



Compliance Program Description

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Introduction of the Compliance Program

Commonwealth Care Alliance, Inc. (CCA), and its affiliates and subsidiaries are committed to conducting its business operations in compliance with ethical standards, internal policies and procedures, contractual obligations and all applicable federal and state statutes, regulations and rules, including but not limited to, those pertaining to the Centers for Medicare and Medicaid Services (“CMS”) Part C and D programs; the Massachusetts Executive Office of Health and Human Services (“EOHHS”), (MassHealth) and the Office of Inspector General (“OIG”). This Compliance Program Description applies to all CCA’s lines of business. CCA’s compliance commitment extends to its own internal business operations, as well as, its oversight and monitoring responsibilities related to its First Tier, Downstream and Related Entities (FDR).

CCA has formalized its compliance activities through a comprehensive Compliance Program. The Compliance Program Description is reviewed on a regular basis and revised as necessary.

The Compliance Program incorporates the fundamental elements of an effective compliance program identified by CFR 422.503(b) (4) (vi) and CFR 423.504(b) (4) (vi) and the Office of the Inspector General (OIG) Federal Sentencing Guidelines.

CCA’s Compliance Program contains the following core elements (with Fraud, Waste and Abuse woven into each element):

- Code of Conduct and Written Policies and Procedures
- Compliance Officer, Compliance Committee and High Level Oversight
- Effective Compliance Training and Education
- Effective Lines of Communication
- Well-Publicized Disciplinary Standards
- Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
- First Tier, Downstream and Related Entity Compliance Oversight
- Procedures for and Prompt Response to Compliance Issues

CCA’s Compliance Program is developed to:

- Promote compliance with all applicable federal and state laws and contractual obligations;
- Prevent, detect, investigate, correct and appropriately report suspected incidents of fraud, waste and abuse;
- Prevent, detect, investigate, correct and appropriately report suspected incidents of program non-compliance;
- Promote and enforce CCA’s Code of Conduct;

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- Train and educate all Workforce and Board of Directors members on compliance topics and their responsibilities with respect to compliance; and
- Engage CCA's Executive Team, Workforce, Board of Directors, and FDRs, when applicable, in the Compliance Program.

The Compliance Program Description does not address every aspect of CCA's activities and all applicable legal issues that may result. If any Workforce member, Board of Directors member, or FDR has a question about the Compliance Program, he/she should seek guidance from his/her CCA contact or CCA's Chief Compliance Officer or CCA's Chief Legal Officer. The Compliance Program Description is available to all Workforce via the company-wide intranet, CommonGround. FDRs may seek the guidance of CCA's Chief Compliance Officer with respect to any compliance issues relevant to their contractual relationship with CCA.

Fraud, Waste and Abuse Program

The mission of CCA's FWA Program is to protect the integrity of CCA, along with federal and state programs to detect, prevent, investigate and appropriately report suspected cases of fraud, waste and/or abuse. All CCA Workforce members, FDRs, and contracted entities are obligated to report any suspicion of fraud, waste and abuse in a timely manner.

The Compliance Program Description outlines the fraud, waste and abuse efforts as they align with the seven core elements of an effective compliance program. The goals of CCA's Fraud, Waste and Abuse Program are to:

- Detect, prevent, investigate and report incidents of fraud, waste and abuse;
- Implement internal policies and procedures to accomplish the mission and to mitigate the risk for recurrence;
- Report instances of substantiated fraud, waste or abuse to the appropriate government agencies and/or law enforcement;
- Cooperate fully with all investigations of fraud, waste or abuse conducted by government agencies and/or law enforcement;
- Recover payments lost to fraudulent, wasteful and/or abusive billings;
- Provide communication and education regarding fraud, waste and abuse;
- Educate CCA Workforce and other entities, as required on how to identify fraud, waste and abuse; and
- Provide methods for internal and external individuals to report suspected incidents of fraud, waste or abuse.

Code of Conduct and Written Policies and Procedures

CCA's Workforce is expected to conduct themselves in an ethical manner and follow CCA's Code of Conduct and relevant policies and procedures. Workforce attests, on an annual basis, that they have reviewed the Code of Conduct.

Code of Conduct

CCA's Code of Conduct is a compilation of the ethical and legal guidelines pursuant to which all persons directly engaged in work on behalf of CCA including all Commonwealth Care Alliance, Commonwealth Care Alliance Clinical Group and Commonwealth Community Care employees, volunteers, interns, trainees, consultants, independent contractors ("Workforce"), and the Board of Directors are to carry out their professional duties. It is reviewed regularly and revised as necessary. CCA's Board of Directors approve the Code of Conduct. The Code of Conduct is distributed to Workforce upon hire, as part of Annual Compliance Training, and is available on CCA's intranet, CommonGround. The Code of Conduct is available on CCA's website <http://www.commonwealthcarealliance.org>.

The Code of Conduct includes, but is not limited to, the following topics:

- Compliance with the Law
- Reporting Compliance Concerns
- Compliance Training and Education
- Cooperating with Audits and Investigations
- Conflicts of Interest
- Extending Business Courtesies
- Accuracy and Retention of Records
- Confidentiality of Member, Workforce and Business Information
- Fraud, Waste, and Abuse
- Non-Retaliation

Policies and Procedures

The Department of Regulatory Affairs and Compliance has policies and procedures related to key compliance functions including, but not limited to: Fraud, Waste and Abuse; Regulatory Compliance Audits; Monitoring; Compliance Training and Education; Reporting, Investigating and Externally Reporting Compliance Concerns, Compliance Risk Assessment; Deficit Reduction Act, False Claims Act & Whistleblower protections, and Corrective Action Plans.

All of CCA's Policies and Procedures can be found on CCA's intranet, CommonGround. CCA regularly updates its policies and procedures to stay current with contractual, legal and regulatory requirements. CCA's policies and procedures may be made available to

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FDRs upon request. CCA's Workforce has the responsibility to comply with all policies, procedures and compliance standards relevant to their responsibilities.

Compliance policies and procedures are distributed to Workforce within 90 days of hire and are reviewed during Annual Compliance Training.

Compliance Officer, Compliance Committee and Oversight

Chief Compliance Officer

CCA has a designated Chief Compliance Officer who reports to the Chief Legal Officer and who is accountable to senior management and has a dotted-line reporting relationship to CCA's Board of Directors and is given the authority to communicate directly with the Board of Directors, as necessary.

The Chief Compliance Officer is a full-time employee of CCA and responsibilities include:

- Development, enhancement, implementation and oversight of CCA's Compliance and Information Privacy and Security Programs.
- Development, implementation and distribution of the Code of Conduct as well as compliance-related policies and procedures to Workforce, Board of Directors, and FDRs when appropriate.
- Implementation and maintenance of the Compliance Training and Education Program that focuses on the elements of an Effective Compliance Program (including Fraud, Waste and Abuse).
- Encourage Workforce to timely report all suspected compliance concerns.
- Ensure effective lines of communication are instituted and communication mechanisms are monitored; and complaints are investigated and treated confidentially, unless circumstances dictate the contrary.
- Ensure inquiries and investigations of any reported or suspected compliance concerns are conducted timely and complete documentation is maintained. Outcomes of investigations are shared with leadership and the Board as required.
- Informing the Board of regulatory issues, trends and compliance risk.
- Oversight of Corrective Action Plans initiated by the Department of Regulatory Affairs and Compliance and as a result of compliance actions.
- Promote readiness for CMS Program Audit by distribution of and monitoring compliance with updated protocols; implementation of best practices; and by addressing and remedying common conditions as outlined annually by CMS.

Internal Compliance Committee

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CCA has an Internal Compliance Committee (also referred to as the Management Compliance Committee), made up of cross-functional representation from operational and clinical leadership within the organization that assists the Chief Compliance Officer in the enhancement and oversight of CCA's Compliance Program as well as compliance-related strategic initiatives.

The Internal Management Compliance Committee provides advice to and advises the Chief Compliance Officer on the implementation and maintenance of the Compliance Program.

The Internal Management Compliance Committee's responsibilities include, but are not limited to:

- Advise the Chief Compliance Officer with the development of appropriate strategies to maintain regulatory compliance;
- Review reports that may include details of:
 - Compliance monitoring and auditing reports;
 - Fraud, waste and abuse investigations; and
 - Reports of compliance concerns;
- Reviews the annual Compliance, Auditing & Monitoring Plan and Information Privacy and Security Plan; and
- Advises CCA's Chief Compliance Officer on innovative approaches to enhance the Compliance Program.

Audit, Compliance and Risk Management Committee

The Audit, Compliance and Risk Management Committee is made up of a select number of Board members and staffed by the Chief Compliance Officer. This Committee assists the Board of Directors with high level oversight of CCA's compliance with regulatory requirements, laws and regulations. The Audit, Compliance and Risk Management Committee also oversees CCA's Compliance Program to ensure effectiveness.

The Chief Compliance Officer and the Audit, Compliance and Risk Management Committee reports periodically to the governing body on the activities and status of the Compliance Program. The Board of Directors is knowledgeable about the Compliance Program and compliance activities at CCA and is made aware of any potential risks.

The mission of the Audit, Compliance and Risk Management Committee is to assist CCA's Board of Directors with reasonable oversight of CCA's Compliance Program.

The Audit, Compliance and Risk Management Committee's responsibilities include, but are not limited to:

- Advise CCA's Chief Compliance Officer on strategic initiatives and innovative approaches to enhance the Compliance Program;

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- Review and approve updates to CCA’s Code of Conduct at the time of significant changes;
- Review the annual Compliance Plan, Auditing & Monitoring Plan, and making recommendations when necessary;
- Oversee the performance of the Chief Compliance Officer;
- Be aware of and reviewing all compliance enforcement actions (i.e. NONC) issued to Commonwealth Care Alliance; and
- Oversee the organization’s systems of disclosure of compliance concerns; the Committee should ensure mechanisms are in place to ensure open communication among the Chief Compliance Officer, senior management and the Board of Directors.

Compliance Training and Education Program

The Compliance Program outlines CCA's Compliance Training and Education Program. Compliance training is a key component of an effective Compliance Program.

Workforce are trained in understanding their role regarding compliance and adhering to CCA's regulatory requirements. Training materials are reviewed on an on-going basis and updated as appropriate.

New Employee Compliance Training

New Workforce members, as appropriate, of CCA receive compliance training within ninety (90) days of their date of hire on the following compliance-related topics:

- New Employee Orientation Compliance Training which includes but is not limited to:
 - An overview of general compliance topics;
 - Review of CCA's non-retaliation policy for reports made in good faith;
 - Overview of key Fraud, Waste and Abuse and HIPAA principles including a review of Federal and State False Claims acts and Whistleblower protections;
 - Overview of Stark Law, Deficit Reduction Act and Anti-Kickback statute;
 - Review of CCA's Code of Conduct;
 - Identification of and instructions on how to timely report compliance concerns;
 - Examples of potential instances of non-compliance;
 - Auditing, Monitoring and Compliance Risk Assessment; and
 - Informing workforce of their compliance responsibilities

- Additional compliance training is also offered within ninety (90) days of hire. This additional training includes:
 - Fraud, Waste and Abuse; and
 - HIPAA Privacy and Security and a review of key Information Privacy and Security Policies and Procedures
 - Review of key Compliance Policies and Procedures

During these mandatory training activities, Workforce members become familiar with CCA's Compliance Program and the role that compliance plays in their day-to-day job responsibilities.

First Tier, Downstream and Related Entity (FDR) Training

CCA's contracts include language stating that the individual or entity will adhere to all applicable federal and state rules and regulations, including MassHealth and Medicare Part C and D Programs. Federal guidance requires that all entities involved with the administration or delivery of the Medicare benefit have access to general compliance and

fraud, waste, and abuse training. CCA makes CMS' Medicare Parts C and D Fraud, Waste and Abuse Training; and Medicare Parts C and D General Compliance Training available on its website.

FDRs who have met the certification requirements through enrollment into the Medicare Part A and B programs or through accreditation as a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) are deemed to have met the training and educational requirements. FDRs who do not meet the deemed status are required to complete CMS' General Compliance and Fraud, Waste and Abuse training upon contract and annually thereafter. CCA reserves the right to periodically perform an audit to monitor adherence to training requirements.

Annual Compliance Training

The Department of Regulatory Affairs and Compliance conducts Annual Compliance Training for all CCA Workforce and Board of Director members, as a review of key compliance-related topics. Annual Compliance Training, includes, but is not limited to, reviews of CCA's Code of Conduct, Fraud Waste & Abuse, HIPAA, Information Privacy & Security; and the elements of an Effective Compliance Program.

Additional Methods of Compliance Training

Compliance Tips of the Month

On a monthly basis, the Department of Regulatory Affairs and Compliance distributes a Compliance Tip of the Month on compliance-related topics via the company-wide intranet, CommonGround.

Compliance Month

The Department of Regulatory Affairs and Compliance conducts a Compliance Month to raise awareness of relevant compliance-related topics.

Direct Communication

CCA uses various methods of direct communication to notify Workforce of any relevant federal and state regulatory changes, fraud alerts, pending changes to legislation, and advisory bulletins as necessary. Workforce is continually advised on how additional compliance information can be obtained.

Documentation

All documentation related to trainings included in the Compliance Training and Education Program are maintained by the Department of Regulatory Affairs and Compliance in accordance with CCA's Record Retention Policy.

Effective Lines of Communication and Reporting

Open communication between the Department of Regulatory Affairs and Compliance and CCA's Workforce, Board of Directors, and FDRs is a vital component to CCA's Compliance Program. CCA provides for routine, confidential and/or anonymous reporting of any compliance issues.

CCA Workforce is encouraged to discuss compliance-related issues directly with their managers/supervisors or with the Chief Compliance Officer. However, in the event a person wishes to remain anonymous, he/she may use CCA's Compliance Hotline or HR & Compliance Concerns Form on CCA's intranet, CommonGround. CCA publicizes the hotline number on posters within office locations, on CommonGround, on its website and in other communications, as appropriate.

Compliance Hotline

The toll-free 24/7 anonymous Compliance Hotline is available to report compliance-related concerns.

The Compliance Hotline number is:

**TOLL-FREE COMPLIANCE HOTLINE
1-800-826-6762**

All reports are referred to CCA's Chief Compliance Officer and are fully investigated. Summaries of reported compliance concerns may be shared with CCA's Senior Leadership, Audit, Compliance and Risk Management Committee; and Internal Compliance Committee, as appropriate.

CCA also posts the Compliance Hotline number and Information about general compliance and Fraud, Waste and Abuse on its website
<http://www.commonwealthcarealliance.org/>.

CommonGround

CCA has a company-wide intranet site called CommonGround which is accessible to all of CCA's Workforce. The home page of CommonGround showcases a section entitled "*Compliance Connect*" which houses key compliance-related documents such as the Compliance Program Description; instructions on how to report a compliance concern; the Fraud, Waste and Abuse Program Description and the Code of Conduct.

Confidentiality and Non-Retaliation

CCA takes all reports of suspected violations and questionable conduct or practices seriously. Verbal communications via Workforce member's manager or supervisor, Chief Compliance Officer, or the Compliance Hotline or those submitted through CCA's intranet are treated confidentially to the extent possible.

CCA prohibits any retaliatory action against a Workforce member for making a report in good faith.

Workforce shall not prevent or attempt to prevent another member of the Workforce from communicating a potential issue. Workforce members who attempt such an action may be subject to disciplinary actions.

CCA takes violations of this reporting policy seriously and the Chief Compliance Officer will review employee disciplinary and/or other corrective action for violations as appropriate with CCA's senior leadership and Board of Directors, as necessary.

Communication and Reporting Related to Fraud, Waste and Abuse

Internal Communication

The Department of Regulatory Affairs and Compliance uses various methods to keep Workforce members informed of fraud, waste and abuse and their responsibilities under CCA's Fraud, Waste and Abuse Program. Topics related to fraud, waste and abuse are reviewed within the scope of the Compliance Training and Education Program.

Communication regarding Fraud, Waste and Abuse with Providers and Members

Providers and members are made aware of CCA's commitment to prevention, detection, identification and reporting of fraud, waste and abuse in the following manners:

- Provider Manual
- CCA's external website (www.commonwealthcare.org)

Reporting

CCA has an internal policy on preventing, detecting, investigating, correcting and appropriately reporting suspected cases of fraud, waste and abuse. CCA provides regular instruction on how to promptly report a suspected fraud, waste or abuse concern. Once a concern is reported, the concern is reviewed and investigated. Fraud, waste and abuse concerns are concluded within a reasonable time frame after initial discovery. After review and/or investigation, if a report of fraud, waste or abuse is substantiated, it is reported to the appropriate external regulatory authority. Documentation of the investigation and results are maintained. CCA requires all staff to not obstruct and cooperate with investigations.

Well Publicized Disciplinary Standards and Enforcement

CCA's Compliance Program includes the enforcement of standards through well-publicized disciplinary guidelines in the Employee Handbook and Code of Conduct. CCA's employee discipline policy and non-retaliation policy are outlined in the Employee Handbook.

Workforce may be subject to disciplinary action for any compliance violation. Examples of conduct subject to enforcement and discipline include, but not limited to:

- Failure to perform any required obligation relating to CCA's Compliance Program or applicable law;
- Failure to timely report, in good faith, any violations or suspected violations of the Compliance Program or applicable law;
- Failure to complete required Compliance training activities; or
- Conduct that leads to the filing of a false or improper claim in violation of federal or state law.

***Effective System for Routine Monitoring, Auditing,
and Identification of Compliance Risks***

CCA has a system of ongoing compliance monitoring and auditing related to its operations and those contracted entities over which CCA has oversight responsibilities. The compliance risk assessment is a mechanism by which topics are selected for monitoring or auditing.

Compliance Monitoring

Departments conduct ongoing monitoring of activities performed within their own department or by a contracted entity overseen by that department.

Operational departments collaborate with the Regulatory Affairs and Compliance department to identify monitoring reports that have a regulatory compliance component, based on risk assessment and other factors. After establishing compliance monitoring reports, departments regularly review data for outliers and patterns to confirm and document ongoing compliance or to detect potential noncompliance or possible incidences fraud, waste and abuse. Regulatory Affairs and Compliance reviews the summary reports for trends that indicate ongoing compliance or the potential for noncompliance and offers feedback to departments.

A benefit of monitoring is early detection of a potential issue for timely correction. As part of monitoring, departments ensure that previously established corrective actions are undertaken and are effective in mitigating or reducing the risk of further noncompliance.

Monitoring Activities related to Fraud, Waste and Abuse

The following activities take place on a routine basis at CCA. Monitoring of these activities may result in the discovery of potential fraud, waste and/or abuse incidents:

- Routine checking of all Workforce, Providers, Contractors and members of the Board of Directors to identify excluded individuals, entities or providers.
- Oversight of and collaboration with CCA's third-party claims administrator,
- Oversight of and collaboration with CCA's Pharmacy Benefit Manager.
- Oversight of and collaboration with CCA's Dental Benefit Manager.

Compliance Auditing

Regulatory compliance audits are conducted by the Regulatory Affairs and Compliance department. Audits review compliance of processes performed by CCA departments or contracted entities, such as FDRs. Audits test and confirm compliance with Medicare and MassHealth regulations, sub-regulatory guidance, CCA's contractual obligations to the Centers for Medicare and Medicaid Services (CMS) and MassHealth under the Massachusetts Executive Office of Health and Human Services (EOHHS), and applicable Federal and State laws, as well as CCA's internal policies and procedures.

The Annual Compliance Audit Plan outlines the planned list of audits, which are selected through a variety of mechanisms, including risk assessment, monitoring results, and reports of potential noncompliance or FWA, FDR risk. Ad hoc audits not appearing on the Annual Compliance Audit Plan may be performed when a high regulatory compliance risk is identified.

Audits may be announced or unannounced and the Regulatory Affairs and Compliance department uses a combination of desk, virtual, and onsite audits. Appropriate and internationally accepted audit methods are used to determine methodology, including sample size, and auditors use statistically valid methods that comply with generally accepted auditing standards.

Regulatory Affairs and Compliance approaches audits as a continuous improvement opportunity. Results are shared and impacted departments and entities are encouraged to provide clarification before finalizing the audit report. Corrective action plans (CAPs) are required for areas found to be non-compliant (findings). Validation is conducted to determine if the implemented corrective actions have fully addressed the underlying problems. Audit results may prompt new or modified compliance monitoring reports.

Corrective Action

In accordance with CCA's policy on Corrective Action Plans (CAP), CCA business owners and/or vendors work with the Department of Regulatory Affairs and Compliance to develop a compliance-related CAP. A formal CAP is initiated when a noncompliance issue is brought to the attention of the Department of Regulatory Affairs and Compliance through an audit, monitoring, a department's or FDR's self-reporting, or through notification by CMS or EOHHS.

The CAP documents a process and completion of specific, tailored actions taken to achieve compliance with a specific requirement. The CAP process, which includes a root cause analysis, is designed to correct and mitigate the risk of recurrence of future noncompliance, as well as document the efforts taken to mitigate the noncompliant issue.

Reporting of Auditing, Monitoring, and Corrective Action Results

The Chief Compliance Officer receives regular summary reports of all monitoring, auditing and corrective action activities and provides select updates to the Internal Compliance Committee, CCA's Senior Leadership and the Audit, Compliance and Risk Management Committee. When appropriate, CCA may disclose an issue to the appropriate regulatory agency.

Disclosing Issues to CMS

The Department of Regulatory Affairs and Compliance maintains a structured decision-making process to determine if an identified issue should be formally disclosed to CCA's CMS Account Manager. Representatives from The Department of Regulatory Affairs and Compliance and Legal Affairs are involved in the decision-making process.

Compliance Risk Assessment

A. Annual Compliance Risk Assessment

The Department of Regulatory Affairs and Compliance facilitates and completes an annual compliance risk assessment. The compliance risk assessment process engages departments throughout CCA to identify and collect information about potential compliance risks. Compliance risks to internal processes, as well as risks to processes performed by FDRs overseen by CCA are incorporated into the assessment.

Identified compliance risks are ranked based on potential impact and likelihood of a risk event occurring. The results of the compliance risk assessment are used to inform the CCA's Annual Compliance Plan, which includes the Compliance Auditing and Compliance Monitoring Plans.

B. Continuous Compliance Risk Assessment

The Department of Regulatory Affairs and Compliance reviews and assesses potential compliance risks throughout the year in order to remain responsive to the changes in CCA's operations, and CMS and MassHealth laws, regulations and requirements. The Department of Regulatory Affairs and Compliance works with departments to identify and assess new (or previously not identified) compliance risks, follow-up on previously identified and assessed compliance risks, and educate departments about accurately identifying compliance risks. New risks are analyzed using the same methodology as used during the annual compliance risk assessment process, and may result in modification of the CCA's Annual Compliance Plan, or Compliance Auditing and Compliance Monitoring Plans.

Participation Review and Background Checks

CCA does not knowingly hire, contract with, or retain on its behalf, any person or entity that is currently suspended, excluded or otherwise ineligible to participate in federal and/or state health care programs.

Review of the OIG LEIE and GSA/SAM Exclusion Databases

Per CCA’s policy, prior to commencement of employment, the Department of Regulatory Affairs and Compliance reviews the OIG List of Excluded Individuals and Entities (LEIE) and the Government Services Administration (GSA) Exclusion databases. In addition, the LEIE and GSA Exclusion databases are reviewed on a monthly basis for all CCA Workforce, members of the Board of Directors, providers, vendors and FDRs.

Procedures for Prompt Response to Compliance Issues and Remediation

CCA's Compliance Program has procedures to ensure a prompt response to detected offenses and conducts a timely, reasonable inquiry upon discovery of evidence of misconduct; CCA develops and conducts appropriate corrective actions in response to identified violations. CCA makes every effort to correct problems promptly and thoroughly to reduce the potential for reoccurrence to ensure ongoing compliance with CMS and MassHealth requirements. When appropriate, CCA voluntarily self-discloses any potential misconduct to the appropriate external regulatory authority.

Notice of Violation or Suspected Violation

Workforce is to promptly and in good faith, report a violation, suspected violation; questionable or ethical conduct in violation of the Compliance Program or applicable law to his/her supervisor/manager, the Chief Compliance Officer, through the Compliance Hotline or via the HR and Compliance Concerns Report form on CCA's Intranet, CommonGround. Upon identification, any FDR should notify CCA of a suspected violation or questionable unethical conduct in relation to business conducted for or on behalf of CCA immediately.

Response to Notice of Violation or Suspected Violation

The Chief Compliance Officer, after investigation and identification that a violation has occurred, notifies applicable senior management staff, the Audit, Risk and Compliance Committee and/or Chief Legal Officer, as appropriate to determine a proper response.

The investigation and risk mitigation activities may include some or all of the following:

- Investigating all aspects of the suspected violation or questionable conduct.
- If the investigation involves Part D potential misconduct, a referral to a Medicare Drug Integrity Coordinator (MEDIC) will be made if CCA does not have the resources to investigate the potential misconduct promptly.
- If CCA conducts an inquiry that is determined to be potential fraud, waste or abuse or misconduct, CCA will refer the misconduct to the appropriate regulatory authority timely.
- When appropriate, CCA will prepare a Corrective Action Plan to address and correct the misconduct in order to mitigate the risk for repeated misconduct.
- When appropriate, CCA will provide refresher education on the area identified in the misconduct.

Response and Resolution Related to Fraud, Waste and Abuse

Any suspected cases of fraud, waste or abuse that are to be reported to the Department of Regulatory Affairs and Compliance are sent to CCA's Special Investigative Unit (SIU) to lead the investigation. After investigation, if an incident is determined to have occurred, appropriate action will be taken. Appropriate action may include:

- Referral of any abuse or potentially fraudulent conduct for further investigation to CMS in relation to Medicare activities; to MassHealth in relation to Medicaid activities; or to the MEDIC in the case of Part D Medicare activities;
- Prompt reporting of potential violations of federal law to the appropriate law enforcement authorities; and
- Disciplinary actions up to and including termination of any Workforce who engages in fraudulent or abusive practices; and potential contract termination for any contracted entity found to have conducted any misconduct.
- When appropriate, CCA will prepare a Corrective Action Plan to address and correct the misconduct in order to mitigate the risk for repeated misconduct. Also, when appropriate, CCA will provide refresher training on the area identified in the misconduct.

First Tier, Downstream, and Related Entity Compliance Oversight

CCA maintains a variety of activities to oversee First Tier, Downstream, and Related Entities (FDRs). CCA is responsible for fulfilling the terms and conditions of contracts with the Center for Medicare & Medicaid Services (CMS) and MassHealth under the Massachusetts Executive Office of Health and Human Services (EOHHS), and is, therefore, accountable for FDR compliance with Medicare program requirements.

FDRs require a heightened level of oversight due to the nature of the contracted services performed on behalf of CCA, the impact on members, and the level of decision-making authority granted by CCA to FDRs.

Workforce within operational departments within CCA are responsible for identifying the need for the use of a FDR and its related oversight activities. These Workforce members are also responsible for understanding and adhering to Medicare and MassHealth program requirements that pertain to their operational functions and are also responsible for reporting all potential issues of non-compliance to the Department of Regulatory Affairs and Compliance.

The Department of Regulatory Affairs and Compliance is responsible for maintaining an effective compliance program, which includes oversight of FDRs. The Department of Regulatory Affairs and Compliance has a role in certain oversight activities, including: first tier entity determination; educating Workforce about their responsibilities for FDR oversight; distributing compliance information and training; compliance and FDR risk assessments; compliance monitoring and auditing; investigating potential issues of reported non-compliance; overseeing regulatory compliance corrective actions; and reporting issues as appropriate to Internal Compliance Committee, Senior Leadership, the Audit, Compliance and Risk Management Committee, CMS, and EOHHS.

Documentation

The Department of Regulatory Affairs and Complaints maintains all required documentation as outlined in CCA's Record Retention policy.

Glossary/Key Terms

Abuse	Includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence among other factors.
Anti-Kickback Statute	Prohibits a person from knowingly offering or paying remuneration to any person to induce that person to refer or purchase, lease, order or arrange for or recommend the purchasing, leasing or ordering of times or services for which payment may be made by a federal health care program.
Audit	A formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.
CAP	Corrective Action Plan
CMS	Centers for Medicare and Medicaid Services. Federal agency under the Department of Health and Human Services responsible for administering the Medicare and Medicaid programs.
DHHS	Department of Health and Human Services. CMS is an agency within the DHHS that administers the Medicare Program.
Downstream Entities	A party that enters into a written arrangement, acceptable to CMS with persons or entities involved with a Medicare Part C or Part D benefit, below the level of the arrangement between CCA and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

EOHHS	Executive Office of Health and Human Service: Massachusetts department which oversees the Massachusetts Medicaid Program, MassHealth.
FCA	False Claims Act is a federal law that imposes liability on persons and companies who defraud governmental programs. It is the federal Government's primary tool in combating fraud against the Government.
First Tier Entity	Any party that enters into a written arrangement, acceptable to CMS, with CCA to provide administrative services or health care services to a CCA member under the Medicare Part C or Part D programs. .
Fraud	Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program.
FWACC	Fraud, Waste and Abuse Case Coordinator. An employee within CCA who coordinates investigations of all reports of suspected fraud, waste or abuse incidents.
HPMS	Health Plan Management System is an information system that services a critical role in the ongoing operations of the Medicare Advantage (MA) and Part D Programs. HPMS services the MA and Part D programs in two central ways. First, HPMS functionality facilitates the numerous data collection and reporting activities mandated for these entities by legislation. Second, HPMS provides support for the ongoing operations of the plan enrollment and plan compliance business functions.
LEIE	List of Excluded Individuals and Entities. OIG's List of Excluded Individuals/Entities (LEIE) provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal health care programs. Individuals and entities who have been reinstated are removed from the LEIE.
MassHealth	Massachusetts Medicaid program

Monitoring	Regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.
NBI MEDIC	National Benefit Integrity Medicare Drug Integrity Contractor. An organization that CMS has contracted with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The NBI MEDIC's primary role is to identify potential FWA in Medicare Parts C and D.
Non-Compliance	Failure or refusal to act in accordance with the organization's Compliance Program, or other standards or procedures, or with federal or state laws or regulations.
OIG	Office of the Inspector General within the Department of Health and Human Services (DHHS). The OIG is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.
PHI	PHI is individually identifiable health information (IIHI) that is transmitted or maintained by a covered entity or its business associate, in any form or media, whether electronic, paper or oral. IIHI is information including demographic information, that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual and that relates to (1) the past, present or future physical or mental health or condition of the individual; (2) the provision of healthcare to the individual; or (3) the past, present or future payment for the provision of healthcare to an individual. PHI excludes information related to a person deceased more than 50 years.
Related Entity	An entity that is related to CCA by common ownership or control, <i>and</i> either performs some of CCA's management functions (contract or delegation) or furnishes services to CCA members (under an oral or written arrangement) or leases real property or sells materials to CCA at a cost of more than \$2,500 during a contract period.
Waste	Overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by

criminally negligent actions but rather a misuse of resources.

Workforce

A Member of CCA or its affiliates Workforce is an employee, non-provider contractor, volunteer, intern, trainee or consultant who is required to have regular and routine access to a CCA facility, member protected health information, and/or confidential or proprietary information in order to perform their obligations (employment or contractual) and functions for CCA. Exceptions to individuals who fall under the Workforce definition must be jointly approved by the Legal and Regulatory Affairs and Compliance Departments.