coordination of internal investigations and the development of appropriate enforcement or disciplinary actions, if necessary;
- Oversee the documentation of all reports of potential non-compliance or FWA received from any source, including through any of the Confidential Reporting Lines (ACTright),

which describes the initial report of non-compliance, the investigation, the results of the investigation, and all enforcement and/or disciplinary action(s) taken as a result of the investigation, as well as the respective dates when each of these events and/or actions occurred, and the names and contact information for the person(s) who took and documented these actions;

- Report all governmental compliance enforcement activity to the CEO on a timely basis.
- Provide a compliance report for all lines of business at least quarterly to the CCC, BCC and Board of Directors.
- Serve as liaison between MCS and CMS, ASES and other regulatory agencies
- Oversee the submission to the NBI-MEDIC and other applicable regulatory and law enforcement agencies of documentation of suspected FWA cases investigated by the Special Investigations Unit (SIU);
- Oversee potential fraud investigations/referrals by the SIU and the appropriate NBI-MEDIC. Respond to documentation and/or procedural requests from the NBI-MEDIC. When an FWA issue is discovered that involves multiple parties, the CCO oversees the coordination with other Medicare plans, State Medicaid programs, Medicaid Fraud Control Units (MCFUs), commercial payers, and other organizations when appropriate;
- Support programs that encourage employees and FDRs to report suspected fraud, waste, abuse, and other improprieties without fear of retaliation and/or intimidation;
- Oversee auditing of First Tier Entities to ensure compliance;
- Oversee compliance, FWA, and First Tier entities Medicare monitoring and auditing activities to ensure compliance;
- Facilitate and oversee audits/investigations by regulatory agencies;
- Oversee development, approval, implementation, and monitoring of action plans by MCS operational areas and First Tier Entities in response to internal and external audits;
- Ensure that employees and First Tier Entities acknowledge that they have received, read and will comply with the MCS Compliance Program and Code of Conduct;
- Respond to questions or concerns from employees, Board of Directors members, and FDRs regarding compliance issues;
- Convey the importance of compliance with regulatory requirements to internal stakeholders in a manner that leads to institutionalization of compliance;
- Oversee the process of screening against the HHS OIG and General Services Administration (GSA) exclusion lists which are checked prior to hiring, and monthly thereafter, for all employees, interns, consultants, members of the Board of Directors and FDRs;
- Oversee investigations regarding internal or FDRs compliance issues;
- Oversee the development, implementation, tracking and remediation of corrective action plans;
- Oversee the Privacy Program;
- Ensure that all company contracts and other documents pertinent to the Medicare program are reviewed and retained;
- Review or delegate the responsibility to review the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements;
- Independently seek advice from legal counsel; and

- Report misconduct or non-compliance to CMS, its designee, or law enforcement.

## PRIVACY OFFICER

The Privacy Officer is a full time employee of MCS, who reports to the CCO and is responsible for the organization's Privacy Program including the daily operations of the program, development, implementation, and maintenance of privacy policies and procedures, monitoring program compliance, investigation and tracking of incidents and breaches and insuring patients' rights in compliance with federal and state laws. In general, responsibilities include, but are not limited to:

- Defines, develops, maintain and implements policies and processes that enable consistent, effective privacy practices which minimize risk and ensure the confidentiality of protected health information (PHI), paper and/or electronic, across all media types;
- Develops and direct responses to questions or concerns from employees, board members, providers and contracted entities regarding privacy compliance issues;
- Serves in a leadership role for privacy compliance;
- Leads Privacy and Security Workgroup to discuss company-wide privacy and security matters in order to ensure the effective implementation of the Privacy Program;
- Monitors patterns of inappropriate access and/or disclosure of protected health information and report them to the CCO;
- Takes a lead role, to ensure the organization has and maintains appropriate privacy and confidentiality consents, authorization forms and information notices and materials reflecting current organization and legal practices and requirements;
- Oversees, develops and delivers initial and ongoing privacy training to the workforce;
- Manages all required breach determination and notification processes under HIPAA and applicable State breach rules and requirements;
- Establishes and administers a process for investigating and acting on privacy complaints;
- Performs required breach risk assessment, documentation, and mitigation;
- Works with Human Resources to ensure consistent application of sanctions for privacy violations;
- Initiates, facilitates and promotes activities to foster information privacy awareness within the organization and related entities;
- Cooperates with the U.S. Department of Health and Human Service's Office for Civil Rights, State regulators and/or other legal entities in any compliance reviews or investigations; and
- Serves as information privacy resource to the organization regarding release of information and to all departments for all privacy related issues.

## INFORMATION SECURITY OFFICER

The Information Security Officer (“ISO”) is an employee of MCS responsible for day-to-day oversight of all ongoing activities that serve to provide appropriate access to and protect the confidentiality and integrity of insured member, provider, employee and other business

information in compliance with applicable laws, regulations, policies and standards in MCS. The ISO is responsible for managing and supervising the execution and use of security measures to protect data and support the Human Resources Department in managing and supervising the conduct of personnel in relation to the protection of data. This responsibility is carried out by working with the other members of the MCS Information Security Leadership structure and appropriate offices and committees to foster the developmental and operational elements needed to assure appropriate information security throughout MCS. In general, the following responsibilities belong to the ISO:

- Manage and supervise the execution and use of security measures to protect data and support the Human Resources Department in managing and supervising the conduct of personnel in relation to the protection of data;
- Work closely with the MCS Privacy Officer to ensure that the information security environment supports the privacy policies;
- Work closely with related enterprises / Third parties, to ensure that the information security environment is well coordinated;
- Serve as an internal information security consultant to MCS;
- Establish and maintain a system that fosters appropriate, demonstrable, and coordinated security policies, procedures, and practices that are compliant with related law, regulation, policy and professional standards;
- Establish and maintain a system that fosters appropriate training and awareness related to information security by using the typical units and means used for training the workforce in MCS;
- Establish and maintain a system that fosters the routine use of risk assessments and risk management planning related to the information security features of systems, networks, and related administrative activities;
- Establish and maintain a system that fosters review and monitoring of assessments, plans, implementations, operations, and usage related to information security throughout MCS;
- Establish and maintain a system that fosters appropriate and effective disaster recovery and contingency plans for information systems in MCS;
- Serve as the HIPAA Security Officer as required in the HIPAA Security Rule; and
- Report periodically to the MCS Executive Management on MCS status with regard to information security;

## SPECIAL INVESTIGATIONS UNIT

The Special Investigations Unit (SIU) is part of the Compliance Department and is responsible for:

- Conducting a FWA risk assessment to determine FWA risks areas that may impact the organization and prioritize the monitoring and annual investigation plan accordingly;

- Provide trainings and education to MCS employees, members of the Board, and FDRs to recognize FWA indicators or issues that may warrant additional investigation by the SIU;
- Referring potential cases of illegal activity, including drug diversion, to the NBI-MEDIC and/or law enforcement and conducting case development and support activities for NBI-MEDIC and/or law enforcement investigations;
- Identifying beneficiaries with drug utilization problems;
- Identifying and recommending providers for exclusion, including physicians, pharmacists, PBMs, and any FDRs who have defrauded or abused the system;
- Assisting law enforcement agencies by providing information needed to develop successful prosecutions;
- Analysis of information obtained from MCS software and applications;
- Review of 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;
- Monitoring the monthly verification of MCS employees and FDRs against the federal exclusion lists;
- Consultation with applicable MCS personnel and/or medical consultants to obtain needed information and counsel;
- Visiting providers to obtain copies of medical records and interview providers' personnel;
- Identifying patterns, schemes, or tendencies, with specific attention to the geographic areas identified by CMS as high-risk counties.

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:

- Compliance and FWA referrals;
- 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;
- Periodic metrics and/or assessments made by the SIU regarding FWA and compliance investigated schemes;
- Periodic metrics and/or reports of corrective actions resulting from compliance and/or FWA investigations;
- Any other information that the SIU identified that may represent a compliance and/or FWA issue for the organization.



## III. EFFECTIVE TRAINING AND EDUCATION

### GENERAL COMPLIANCE TRAINING

MCS cultivates a culture of compliance by establishing, implementing, and providing effective training and education to the members of the Board, all employees, and FDRs. MCS supports the Compliance Program and Code of Conduct by ensuring that each of these individuals is provided with appropriate training to understand regulatory mandates, as well as his or her responsibilities associated with compliance. General Compliance Trainings are provided to all employees and members of the Board within ninety (90) days of initial hiring, or appointment, when there are updates and annually thereafter. Attendance and participation in trainings and education is a mandatory condition of employment for MCS employees and is a criterion in employee evaluations. General Compliance trainings cover the following information:

- The MCS Compliance Program, Code of Conduct, and compliance policies and procedures;
- MCS's commitment to ethics and compliance with all pertinent laws and regulations related to compliance, and privacy and security, including but not limited to Medicare program requirements;
- Effective lines of communication, including how to ask compliance questions and report potential non-compliance and/or FWA with emphasis on confidentiality, anonymity, non-retaliation and non-intimidation;
- The requirement to report actual or suspected Medicare program non-compliance or potential FWA;
- Review of the disciplinary guidelines for non-compliant or fraudulent behavior;
- Examples of reportable non-compliance that an employee might observe;
- A review of policies related to contracting with the government, such as the laws addressing gifts and gratuities for government employees;
- A review of potential conflicts of interest and MCS' process for disclosing potential conflicts of interest;
- An overview of HIPAA/HITECH, the CMS Data Use Agreement, and the importance of maintaining the confidentiality of Personal Health Information;
- An overview of the monitoring and auditing process;
- A review of the laws that govern employee conduct in the Medicare program.

Separate trainings related to FWA, are also provided by MCS. These FWA trainings cover the following, among other topics:

- Laws and regulations related to Medicare Part C and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, etc.);
- Definitions and identification of fraud (e.g., kickbacks and drug diversion), waste (e.g. payment and utilization errors), and abuse (e.g., over utilization) with an emphasis on prompt detection and escalation procedures of a fraud allegation;
- Obligations of FDRs to have appropriate policies and procedures to address FWA;

- Identification of any false statements or misrepresentation by a beneficiary, a person calling on behalf of a beneficiary, a pharmacy provider, or employee of the pharmacy;
- A description of the process for reporting suspected FWA to MCS;
- A description of the protections available to employees who report suspected FWA;
- Description of Federal Exclusion Programs;
- Examples of the types of FWA that can occur in the settings in which employees work;
- Review of policies and procedures as available internal resources covering all aspects of the program, including standards of conduct, compliance, and methods of reporting FWA.

The purpose of these trainings is to ensure that all employees receive, understand, and retain appropriate information to conduct business in an ethical and compliant manner. Also, training may be provided when employees are found to be noncompliant, as a corrective action, to address a noncompliance issue; and when an employee works in an area implicated in past FWA.

### SPECIALIZED COMPLIANCE TRAINING

MCS provides specialized compliance and/or FWA trainings to employees in order for them to become aware of Medicare, Commercial, or other compliance requirements related to their job function. These trainings are provided at initial hiring , when there are updates and/or as result of an Internal/External Audit, Monitoring or Investigation process. For more information, refer to *MCS-Policy-003 Effective Training and Education* and related procedures.

### EFFECTIVENESS OF TRAINING AND EDUCATION

MCS uses a variety of mechanisms to evaluate training and education effectiveness to ensure that all employees receive, understand, and retain appropriate information to conduct business in an ethical and compliant manner. For more information, refer to *MCS-Policy-003 Effective Training and Education* and related procedures.

### EDUCATION TO MCS EMPLOYEES

MCS reinforces the compliance culture through different mechanisms such as:

- Newsletters
- Individual and group meetings
- General and specialized compliance and/or FWA alerts
- Posters
- Pagers
- Brochures
- Awareness campaigns
- Workgroups
- Flyers
- Letters
- Pamphlets

## FDRs TRAINING AND EDUCATION

MCS distributes the general compliance trainings to First Tier entities when the initial contract is executed, when there are updates and annually thereafter. MCS First Tier Entities are required to:

- Provide effective General Compliance Trainings and FWA Trainings and education to their employees and members of the Board, as applicable, within ninety (90) days of initial hiring or appointment, when there are updates and annually thereafter.
- Identify, develop and provide specialized compliance trainings related to the service delegated by MCS, in accordance with the risk and needs of the job functions of their employees.

First tiers must maintain all documentation related to trainings including the mechanisms used to measure the effectiveness of the trainings for a period of ten (10) years. For more information, refer to *MCS-Policy-003 Effective Training and Education* and related procedures.

## EDUCATION TO MCS MEMBERS

MCS has identified that the compliance culture should be expanded to our beneficiaries and subscribers. MCS has different mechanisms to educate our beneficiaries on compliance, on how to identify and report potential FWA and the protections for whistleblowers. These mechanisms may include:

- Newsletters
- MCS's Webpage
- Awareness campaigns
- Other documents provided to enrollees as part of the enrollment process or regular operations (i.e. ANOC, EOC, EOB among others)

## IV. EFFECTIVE LINES OF COMMUNICATION

### COMMUNICATION AND REPORTING MECHANISMS

MCS has implemented a way to communicate information from the Chief Compliance Officer to others. Such information commonly includes laws, regulation, statutory, regulatory, and sub-regulatory changes (e.g., HPMS memos) that serves as guidance for MCS and FDR's operations.

The dissemination of information from the CCO is made within a reasonable time using a variety of mechanisms described in the EFFECTIVE TRAINING AND EDUCATION section of this Program.

MCS recognizes that having open lines of communication and appropriate reporting mechanisms is crucial for an effective compliance program. Thus, MCS has implemented a system to receive

record, respond to, and track compliance questions or reports of suspected or detected non-compliance or potential FWA from employees, members of the Board, beneficiaries, and FDRs and their employees. MCS educates beneficiaries, employees, and FDRs about identification and reporting of potential FWA. Education methods are described in **EFFECTIVE TRAINING AND EDUCATION** section of this Program, as applicable.

MCS's reporting mechanisms ensures confidentiality (to the greatest extent possible) to the Chief Compliance Officer , members of the Corporate and Board Compliance Committee, employees, members of the Board, and FDRs. MCS utilizes reports to demonstrate operational compliance including those of suspected non-compliance and/or FWA which are maintained and reviewed by the Chief Compliance Officer, Corporate Compliance Committee, Senior Management, Board Compliance Committee, or the Board of Directors, as appropriate. In some instances, as required by federal and local laws and other applicable regulations or guidelines, such reports are also submitted to regulatory agencies and/or their designees.

MCS presents reports to the Corporate Compliance Committee on a regular basis at the Committee meetings. Such reports include the Compliance recommendations for corrective action plans for any identified areas of non-compliance. If a report indicates that a corrective action plan is necessary, management takes the necessary steps to correct problems, mitigate negative impact, and prevent deficiencies from recurring.

## **ROLE IN REPORTING ACTUAL OR POTENTIAL NON-COMPLIANCE, MISCONDUCT AND FWA**

Members of the Board, employees, and FDRs are required to report actual or potential non-compliance, misconduct, FWA or violations of the Compliance Program, Code of Conduct, and compliance policies and procedures or other incidents of non-compliance or non-ethical behavior. Reporting may be done without fear of intimidation or retaliation.

## **HOW TO REPORT ACTUAL OR POTENTIAL NON-COMPLIANCE**

All employees, members of the Board, and FDRs must promptly report any situation that involves an actual or potential issue of ethics, compliance, misconduct, and/or FWA by contacting any of the following **Confidential Reporting Lines**:

- Your immediate supervisor or manager
- The Chief Compliance Officer or any member of the Compliance Department
- The **ACTright** Hotline & Web Reporting Line (available 24 hours/7 days to all Covered Persons and members of the Governing Board) at:  
[1-877-627-0004](tel:1-877-627-0004) / [mcs.com.pr](https://mcs.com.pr)
- The Email: [mcscompliance@medicalcardsystem.com](mailto:mcscompliance@medicalcardsystem.com)
- The Human Resources Department
- Any attorney in the Legal Department

If you wish to report anonymously a suspected violation of this Compliance Program or any other behavior that is of concern to you, you may call [1.877.627.0004](tel:1.877.627.0004) or access [mcs.com.pr](https://mcs.com.pr). Please refer to policy *MCS-Policy-004 Effective Lines of Communication* and related procedures for additional details regarding how to utilize the [Hotline & Web Reporting Line \(ACTright\)](#).

If you feel uncomfortable using these channels, you may write to the members of the Board of Directors at:

MCS Board of Directors  
JLL Partners  
450 Lexington Avenue  
31st Floor  
New York, NY 10017

## CONFIDENTIAL REPORTING

MCS strives to preserve the confidential nature of the reports it receives, including the identity of the person making the report, if requested. As outlined in this Program, all Covered Persons have the option of reporting compliance concerns anonymously through the [Hotline & Web Reporting Line \(ACTright\)](#) and may feel secure that their anonymity will be maintained, except when (a) disclosure becomes necessary for a proper investigation, and even then, disclosure will be made solely on an as-needed basis, or (b) when disclosure is legally required by subpoena or court order. MCS conducts investigations of any actual, potential or suspected misconduct with utmost discretion and confidentiality, being careful to protect the reputations and identities of those being investigated. Please refer to policy *MCS-Policy-004 Effective Lines of Communication* and related procedures for additional details.

## NON-RETALIATION AND NON-INTIMIDATION

MCS prohibits retaliation and intimidation against any Covered Person for good faith participation in the compliance program and making a good-faith report of concerns about actual or potential wrongdoing, including violations of the Code, the MCS Compliance Program, policies and procedures, or of any applicable law or regulation. No adverse action will be taken by MCS against a Covered Person for complaining about, reporting, participating, investigating or assisting in the investigation of a suspected violation, unless the allegation made or information provided is found to be intentionally false. Retaliation and intimidation against any Covered Person, who in good faith assists in the investigation of any reported concern, is also prohibited. Any Covered Person, who engages in retaliation, intimidation and/or harassment, may be subjected to disciplinary action in the case of employees, or other appropriate action in the case of contractors.

All, employees, and FDRs are responsible for ensuring the effectiveness of the MCS Compliance Program and Code of Conduct by actively participating in the reporting of potential compliance violations and any instances of suspected retaliatory and intimidating acts. MCS abides by all

federal regulatory requirements regarding reporting compliance concerns and maintaining a culture of non-retaliation and non-intimidation, including but not limited to the False Claims Act and associated whistleblower provisions.

Concerns about retaliatory or intimidating behavior should immediately be reported through the MCS [Confidential Reporting Lines](#). Please refer to policy *MCS-Policy-008 Non Retaliation and Non Intimidation* and related procedures.

## ACCESSIBILITY OF THE COMPLIANCE OFFICER

The CCO serves as a consultant to all employees, FDRs, beneficiaries, and members of the Board to ensure that compliance concerns are handled according to federal, local, and other applicable laws, regulations, and policies and/or procedures. MCS employees, FDRs, beneficiaries, and members of the Board are encouraged to contact the Compliance Officer via telephone, e-mail, memorandum, or visits to his or her office whenever a concern or question arises regarding compliance. MCS maintains an “open door” policy and encourages communication among MCS operational areas and FDRs.

## DOCUMENTATION

Documentation is critical to reporting. All activities involved in receiving, investigating, and responding to reports of non-compliance or FWA are thoroughly documented. Detailed, accurate, and timely documentation demonstrates that MCS takes the responsibility of reporting seriously. MCS encourages all employees to report and document appropriately. MCS investigates and takes appropriate actions in response to reports, and tracks trends across all operational areas of the organization.

## INVESTIGATION OF COMPLIANCE CONCERNS

Upon receipt of a report of potential non-compliance and/or FWA through the reporting mechanism, MCS will initiate an investigation of the report as quickly as possible, but no later than two (2) weeks from the date the incident was identified or reported. Investigation activities include, but are not limited to, review of all related documentation, and interviews of appropriate individuals. The Compliance Department will provide status of the evaluation and/or investigations when requested by the reporter. The status will indicate if the investigation is in progress or closed. In order to protect the confidentiality of the process and/or individuals involved in the investigation and/or evaluation, the Compliance Department will not provide specific details. A determination will be made, and cases of confirmed non-compliance may result in employee disciplinary actions, up to and including employment termination and, with respect to contractors, in corrective actions, monetary penalties and/or contract termination.

## AUDITS AND INVESTIGATIONS

All Covered Persons are required to cooperate fully in all audits, inquiries, investigations or other reviews conducted by MCS, its designee, outside parties and/or regulators. Full cooperation

includes promptly, completely and truthfully complying with all requests for documents, information and interviews, including, but not limited to:

- Retaining and producing, as requested, all potentially relevant records;
- Attending interviews and responding completely and truthfully to interview questions;
- Complying with outside party requests, as directed by the Compliance, Human Resources, or Legal departments, when there is an audit, inquiry, investigation or other review being conducted.

Failure of MCS employees to comply with this provision of the Code of Conduct and Compliance Program may lead to disciplinary action, up to and including termination. Appropriate measures will be undertaken in the case of contractors.

## V. WELL-PUBLICIZED DISCIPLINARY STANDARDS

MCS is committed to encouraging good faith participation in the Compliance Program by publicizing disciplinary standards for employees and FDRs. A variety of mechanisms are used to publicize expectations described in the MCS Compliance Program, Code of Conduct, and compliance policies and procedures, that include expectations for reporting compliance issues and assisting in their resolution; identify non-compliance and/or ethical behavior; provide for timely, consistent, and effective enforcement of the standards when non-compliance and unethical behavior is determined. Such publication mechanism may include:

- Newsletters
- Individual and group meetings
- General and Specialized Compliance alerts
- Posters
- Pagers
- Brochures
- Awareness campaigns
- Flyers
- Letters
- Pamphlets

## ENFORCEMENT OR DISCIPLINARY ACTIONS

MCS enforces effective correction through disciplinary measures, including but not limited to employment or contract termination. Enforcement and/or disciplinary actions are designed to correct the underlying problem that results in Compliance Program and Code of Conduct violations and to prevent future non-compliance.

Failure to detect or report an offense is a serious act of non-compliance and equally as deserving of discipline as the actual misconduct. Compliance is an active, on-going process that is everyone's responsibility.

MCS expects the conduct of all employees to be governed by the highest ethical standards, for employees to exercise good judgment, to meet their job responsibilities and have consideration of others. Any act that may be considered to be contrary to the policy and purpose of the Program, Federal and Commonwealth laws and regulations, MCS Code of Conduct and compliance policies and procedures or harmful to another person, may result in employee disciplinary actions, up to and including employment or contract termination. Acts that are subject to immediate corrective action include, but are not limited to, the following:

- Violating laws, regulations, this Program, the MCS Code of Conduct, the MCS Employee Handbook, or MCS policies and procedures.
- Directing or encouraging others to violate laws, regulations, this Program, the MCS Code of Conduct, the MCS Employee Handbook, or MCS' policies and procedures.
- Failing to report known or suspected violations of laws, regulations, the Program, the MCS's Code of Conduct, the MCS Employee Handbook, or MCS' policies and procedures.
- Failing to detect misconduct on the part of employees or business partners under your supervision.
- Interfering with or being uncooperative during an internal or external investigation.
- Knowingly, willfully or negligently providing false or incorrect information to MCS or to a government agency, beneficiaries or contractors or falsifying any document or MCS record.
- Intentional or willful destruction of MCS's records or of any evidence relevant to an investigation of a suspected violation of law or of MCS's Code of Conduct, Compliance Program and/or regulatory policies and/or procedures.
- Retaliating against others or intimidating for reporting a concern or a suspected or actual violation.

Enforcement and disciplinary actions for violations of the Program may include documenting meetings, verbal or written corrective notifications, performance improvement plans, suspension or termination of employment and, with respect to contractors, corrective action plans, monetary penalties or contract termination. The corrective action will be timely, consistent and proportional with the seriousness of the violation. Covered Persons also should be mindful that violations of laws, regulations, this Program, the MCS Code of Conduct, the MCS Employee Handbook, or MCS's policies and procedures could trigger external legal action against the wrongdoers in an individual or collective level. Criminal or government enforcement action can include suspension or revocation of licenses, sanctions, monetary fines, criminal penalties, and imprisonment.

MCS maintains for a period of ten (10) years all records of compliance violations, enforcement and/or disciplinary actions, capturing the date the violation was reported, a description of the violation, date of investigation, a summary of findings, disciplinary actions taken, and the date they were taken. MCS periodically reviews these records of discipline to ensure that disciplinary actions are appropriate to the seriousness of the violation, fairly and consistently administered, and imposed within a reasonable timeframe.



## EMPLOYEES

Enforcement and/or disciplinary actions resulting from a compliance and/or ethical violation by an employee are reviewed and evaluated on a case by case basis and disciplinary action will be applied in a timely and consistent manner. Disciplinary action may include remedial steps such as additional training, also based on the severity of the infraction, and may apply the following:

- Written warning
- Performance Improvement Plan
- Suspension
- Termination

*For more information refer to MCS-Policy-026 Employee Disciplinary Standards - Non Compliance Instances and related procedure.*

## FDRs

Failure to develop and implement action plans, as required, and/or ethical violation is subject to enforcement action. Enforcement actions may include remedial steps such as additional training, also based on the severity of the infraction, may apply the following:

- Sanctions
- Penalties
- Contract non-renewal
- Contract termination

## VI. EFFECTIVE SYSTEM FOR ROUTINE MONITORING AND IDENTIFICATION OF COMPLIANCE RISK

MCS is committed to overseeing the accuracy, timeliness, and effectiveness of its own and FDR's performance to ensure compliance with federal and local laws and regulations, other applicable laws and regulations, MCS policies and procedures, and contractual obligations. Thus, MCS has established and implemented an effective system for routine monitoring and identification of compliance risks. The system includes internal monitoring and audits and, as appropriate, external audits, including FDRs compliance with regulatory agencies requirements, such as CMS, and the overall effectiveness of the Compliance Program. MCS develops monitoring and auditing work plans that address FWA risks and regulatory risks

## ANNUAL RISK ASSESSMENT

MCS conducts an annual risk assessment of all operational areas and First Tiers Entities in order to determine where MCS is at risk for potential non-compliance or FWA and identification of areas in which additional controls should be implemented. Through this process MCS assesses major compliance and FWA risk areas. Each operational area must be assessed for the types and

levels of risks the area presents to the Medicare program and to MCS. The risks are evaluated based on the following elements:

- Financial / Dollar Impact in terms of revenues or losses
- Reputation / Customer Satisfaction
- Legal / Regulatory Impact
- Member Impact
- Previous Risk Experience
- Complexity of Operations
- Management Confidence
- System (timely, reliable, accessible, available, cost)

Risks identified by the annual risk assessment are used to determine which risk areas will have the greatest impact, and prioritize the monitoring and auditing strategy accordingly. Risk areas identified through CMS or other governmental audits and oversight, as well as through MCS's monitoring, audits and investigations are priority risks.

The Assessment is presented to the CCC, BCC and Board of Directors for approval.

## MONITORING AND AUDITING WORK PLANS

Once the risk assessments are completed, monitoring and auditing work plans are developed prioritizing the identified compliance and FWA risks. MCS uses the monitoring and auditing work plans as a guideline to assure identified operational areas and First Tiers Entities are monitored and/or audited through the year and to allocate the available resources.

The work plans may include, but are not limited to:

- Audit or monitoring activity to be performed;
- First Tier Entity, Department(s) or operational area(s) impacted by activity;
- Scheduled time for the audit or monitoring activity to be started;
- Scheduled time for the audit or monitoring activity to be completed.

The work plans must include a schedule that lists all of the monitoring and auditing activities for the audit year that includes MCS operational areas and First Tiers Entities. For more information see the procedures: *CA-COMP-008 Risk Assessment*, *CA-COMP-039 Delegation Oversight and CA-COMP-040 Internal Compliance Audit and Monitoring*. The monitoring and auditing 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.

The monitoring and auditing work plans are presented to the CCC, BCC and Board of Directors for approval. The CCO oversees the auditing and monitoring activities and the status and effectiveness of corrective actions taken.

Results of auditing and monitoring activities, as well as action plans status and changes in the monitoring and auditing work plans, are discussed in the CCC and BCC meetings.

Corrective actions and follow-up are overseen by the CCO and assisted by the Compliance Department Units, and include actions such as reporting findings to CMS or to the NBI MEDICs, if necessary.

The Compliance Program's effectiveness is audited on an annual basis and audit results are presented to the CCC and BCC. However less formal measures are used to monitor the Compliance Program effectiveness.

## AUDITS AND MONITORING

An audit is a formal review of compliance with a particular set of standards (i.e. policies, and procedures, laws and regulations) used as base measures. MCS audits its operational areas and those of its First Tier Entities using one or a combination of the following:

- On-site audit - A scheduled or unscheduled review of an MCS operation or First Tier Entity in which auditors are present in the facility or audited area.
  - For scheduled audits, management is given sufficient notice to allow sample selection, document review and preparation of other supporting materials.
  - For unscheduled audits, notification may take place the same day and/or upon arrival at the department or FDRs.
- Desk audit - An audit at MCS facilities that include the review of documents and records submitted by a specific MCS operational area or First Tier Entity to determine accuracy and compliance with established standards.
- External review - Review of an operational area or First Tier Entity by an individual or entity independent of MCS.

A monitoring activity is a regular review performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

The Audit team may involve subject matter experts for the area under review. However, the following criteria always exists regarding how audits will be conducted. Auditors must:

- Have access to all department documents and appropriate personnel.
- Draft audit reports including issues of non-compliance, corrective actions required and recommendations.
- Present such reports and proposed corrective actions to the CCO for electronic approval and/or signature prior to distribution and follow up monitoring.

Further detail regarding the audit process, the audit schedule and methodology is included in the following procedures: *CA-COMP-039 Delegation Oversight Procedure* and *CA-COMP-040 Internal Compliance Auditing and Monitoring*.

## AUDIT AND MONITORING REPORTS

Each audit and monitoring activity performed by the Compliance Department is documented through a written report that records results and serves as an effective vehicle to communicate those results to the impacted operational area or First Tier Entity. The report identifies deficiencies that require remediation and recommendations for ways to improve performance and prevent future deficiencies. The reports are discussed with the Business Owner. The reports are discussed with the CCO prior to submission to the areas. All summary of findings are presented to the CCC and in addition those of First Tiers are also presented to Delegation Oversight Committee. Final reports including all corrective actions and/or recommendations are available to CCC members and Delegation Oversight Committee upon request. MCS prepares standard audit reports in accordance with the procedures *CA-COMP-039 Delegation Oversight and CA-COMP-040 Internal Compliance Auditing and Monitoring*.

## AUDIT OF MCS'S COMPLIANCE PROGRAM

MCS's CCO along with the Compliance Committee ensure the audit functions are appropriately supported based upon MCS's structure. In general, MCS's audit activities are performed or coordinated by the compliance department. All auditors are knowledgeable about CMS' operational requirements and independent. MCS audits annually the effectiveness of the compliance program through external auditors in order to avoid self-policing, and the results are shared with the CCC and BCC.

## MONITORING AND AUDITING FDRs

MCS may enter into agreements with appropriate entities to carry out core administrative functions. An example of such delegation is the administration of pharmacy benefits to a PBM. MCS remains accountable for all functions carried out by the Delegated Entity.

MCS validates the First Tier Entities ability to perform the proposed delegated activities prior to delegation. The pre-delegation assessment focuses on determining whether a prospective delegate meets applicable performance standards, fiscal stability requirements and regulatory mandates and is capable of performing the proposed delegated responsibilities.

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.

Depending on the type of service delegated and the skill set and knowledge required for the audit, subject matter experts ("SMEs") from applicable MCS operational areas (e.g., Claims, Credentialing) support the audit. Such an audit typically involves a site visit and document review of the proposed delegate's administrative capabilities, financial solvency, understanding of the standards and the delegated tasks, staffing capabilities, performance record and compliance program, as appropriate.

The Agreement specifies the delegated activities, responsibilities of the parties, reporting frequency, the process for evaluation, and remedies available to MCS. Prior to any sub-delegation, a First Tier Entity must obtain approval from MCS. Sub-delegation (downstream) agreements must meet the aforementioned specifications. MCS determines who will directly monitor the downstream or related entity's compliance with requirements, as per contract requirements.

## ROUTINE MONITORING AND IDENTIFICATION OF FWA

MCS engages in a variety of monitoring 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.

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 monitoring activities include:

- Analysis of prescription data in order to identify outlier prescription claims that may be the result of fraudulent or abusive behaviors, for example:
  - Abnormal number of prescriptions/prescription patterns within suspected classe;
  - Patients that use multiple pharmacies or physicians;
  - Controlled substances prescribing patterns;
  - Excessive prescribing of medications intended for acute use;
  - High dollar claims utilization or high quantity dispensed;
  - 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;
  - Duplicate therapies. Beneficiaries who are receiving multiple prescriptions within a therapeutic class within the same time frame.
- Examination by MCS contracted PBM of utilization activity for specific clinical patterns.
- PBM desk and onsite audits of pharmacies to identify claims discrepancies and overpayments.
- Part D and Part C claims review by a contracted vendor to detect coding and billing errors (potential overpayment or underpayment).
- PBM attendance at quarterly NBI-MEDIC meetings to coordinate efforts with other Medicare Part D plan sponsors, the NBI-MEDIC, and HHS-OIG. All pharmacies identified in these meetings are added to the PBM investigative audit program for further evaluation.
- Analysis and evaluation of claims based on regulatory and/or law enforcement fraud alerts, such as:

- CMS Fraud Alerts
- CMS-Pharmacy Quarterly Risk Assessment
- CMS Fraud Handbook
- HHS-OIG Annual Plan
- PLATO, NBI MEDIC tool that provides information regarding FWA investigations made by other health care organizations.

## FWA REPORTING

MCS, through the SIU prepares periodic reports for presentation to the CCO, including, data trends, cases investigated, and submitted to the NBI-MEDIC and other regulatory and law enforcement agencies and recovery amounts.

MCS reports case-specific information to the SI Committee during quarterly meetings, or as needed. This Committee supports the work of the SIU by hearing information regarding specific cases and discussing the handling of such cases. The Committee may recommend further investigation, a second opinion, or submission of the case to the applicable regulatory or law enforcement agencies.

Upon recommendation of the SI Committee and review from the CCO the SIU submits cases to the NBI-MEDIC for Medicare Part C and Part D cases and other regulatory and law enforcement agencies, as appropriate and indicated below:

- Commercial cases are sent to OCI.
- Submission to the NBI-MEDIC is mandatory for potential FWA cases involving the Medicare Prescription Drug Program. This is an absolute requirement in all cases of:
  - Abusive or potentially fraudulent conduct with respect to administration or utilization of the pharmaceutical benefits program;
  - Inappropriate utilization;
  - Overpayment for prescription drugs.

The SIU maintains close communication with other operational areas as well as to ensure that benefits, including Medicare Part C and Part D are protected from fraudulent, abusive and wasteful schemes throughout the administration and delivery of benefits, both at MCS and FDR's levels.

## EXCLUSION FROM FEDERAL PROGRAMS

MCS abides by CMS's requirement to screen 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, and FDRs, at time of hire, appointment or execution of a contract and monthly thereafter. 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.

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 Tiers Entities are conducting this screening. For further detail regarding this monitoring and enforcement action, see the following procedures:

- HR-HUMRES-001: Disciplinary Process
- HR-HUMRES-061 Background Checks
- HR-HUMRES-004 Review of Employees and Human Resources vendors on the Exclusions Lists of HHS/OIG and GSA
- CA-COMP-039: Delegation Oversight
- CA-COMP-060 Screening of all affected individuals and entities associated with MCS against the DHHS-OIG and General Services and Administration (GSA) screening

## VII. PROCEDURES AND SYSTEM FOR PROMPT RESPONSE TO COMPLIANCE ISSUES

MCS has established and implemented policies and procedures for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with regulatory requirements.

### PROMPT RESPONSE

MCS implements appropriate corrective actions in response to potential noncompliance or potential FWA. MCS initiates a reasonable inquiry as quickly as possible, but not later than two (2) weeks after the date the potential non-compliance or potential FWA incident was identified. The corrective actions are designed to correct the underlying problems that result in program violations and to prevent future noncompliance. A root cause analysis determines what caused or allowed the FWA problem or deficiency to occur. The corrective actions are tailored to address the particular FWA problem or deficiency identified and include timeframes for specific achievements. MCS adheres to the CMS defined levels of corrective action based upon its published audit protocols. As such, the following actions may be requested or suggested as a result of an identified non-compliance and/or FWA findings:

- a. Immediate Corrective Action Required (ICAR) - If MCS identifies systemic deficiencies during a review so severe that they require immediate correction, MCS will issue an ICAR. Identified issues of this nature would be limited to situations where the condition resulted in a beneficiary's lack of access to

medications and/or services, or posed an immediate threat to beneficiary health and safety.

- b. Corrective Action Required (CAR) – If MCS identifies systemic conditions during a review that must be corrected, but the correction can wait until the findings report is issued, MCS will issue a CAR. While these issues may affect beneficiaries, they are not of such a severe nature that beneficiaries' immediate health and safety is affected. Generally, CARs involve deficiencies with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations, or staffing.
- c. Observations—If MCS identifies cases of non-compliance that are not systemic, or represent an anomaly or “one-off” issue, MCS will issue an observation.

Details regarding the format for responses are included in the policy MCS-Policy-007 Prompt Response to Compliance Issues and procedures *CA-COMP-039 Delegation Oversight and CA-COMP-040 Internal Compliance Auditing and Monitoring*.

## SELF-REPORTING FWA AND NON-COMPLIANCE

MCS recognizes self-reporting of potential FWA and non-compliance issues are an important practice in maintaining an effective compliance program. If after a preliminary investigation of the matter by the CCO or a delegated member of his/her staff and/or the SIU, it is determined that a potential misconduct has occurred, MCS will report the issue to the appropriate regulatory agencies, such as NBI-MEDIC, Office of Inspector General (OIG), CMS, etc.

If the issue appears to involve potential FWA and MCS does not have either the time or the resources to investigate the potential FWA in a timely manner, it will refer the matter to the NBI-MEDIC within thirty (30) days of the date the potential fraud or abuse is identified so that the potentially fraudulent or abusive activity does not continue.

MCS provides the NBI-MEDIC with specific details on each case submitted, including contact information and a description of the allegations. If the NBI-MEDIC requests additional information on the case, MCS provides the requested information within thirty (30) days, unless the NBI-MEDIC specifies otherwise. MCS provides updates to the NBI-MEDIC when new information regarding the case is identified.

Suspected or confirmed FWA cases that meet any of the following criteria are referred to the NBI-MEDIC:

- Potential criminal, civil, or administrative law violations
- FWA cases that involve multiple health plans, multiple states, or widespread schemes
- Allegations involving known patterns of fraud
- Patterns of fraud or abuse threatening the life or well-being of beneficiaries
- Schemes with large financial risk to the Medicare program or beneficiaries.



If MCS discovers an incident of significant or serious Medicare program non-compliance, MCS reports the incident to its CMS Account Manager as soon as possible after its discovery.

## ACTION PLAN DEVELOPMENT

The MCS operational area or First Tier Entity identified as responsible for a deficiency must develop and submit an action plan to the Compliance Department within the timeframe established by the Compliance Department.

The MCS operational area or First Tier Entity found to have deficiencies must follow a standard format supplied by the Compliance Department to develop the action plan. The action plan must include:

- A brief description of the regulatory or operational requirement.
- Description of the issue or finding.
- Root cause(s)
- The person(s) responsible for overseeing implementation of the action plan.
- Objectives in the implementation - steps taken or that will be taken to resolve the issue or findings.
- Applicable timeframes for objectives and complete resolution.
- Methods of monitoring ongoing compliance or preventing reoccurrence.
- A reporting schedule to document progress of the action plan.

Once the action plan is approved by the CCO, the Compliance Department ensures that MCS operational areas or FDRs monitor the implementation and effectiveness of the action plan. The Compliance Department conducts validation procedures to ensure that deficiencies noted were corrected. Thorough documentation must be maintained of all deficiencies identified and corrective actions taken.

Failure to develop and implement action plans, as required, and/or ethical violation(s) are subject to enforcement or disciplinary actions. Enforcement or disciplinary actions may include remedial steps described under the [ENFORCEMENT OR DISCIPLINARY ACTIONS](#) section.

## CONCLUSION

Your commitment to act in compliance and follow this Compliance Program maintains a culture of integrity in MCS. You can access the MCS Compliance Program through MCS Compliance 360, Policy and Procedures (Corporate Policies, Code of Conduct and Compliance Program Folder). Thank you for your individual and group efforts to achieve our shared goal.

## DEFINITIONS

1. ASES: Spanish acronym for the Puerto Rico Health Insurance Administration, a public corporation having full legal capacity to administer and enter into contracts with private health care service providers to the medically indigent population of Puerto Rico.
2. Centers for Medicare and Medicaid Services (CMS): The Federal agency within the Department of Health and Human Services (DHHS) that administers the Medicare program.
3. FDR: First Tier, Downstream and Related Entity
  - First Tier Entity: is any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. (See, 42 C.F.R § 422.501 and § 423.501).
  - Downstream Entity: is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage (MA) benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization (MAO) or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See, 42 C.F.R. § 422.501 and §, 423.501).
  - Related Entity: means any entity that is related to an MAO or Part D sponsor by common ownership or control and performs some of the MAO or Part D plan sponsor's management functions under contract or delegation; furnishes services to Medicare enrollees under an oral or written agreement; or leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See, 42 C.F.R. § 422.501 and §423.501).
4. HIPAA: The Health Insurance Portability and Accountability Act is a federal legislation approved by Congress regulating the continuity and portability of health plans, mandating the adoption and implementation of administrative simplification standards to prevent, fraud, abuse, improve health plan overall operations and guarantee the privacy and confidentiality of individually identifiable health information, among others requirements.
5. NBI-MEDIC: Health Integrity is the Medicare Part C and Part D program integrity contractor for the Centers for Medicare & Medicaid Services (CMS) under the National Benefit Integrity Medicare Drug Integrity Contract (NBI MEDIC). The purpose of the NBI 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.
6. OCI: Acronym for the Office of the Commissioner of Insurance of Puerto Rico. It is responsible for authorizing, regulating and auditing persons or entities who engage in the insurance business in Puerto Rico.
7. PBM: Acronym for the Pharmacy Benefits Manager contracted to provide services with pharmacy networks, to process and adjudicate pharmacy claims, and manage preauthorization for medication, among other functions.



**Every Day is Compliance Day!**