Carolina SeniorCare

An EveryAge Program

COMPLIANCE PROGRAM

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Carolina SeniorCare
Compliance Program
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I. INTRODUCTION

A. Purpose

Carolina SeniorCare has adopted this Compliance Program ("Compliance Program" or "Program") to reaffirm its commitment to complying with all applicable federal and state laws, and PACE program requirements. This Program is intended to follow all relevant compliance program regulations as well as guidelines issued by CMS from time to time, including, but not limited to, §460.63 of the PACE regulations, §423.504(b)(4)(vi) of the Part D regulations, and Chapter 9 of the Medicare Prescription Drug Benefit Manual/Chapter 21 of the Medicare Managed Care Manual. This Program:

- Articulates Carolina SeniorCare's commitment to complying with applicable federal and state standards;
- Articulates Carolina SeniorCare's commitment to detecting, correcting, and preventing noncompliance with CMS's program requirements, including detecting, correcting, and preventing fraud, waste, and abuse;
- Describes standards of conduct (*See Tab A: Model Standards of Conduct*) and compliance expectations that the Board, employees and contractors of Carolina SeniorCare are expected to adhere to;
- Outlines procedures that Carolina SeniorCare follows in monitoring and auditing for compliance with CMS requirements and the overall effectiveness of the compliance program; and in investigating and resolving any potential improper conduct when identified;
- Provides guidance for Carolina SeniorCare employees and contractors in reporting compliance issues and addressing questions relating to fraud, waste, and abuse; and
- Identifies specific risk areas for Carolina SeniorCare overall as well as Carolina SeniorCare's PDP that merit attention and monitoring.

Carolina SeniorCare has a policy of non-intimidation and non-retaliation for good faith participation in the Compliance Program.

B. Glossary

These terms will have the following meaning when used in the Program:

Abuse includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare and Medicaid Programs, 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. Examples of abuse include:

- Payment for services not provided as billed;

- Failure to provide medically necessary services, or other services determined necessary by the interdisciplinary team to maintain or improve participants' health status;

- Payment for services provided by an individual who is not appropriately qualified to provide the billed service (e.g., an unlicensed person or a person acting outside the scope of his or her license);

- Encouraging disenrollment in response to decline in participant's health status;

- Reporting diagnoses for risk adjustment that are not supported by the participant's medical condition;

- Inadequate controls that result in failing to report rebates or discounts;

- Drug-seeking behavior on the part of beneficiaries; and

- Issuing refills for a prescription that is not medically necessary.

Anti-Kickback Statute ("AKS") means the Medicare and Medicaid Patient and Program Protection Act (found at 42 USCA §1320a-7b(b)). The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal Health Care Program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal Health Care Program, the AKS is violated. "Remuneration" is defined in the AKS as including the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

Appeal means any of the procedures that deal with the denial of service delivery or payment requests, enrollment denials, or involuntary disenrollments.

Audit means a formal review of compliance with internal (e.g., compliance plan, policies and procedures) and external (e.g., laws and regulations) standards used as base measures.

CMS means the Centers for Medicare and Medicaid Services, the federal government agency in charge of administering Medicare and Medicaid.

Compliance Officer means the individual appointed by Carolina SeniorCare as responsible for the Organization's Compliance Program.

Compliance Program means the program adopted by Carolina SeniorCare to ensure compliance with all applicable laws, regulations and contractual requirements.

Conflict of interest means a situation in which the outside professional activities, private financial interests or other interests of, or the receipt of benefits from third parties impair, or appear to impair, an individual's independent, unbiased judgment.

Contractor means an outside organization, agency, or individual, including a FDR that furnishes administrative or care-related services on behalf of Carolina SeniorCare.

Deemed Provider or Supplier means a provider or supplier that has been accredited by a national accreditation program (approved by CMS) as demonstrating compliance with certain conditions.

Downstream Entity means any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of Carolina SeniorCare and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

FDR refers to First Tier, Downstream or Related Entity that has entered into an agreement with Carolina SeniorCare and provides services under the Part D program. Medicare Part D program requirements apply to FDRs to whom Carolina SeniorCare has delegated administrative or health care functions relating to its Medicare Part D plan.

Federal Health Care Program means any plan or program that provides health care benefits to any individual, whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by a United States Government or state health care program, including Medicare, Medicaid, CHAMPUS, and Department of Veterans Affairs but excluding the Federal Covered Persons Health Benefit Program (FEHBP).

First Tier Entity means any party that enters into a written arrangement, acceptable to CMS, with Carolina SeniorCare to provide administrative services or health care services for a Medicare eligible individual under the Part D program.

Formulary means the entire list of Part D drugs covered by Carolina SeniorCare's Part D plan and all associated requirements outlined in Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6.

Fraud is 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. Examples of fraud include:

- Embezzlement of Medicare and/or Medicaid program funds;
- Enrolling, and receiving payments for, fictitious individuals;
- Misrepresenting information about potential participants to enroll individuals who would not otherwise be eligible for PACE;
- Knowingly submitting unsupported diagnoses to CMS for use in risk-adjusting Medicare capitation payment amounts;
- Falsifying encounter data;
- Altering PDE data, or submitting fictitious PDE data, to CMS for the purpose of increasing risk-sharing and other CMS subsidies; and
- Reporting that a brand-name drug was dispensed when a generic was dispensed, with the intent of receiving increased federal reimbursement.

FWA means Fraud, Waste, and Abuse.

Governing Body means that group of individuals at the highest level of governance of Carolina SeniorCare, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control Carolina SeniorCare in the best interest of the organization and its Participants. As used in this chapter, governing body does not include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless

persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of Carolina SeniorCare.

MEDIC means any Medicare Drug Integrity Contractor retained by CMS to assist with Parts C and D fraud prevention and detection. MEDIC activities include: data analysis to identify potential Parts C and D fraud; investigation of potential Parts C and D fraud; development of potential Parts C and D fraud cases for referral to law enforcement; liaison to law enforcement for Parts C and D issues; and audits of sponsor and subcontractor Parts C and D operations.

MMA means the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the federal statute that created the Part D drug benefit.

OIG means the Office of the Inspector General for the federal Department of Health and Human Services (HHS).

PACE Organization means Carolina SeniorCare.

Participant means an individual enrolled in Carolina SeniorCare.

Prescription Drug Plan (PDP) means a Medicare Part D Prescription Drug Plan sponsored by a Carolina SeniorCare.

Pharmacy Benefits Manager (PBM) means an entity contracted by Carolina SeniorCare to administer the Medicare Part D drug benefit, which activities may include formulary development, claims processing, pharmacy network management, and data reporting.

Prescription Drug Event (PDE) data means the data elements constituting a summary record that documents the final adjudication of a dispensing event that must be submitted to CMS on a monthly basis.

Related Entity means any entity that is related to Carolina SeniorCare by common ownership or control and: (1) performs some of the Carolina SeniorCare's Part D management functions under contract or obligation; (2) furnishes services to Medicare Participants under an oral or written agreement; or (3) leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

SAM means the General Services Administration (GSA) System for Award Management database service at (SAM.gov) that combines several federal procurement systems and the Catalog of Federal Domestic Assistance into one system to search for excluded, sanctioned or debarred persons or companies.

Search Warrant means a judicial order issued by a judge or magistrate which authorizes government or law enforcement agents to locate and remove specific documents or items from the premises. To be valid, a search warrant must be signed by a judge or magistrate, must be supported by an affidavit, and must not have expired.

State Administering Agency (SAA) refers to the state agency which enters into the three-way PACE program agreement with CMS and Carolina SeniorCare, and which is responsible for oversight of Carolina SeniorCare.

Subpoena means a legal document ordering the production of either testimony (a subpoena ad testificandum, ordering a witness to appear and give testimony) or documents (a subpoena duces tecum, directing the recipient to produce books, papers, documents and other

things). Subpoenas usually do not require the production of the witness or documents immediately; they may set a time-frame within which information must be produced.

Third-Party Administrator ("TPA") means an entity contracted by a Prescription Drug Plan to process claims for the Medicare Part D drug benefit and provide related services (such as enrollment management, risk adjustment and encounter data submission)

Waste means the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare and Medicaid programs. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources. Examples of waste include:

- Ineffective Interdisciplinary Team decision-making or utilization management activities that lead to unnecessary utilization of goods and services and/or unnecessary costs;
- Poor or inefficient record-keeping that results in additional costs;
- Improper drug utilization or other protocols that result in poor quality of care, requiring additional medications paid for with federal health care program dollars; and
- Failing to adequately differentiate between Part A, Part B and Part D drugs and receiving higher Medicare payments as a result.

II. HIGH-LEVEL OVERSIGHT

A. Governing Body

1. Duties of the Board

Carolina SeniorCare's Board of Directors (herein referred to as the "Board") shall exercise reasonable oversight with respect to the implementation and effectiveness of the Compliance Program. When compliance issues are presented to the Board, it should make further inquiry and take appropriate action to ensure the issues are resolved. The Board may delegate compliance program oversight to the Compliance Committee, but the Board as a whole remains accountable for reviewing the status of the Compliance Program. The scope of the delegation from the full Board to the Compliance Committee must be clear in the Committee's charter and reporting. The Board shall receive training and education as to the structure and operation of the Compliance Program.

Reasonable oversight shall include (assisted by the Compliance Committee if desired):

- Approving the Standards of Conduct;
- Understanding the Compliance Program structure;
- Remaining informed about the Compliance Program outcomes, including results of internal and external audits;
- Remaining informed about governmental compliance enforcement activity;
- Receiving regularly scheduled, periodic updates from the Compliance Officer and Compliance Committee; and

- Reviewing the results of performance and effectiveness assessments of the Compliance Program.

The Board may wish to be involved in, or may delegate to senior management or to the Compliance Committee, the following activities:

- Development, implementation and regular review of compliance policies and procedures;
- Approval of compliance policies and procedures;
- Review and approval of compliance and FWA training;
- Review and approval of compliance risk assessment;
- Review of internal and external audit work plans and audit results;
- Review and approval of corrective action plans resulting from audits;
- Review and approval of appointment of the compliance officer;
- Review and approval of performance goals for the compliance officer;
- Evaluation of the senior management team's commitment to ethics and the compliance program; and
- Review of dashboards, scorecards, self-assessment tools, etc., that reveal compliance issues.

2. Reviewing the Effectiveness of the Compliance Program

The Board should collect and review measurable evidence that the Compliance Program is detecting and correcting noncompliance on a timely basis.

Some indicators of an effective Compliance Program are:

- Use of quantitative measurement tools (e.g., scorecards, dashboard reports, key performance indicators) to report, and track and compare over time, compliance with key PACE program and other legal requirements;
- Use of monitoring to track and review open/closed corrective action plans;
- Implementation of new or updated Federal and State requirements and confirm appropriate and timely implementation;
- Increase or decrease in number and/or severity of complaints from employees, contractors, providers, participants, caregivers;
- Timely response to reported noncompliance and potential FWA, and effective resolution (i.e., non-recurring issues);
- Consistent, timely and appropriate disciplinary action; and

- Detection of noncompliance and FWA issues through monitoring and auditing:
    - Whether root cause was determined and corrective action appropriately and timely implemented and tested for effectiveness;
    - Detection of noncompliance trends and schemes via daily claims reviews, outlier reports, audits (e.g., Part D pharmacy audits), investigative findings, etc.; and
    - Actions taken in response to compliance reports.

Carolina SeniorCare should ensure that CMS and the SAA are able to validate, through review of the Board's meeting minutes or other documentation, the active engagement of the Board in the oversight of the Compliance Program.

B. Senior Management Involvement in Compliance Program

The Executive Director and other senior management shall be engaged in the Compliance Program.

1. Duties of Executive Director

The Executive Director shall:

- With the cooperation of other senior management, ensure that the Compliance Officer is given the credibility, authority and resources necessary to operate a robust and effective Compliance Program;
- Receive periodic reports from the Compliance Officer of risk areas facing the Carolina SeniorCare, the strategies being implemented to address them, and the results of those strategies; and
- Be advised of all governmental compliance enforcement activity, including formal enforcement actions.

III. COMPLIANCE OFFICER AND COMPLIANCE COMMITTEE

A. Compliance Officer

The Compliance Officer shall be a member of senior management and shall develop, operate, and monitor the Compliance Program. The Compliance Officer shall report directly to the Board on matters related to program compliance, as necessary. The Compliance Officer will oversee the Compliance Committee, which shall advise the Compliance Officer and assist in the implementation of the Compliance Program.

The Compliance Officer's job duties include:

- Developing and updating compliance policies and procedures;
- Reporting on a periodic basis to the Board, the Executive Director, other senior management, and the Compliance Committee regarding the activities and status of Carolina SeniorCare's Compliance Program, including: the identification, investigation, and resolution of potential or actual instances of noncompliance; the results of auditing and monitoring activities, including the effectiveness of the

Compliance Program; areas of risk facing Carolina SeniorCare, strategies used to address the areas of risk, and the results of those strategies; and any instances of government compliance investigation, compliance enforcement or compliance penalties such as Notices of Non-compliance, Warning Letters or more formal sanctions;

- Developing and implementing training programs regarding Carolina SeniorCare's Compliance Program;

- Developing and maintaining compliance reporting mechanisms that are accessible and confidential and that allow employees and contractors to report suspected fraud, waste, and abuse and other non-compliance on an anonymous basis and without fear of retaliation;

- Developing and maintaining effective lines of communication between the Compliance Officer and members of the Compliance Committee, Carolina SeniorCare senior leadership, Carolina SeniorCare employees, and Carolina SeniorCare contractors, including receiving regular reports on the results of auditing and monitoring activities and widely publicizing compliance policies and procedures throughout Carolina SeniorCare and its contractors;

- Responding to reports of compliance issues concerning Carolina SeniorCare, including compliance concerns involving contractors, and coordinating investigations and developing corrective action plans;

- Reporting instances of fraud to the appropriate NBI MEDIC, CMS, and/or the SAA and other state-specific entities as required, when Carolina SeniorCare determines that such a report is appropriate;

- Maintaining appropriate documentation regarding the Compliance Program;

- Ensuring HHS OIG and SAM exclusion lists, CMS preclusion list, state nurse aide registry, Medicare opt-out list, and state Medicaid exclusion lists, as applicable, have been checked monthly with respect to employees, governing body members, and contractors, as applicable, and coordinating results with Human Resources, Security, Legal or other departments as appropriate; and

- Regularly checking the CMS website for relevant new or revised regulations and guidance materials, and making recommendations to the Board for incorporating new or revised regulations and guidance into the Compliance Program, as appropriate.

The Compliance Officer shall have the authority to:

- Provide unfiltered, in-person reports to Carolina SeniorCare's senior-most leadership, i.e., the Executive Director, EveryAge CEO and the Board, at the Compliance Officer's discretion;

- Interview Carolina SeniorCare's employees and other relevant individuals regarding compliance matters;

- Review contracts and other pertinent documents;

- Review the submission of data to CMS and the SAA to ensure that it is accurate and in compliance with applicable reporting requirements;

- Independently seek advice from legal counsel;

- Report potential fraud or misconduct to CMS, the SAA, their designee or law enforcement, as appropriate;

- Conduct and/or direct audits and investigations of contractors; and

- Conduct and/or direct audits of any area or function of Carolina SeniorCare's program.

B. Compliance Committee

The Compliance Committee serves to advise the Compliance Officer and is accountable, and must provide regular compliance reports, to Carolina SeniorCare's Board, Executive Director, and other senior management.

The Compliance Committee's duties include:

- Meeting at least on a quarterly basis, or more frequently as necessary to enable reasonable oversight of the Compliance Program;

- Developing strategies to promote compliance and the detection of any potential violations;

- Reviewing and approving compliance training, and ensuring that training and education are effective and appropriately completed;

- Assisting with the creation and implementation of the Compliance Program risk assessments and the monitoring and auditing work plan;

- Assisting in the creation, implementation and monitoring of effective corrective actions;

- Developing ways to implement appropriate corrective and preventative action;

- Reviewing the effectiveness of the Compliance Program;

- Supporting the Compliance Officer's needs for sufficient staff and resources to carry out his/her duties;

- Ensuring that Carolina SeniorCare has appropriate, up-to-date compliance policies and procedures;

- Ensuring that Carolina SeniorCare has a system for employees and contractors to ask compliance questions and report potential instances of program noncompliance and potential FWA confidentially or anonymously (if desired) without fear of retaliation;

- Ensuring that Carolina SeniorCare has a method for Participants to report potential program noncompliance and FWA;

- Reviewing and addressing reports of monitoring and auditing in areas in which Carolina SeniorCare is at risk for program noncompliance or potential FWA and ensuring that corrective action plans are implemented and monitored for effectiveness; and

- Providing regular and ad hoc reports on the status of compliance with recommendations to Carolina SeniorCare's Board.

The Compliance Committee should include individuals with a variety of backgrounds, including members of senior management including, but not limited to, Carolina SeniorCare's Compliance Officer, Executive Director, Medical Director, EveryAge Chief Quality and Compliance Officer, and EveryAge Chief Operations Officer. Additional member may include but are not limited representatives from administration, clinical services, finance, human resources, medical records, information technology, risk management, and marketing. Members of the Compliance Committee should have decision-making authority in their respective areas of expertise.

C. Communications and Reporting

The Compliance Officer shall coordinate regular meetings of the Compliance Committee to ensure appropriate oversight and discussion of compliance activities. At least quarterly, and more frequently as circumstances warrant, the Compliance Officer shall provide regular reports to the Board, the Executive Director, and other senior management on the operation and effectiveness of the Compliance Program, including reports on Compliance Program risk assessments; monitoring and auditing activities; and, as necessary, on any potential violations, government enforcement activities or other compliance concerns, including reports about investigations into such matters and correction of any problems identified.

IV. EFFECTIVE LINES OF COMMUNICATION

An open line of communication between the compliance officer and Carolina SeniorCare personnel, as well as among the organization, contractors and participants, is critical to the successful implementation of a compliance program and the reduction of any potential for fraud, abuse and waste.

Carolina SeniorCare shall establish and implement effective lines of communication, ensuring confidentiality between the Compliance Officer, members of the Compliance Committee, employees, managers and the Board, and Carolina SeniorCare's contractors and participants. Such lines of communication shall be accessible to all and allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified. For more information on reporting of compliance issues refer to Section VIII: Internal Reporting of Wrongdoing.

In addition, Carolina SeniorCare shall have an effective way to communicate information from the Compliance Officer to others. Such information should include:

- The Compliance Officer's name, office location and contact information;

- Applicable/relevant laws, regulations, and guidance for Carolina SeniorCare and contractors, such as statutory, regulatory, and sub-regulatory changes (e.g. HPMS memos);

- Changes to policies and procedures and Standards of Conduct.

Carolina SeniorCare may communicate information via physical postings of information, e-mail distributions, internal websites, and individual and group meetings with the Compliance Officer. The Compliance Officer shall disseminate information within a reasonable time and to all appropriate parties.

V. RISK ASSESSMENT [Required for PDP Activities as per §423.504(b)(4)(vi)(F)]

Referring to Section 50.6.2 Development of a System to Identify Compliance Risks, in Chapter 9 of the CMS Prescription Drug Benefit Manual/Chapter 21 of the CMS Medicare Managed Care Manual, "Areas of particular concern for Medicare Parts C and D sponsors include, but are not limited to, marketing and enrollment violations, agent/broker misrepresentation, selective marketing, enrollment/disenrollment noncompliance, credentialing, quality assessment, appeals and grievance procedures, benefit/formulary administration, transition policy, protected classes policy, utilization management, accuracy of claims processing, detection of potentially fraudulent claims, and FDR oversight and monitoring." These are among the areas of concerns for PACE organizations as well.

Carolina SeniorCare shall establish and maintain a risk assessment system to determine where the organization is at risk for noncompliance and to prioritize (rank) such risks. Under this system, the Compliance Officer (or his/her designee) at least annually shall conduct an overall risk assessment to identify priority compliance risk areas where additional safeguards may be needed. The Compliance Program risk assessment will identify priority risk areas by referencing: areas of concern identified by CMS, the SAA or other regulators; areas of concern identified by Carolina SeniorCare; and areas of concern identified by participants, providers, contractors, or others. Carolina SeniorCare will document the procedures used to implement the risk assessment. The Compliance Risk Assessment will address Part D/FWA issues.

The Compliance Risk Assessment should inform the compliance priorities in the yearly audit and monitoring work plan described below in Section VI.A of this Compliance Program.

In developing and updating its annual Compliance Risk Assessment, Carolina SeniorCare will consider, and incorporate as appropriate, relevant information from the following resources:

- Carolina SeniorCare's past CMS and SAA audit reports;
- CMS PACE Audit and Enforcement Report (See https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits)
- OIG Annual Work Plan (See http://oig.hhs.gov/publications/workplan.asp);
- Current CMS PACE Application (See https://www.cms.gov/Medicare/Health-Plans/PACE/Overview);
- Current CMS PACE Part D Application (See https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance);
- CMS PACE Audit Guide (See https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits);
- CMS review and audits;
- State review and audits;

- Enforcement and compliance actions (See https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions);

- Current Call Letter for Medicare Advantage Organizations and PDP sponsors, as applicable to PACE (See https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html);

- Relevant guidance/information provided through the Health Plan Management System ("HPMS");

- Recent guidance from CMS, the SAA, the OIG and/or other relevant authorities;

- Recent amendments or additions to the PACE or Part D regulations (See https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr460_main_02.tpl and https://www.ecfr.gov/cgi-bin/text-idx?SID=810c06305ee5c7d97bd208d69b0147a8&mc=true&tpl=/ecfrbrowse/Title42/42cfr423_main_02.tpl); and

- Recent amendments or additions to Chapter 9 of the Medicare Prescription Drug Benefit Manual/Chapter 21 of the Medicare Managed Care Manual (See https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals).

VI. MONITORING AND AUDITING [Required for PDP Activities as per §423.504(b)(4)(vi)(F); With respect to exclusion/preclusion checks in particular, required for All PACE Program Operations as per §§460.68 and 460.86]

A. Risk Area Monitoring and Audits, including Preclusion/Exclusion Checks

1. Consistent with its annual risk assessment as described in Section V. above and in response to specific issues as they arise, Carolina SeniorCare will conduct periodic monitoring and auditing activities to detect and prevent potential noncompliance, including FWA and to ensure compliance with all applicable federal and state laws, PACE program requirements, and Carolina SeniorCare's policies and procedures. The Compliance Officer shall develop a monitoring and auditing work plan outlining, and include a schedule of, the planned monitoring and auditing activities for each contract year. *(See Tab E: Annual Compliance Monitoring and Auditing Work Plan.)* Any monitoring and auditing work plans so developed should meet the relevant requirements of Sections 50.6.3 through 50.6.6, Chapter 9 of the CMS Prescription Drug Benefit Manual/Chapter 21 of the CMS Medicare Managed Care Manual (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals. Monitoring may occur to ensure corrective actions for any identified problems are undertaken or when no specific problems have been identified to confirm ongoing compliance.

Monitoring and/or auditing will extend to all areas of Carolina SeniorCare's operations, including its Part D plan, that are vulnerable to noncompliance, including:

- Marketing, including agent/broker misrepresentations, if applicable

- Enrollment and Disenrollment

- Credentialing
- Service delivery requests, appeals, and grievances;
- Clinical appropriateness and care planning;
- Emergency preparedness;
- Personnel records;
- Quality Improvement;
- Risk Adjustment Processing System (RAPS), Encounter Data System (EDS) and other data submissions;
- Contractor oversight and monitoring;
- Provider claims adjudication to assure payments are consistent with contract requirements, etc.;
- Part D plan-specific areas (refer to Part D Compliance Section VII.D. for more detail)
    - Transition policy, if applicable;
    - Protected classes policy, if applicable;
    - Utilization management;
    - Operations of FDRs (*See Part D Compliance, Section VII.D.1., Compliance by First Tier, Downstream, and Related Entities and Section VII.D.7., Monitoring PBMs and Pharmacies*);
    - Part D claims processing;
    - Pricing, rebates and other price concessions;
    - Formulary development and Pharmacy & Therapeutics (P&T) Committee (if a formulary is used);
    - FDR oversight and monitoring;
    - CMS payments (PDE and other data submission, comparison to the bid, etc.); and
- Other areas identified through Carolina SeniorCare's Compliance Program risk assessment.

2. Monitoring and auditing for compliance issues shall include, but will not be limited to:

- Review of CMS-Issued Fraud Alerts and Carolina SeniorCare's past paid claims from entities identified in the fraud alerts to determine whether such claims should be removed from its prescription drug event data submissions;

- Maintenance and review of files of in-network and out-of-network providers who have been the subject of complaints, investigations, violations, and prosecutions over the past ten (10) years;

- Engage in regular analysis of data maintained and/or submitted for Carolina SeniorCare's Part D plan. Data will be compiled, sorted, and analyzed to identify any anomalies, outliers, or patterns of aberrant and potentially abusive utilization. (*See Part D Compliance, Section VII.D.2., Data Reporting Compliance*.) Data analysis procedures will be provided to CMS upon request; and

- Review of the OIG Annual Work Plan and related reports to determine priority risk areas.

3. The Compliance Officer may also utilize any of the following methods to monitor and audit risk areas:

- Review of medical records and other related documentation;

- Interviews with employees and/or contractors and on-site observation of activities;

- Review of complaints/reports submitted to the Integrity Hotline 1-800 826-6762;

- Use of objective, independent auditors that are knowledgeable regarding CMS, State and other requirements and not employed in the area under review;

- Sampling and extrapolation;

- On-site visits with contractors, such as home care agencies, transportation providers, medical specialists, pharmacies and PBMs;

- Unannounced "spot checks" or internal audits of Carolina SeniorCare and/or its contractors;

- Review of areas previously found noncompliant to determine if corrective actions are being implemented and have fully addressed the underlying problem; and

- Review of conflict of interest disclosure statement.

4. Carolina SeniorCare will screen all employees, contractors (including FDRs) and members of the Board against the HHS OIG and SAM exclusion lists, and/or any state exclusion lists maintained by state Medicaid programs, at the time of initial hire/contract/appointment/election, and at least monthly thereafter. Employees and contractors found to be excluded will be removed immediately from any work on programs involving Federal Health Care Programs. Board members found to be excluded will be removed from the Board in accordance with the disqualification provisions in the corporate bylaws. Carolina SeniorCare will also screen applicable providers against CMS's preclusion list, state

nurse aide registry and Medicare opt-out list.

The Compliance Officer shall maintain documentation of all exclusion/preclusion checks performed.

B. Audits of the Compliance Program

Audits of the effectiveness of the Compliance Program will occur at least annually. In order to avoid self-policing, the compliance department may not conduct the formal audit of the effectiveness of the Compliance Program. The Compliance Officer may train employees who are not part of the compliance department to perform the audit or outsource the audit to external auditors. In addition to the above, the Compliance Officer shall develop informal audit and monitoring mechanisms to evaluate the effectiveness of the Compliance Program itself, including compliance with Carolina SeniorCare's policies and procedures. Evaluations of the Compliance Program shall include effectiveness of training, use of the Integrity Hotline 1-800 826-6762, completion of audit work plans, effectiveness of internal investigations and disciplinary actions, and how Carolina SeniorCare responds to particular incidents under the Compliance Program. The Compliance Officer will report the results of such informal evaluations and shall present the results of the external audit to the Board of Directors.

C. Monitoring Reports of Suspected Noncompliance

1. Carolina SeniorCare will ensure that any complaints, reports, or concerns are logged and tracked in accordance with Carolina SeniorCare's Compliance Program policies and procedures. The Compliance Officer or his/her designee will address complaints, reports, and concerns regarding noncompliance on an individual basis in accordance with this Compliance Program. (*See Section IX, Responding to Incidents of Noncompliance.*)

2. The *Compliance* Officer or his/her designee will review compliance complaints, reports, and concerns on a quarterly basis to identify any trends or recurring incidents of noncompliance. See Carolina SeniorCare's Complaint Tracking Log. The Compliance Officer, in conjunction with the Compliance Committee, will ensure that any identified systemic problems or recurring incidents of noncompliance are addressed.

D. External Audits

1. If Carolina SeniorCare identifies a serious issue for which external consultation would be appropriate or helpful, the Compliance Officer or his/her designee, will arrange for external audits by independent outside auditors or legal counsel as appropriate. When legal counsel is engaged to conduct the audit or to retain the outside auditors, the Compliance Officer will review the steps necessary to protect any attorney-client privilege and attorney work product. Upon completion of an external audit, the Compliance Officer or his/her designee will provide a written report to the Compliance Committee, Executive Director, EveryAge CEO and Board. Based on a review of the report, the Compliance Officer and the Compliance Committee will recommend and oversee the implementation of any of the following, as necessary to correct identified compliance issues and to deter recurrence of such issues:

- Modification to existing policies and procedures;
- Implementation of new policies and procedures;
- Additional training and education initiatives;
- Disciplinary action;

- Modification or termination of contractual arrangements or other business relationships;

- Report and refund of any overpayments received;

- Report any inaccuracies discovered in data submitted to CMS; and

- Make such other reports as Carolina SeniorCare may deem necessary to contractors and applicable government authorities in accordance with the procedures in *Section IX. B., Self-Reporting*

2. Notice of modifications to the Compliance Program or other policies and procedures will be disseminated to employees and contractors as appropriate. The Compliance Officer or his/her designee may conduct a follow-up audit or review of specific issues or practices to ensure responsive action was appropriate and effective.

VII. KICKBACKS, FALSE CLAIMS, PART D AND OTHER LEGAL REQUIREMENTS

A. Anti-Kickback and False Claims

1. As a recipient of federal funds from the Medicare and Medicaid programs, Carolina SeniorCare is subject to the requirements of various federal and state laws, including laws prohibiting the payment of kickbacks or other remuneration in order to influence Federal Health Care Program business. Specifically, the Anti-Kickback Statute prohibits:

- the knowing and willful solicitation or receipt of any remuneration (direct or indirect, overtly or covertly, in cash or in-kind, including kickbacks, bribes or rebates) in return for a referral for the furnishing of any item or service payable under a Federal Health Care Program; or

- the knowing and willful solicitation or receipt of any remuneration (direct or indirect, overtly or covertly, in cash or in-kind, including kickbacks, bribes or rebates) in return for purchasing, leasing or ordering or recommending purchasing, leasing or ordering, any good, facility, service or item payable under a Federal Health Care Program.

For purpose of Carolina SeniorCare, the Anti-Kickback Statute prohibits conduct such as:

- Payment to any provider for referrals of participants to Carolina SeniorCare;

- A contracted vendor giving Carolina SeniorCare an inducement for a contractual arrangement;

- A pharmaceutical company's payment of a fee to a physician for every prescription the physician writes for that company's drugs; and

- A P&T Committee member accepting a free trip from a pharmaceutical company in exchange for including the company's new drugs on a plan formulary.

2. A violation of the Anti-Kickback Statute and similar federal and state laws may result in significant criminal and civil penalties, including civil monetary penalties and possible exclusion from participation in Medicare and Medicaid.

3. The False Claims Act prohibits knowingly presenting (or causing to be presented) a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement material to a false or fraudulent claim. A "claim" could include PDE and other data submitted to CMS, Carolina SeniorCare's "bid" and all other reports submitted to CMS for the purpose of receiving federal reimbursement. It also requires return of any overpayments within sixty (60) days of identifying the overpayment.

For purpose of Carolina SeniorCare, the False Claims Act prohibits conduct such as:

- Submitting fabricated PDE data to CMS;
- Prescribing a particular drug for which there is no medical necessity;
- Falsifying data or providing misleading data in order to induce a higher reimbursement or capitation rate; and
- Submitting data to CMS or private reinsurer showing actual costs incurred for purposes of reinsurance or other subsidy, when in fact such costs were not incurred.

Submission of a false claim in violation of the False Claims Act and similar federal and state laws could result in significant criminal and civil penalties, including civil monetary penalties plus three times the amount of damages the government sustained because of the false claim, and possible exclusion from participation in Medicare and Medicaid.

4. Any financial or other business arrangements between Carolina SeniorCare and physicians, pharmacies, PBMs, pharmaceutical companies and other health care entities or providers must be structured to comply with all applicable laws and regulations, including the Anti-Kickback Statute and the False Claims Act. If the Compliance Officer or other Carolina SeniorCare personnel have questions regarding whether a proposed business arrangement is in compliance with such laws, legal counsel must be consulted to determine whether the proposed arrangement is acceptable.

5. When Carolina SeniorCare personnel or contractor are in a position to make referrals or recommendations, they must make such referrals based on the best interests of the Participant and the arrangements Carolina SeniorCare has with contracted providers. Carolina SeniorCare personnel and contractors must not receive anything of value in exchange for making a referral or accepting a referral, or for recommending a health care service provider. In addition, Carolina SeniorCare personnel and contractors must not offer anything of value in order to obtain referrals of patients or services covered under a federal Health Care Program.

6. The following activities are specifically prohibited by Carolina SeniorCare, and will not be tolerated:

- Payment to any provider for referrals of participants to Carolina SeniorCare;
- Providing to a vendor or receiving from a vendor any inducement for the provision of Carolina SeniorCare's services;

- Submitting false data to CMS for purposes of obtaining reimbursement (including reinsurance and LICS payments) for items or services not provided as claimed, or other costs not incurred as claimed;

- Submitting data for items or services that are known not to be reasonable and medically necessary;

- Intentionally misrepresenting the type of drug that was actually dispensed (e.g., claiming that a brand-name drug was dispensed when in reality a generic was dispensed); and

- Knowingly submitting data for prescription drugs dispensed to, or obtained by, individuals not eligible for Medicare Part D.

7. Carolina SeniorCare personnel and contractors must be trained periodically on these requirements. The Compliance Officer will monitor the Integrity Hotline 1-800 826-6762 for any allegations regarding kickbacks or false claims.

B. Other Legal Requirements

There are numerous other federal and state laws applicable to Carolina SeniorCare's operations, including the HIPAA Privacy and Security Rules, the Deficit Reduction Act of 2005 ("DRA"), Section 504 of the Rehabilitation Act of 1973, Section 1557 of the Patient Protection and Affordable Care Act and implementing regulations, and other state and federal laws with which Carolina SeniorCare must comply. With regard to DRA compliance, Carolina SeniorCare will disseminate the summary of information on laws concerning false claims to Carolina SeniorCare's employees, contractors, and agents, consistent with Section 6032 of the DRA.

C. Conflict of Interest Disclosures/Attestations

1. Conflict of Interest Questionnaire

All employees, including senior management, with involvement in Carolina SeniorCare's PDP, must complete a questionnaire relating to conflicts of interest upon hire and annually thereafter. This questionnaire will require disclosure of all actual and potential conflicts of interest. Carolina SeniorCare will also ensure compliance with its policy and procedures for disclosing and addressing actual or potential conflicts of interest on the part of the Board, in accordance with §460.68(b) of the PACE program requirements. *See Part D Annual Conflicts of Interest Questionnaire*. This questionnaire will require employees to disclose all actual and potential conflicts of interest.

2. Procedures

(i) The Compliance Officer and Human Resources will review the conflict of interest questionnaires when submitted by new employees, and on an annual basis, to determine whether any actual conflicts of interest exist. When a conflict is identified, the Compliance Officer will determine the appropriate course of action, including (but not limited to) "walling off" the affected individual from any involvement in particular matters.

(ii) If an employee determines that he or she has a conflict of interest regarding a matter under consideration, the individual must inform the Compliance Officer, and refrain from making any decisions, exercising any authority or taking any action with respect to the matter.

(iii) Employees are under a continuing obligation to disclose conflicts of interest as they arise. If an individual's circumstances change after submission of the annual conflicts of interest questionnaire such that a potential or actual conflict later arises, the individual is required to notify the Compliance Officer as soon as possible.

See Conflict of Interest Policy

D. Part D Compliance

1. Compliance by First Tier, Downstream, and Related Entities (FDRs)

(i) Carolina SeniorCare shall determine which of the entities it contracts with are properly classified as FDRs and are therefore required to comply with the provisions of this Compliance Program pertaining to FDRs or Part D Medicare program requirements. Carolina SeniorCare should consider the following factors to evaluate and categorize its third-party contractors as an FDR:

- Functions performed by the delegated entity; such functions may include, but are not limited to:
  - Sales and marketing;
  - Utilization management;
  - Quality improvement;
  - Application processing;
  - Enrollment, disenrollment, membership functions;
  - Claims administration, processing and coverage adjudication;
  - Appeals and grievances;
  - Licensing and credentialing;
  - Pharmacy benefit management;
  - Hotline operations;
  - Customer service;
  - Bid preparation;
  - Outbound enrollment verification;
  - Provider network management;
  - Processing of pharmacy claims at the point of sale;
  - Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs;

- Administration and tracking of Participants' drug benefits, including TrOOP balance and processing;
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs;
- Entities that generate claims data; and
- Health care services.

- Whether the function is something Carolina SeniorCare is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance;
- The extent to which the function directly impacts Participants;
- The extent to which the delegated entity has interaction with Participants, either orally or in writing;
- Whether the delegated entity has access to Participant information or personal health information;
- Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from Carolina SeniorCare;
- The extent to which the function places the delegated entity in a position to commit health care fraud, waste, or abuse; and
- The risk that the entity could harm Participants or otherwise violate Medicare program requirements or commit FWA.

(ii) Carolina SeniorCare will require all FDRs with which it contracts or does business (including PBMs, TPAs and pharmacies) in connection with its PDP to comply with all applicable laws, rules, and regulations, and shall develop procedures to promote and ensure FDR compliance, including a method to demonstrate that FDR employees have received the **Carolina SeniorCare's** Standards of Conduct, Compliance Program, and applicable policies and procedures. Even if Carolina SeniorCare has delegated particular PDP-related tasks to a third party through a contract, Carolina SeniorCare maintains ultimate responsibility for fulfilling the terms and conditions set forth in its contract with CMS, and for complying with all applicable laws and regulations.

(iii) Carolina SeniorCare, via its Compliance Officer, shall have a system in place to monitor FDRs with respect to compliance in its Part D delegated responsibilities and shall be able to demonstrate that the method of monitoring is effective. (*See Tab G: FDR Oversight and Monitoring Risk Assessment Tool*, for a risk assessment tool that can be used as part of this monitoring process.)

(iv) Carolina SeniorCare will screen FDRs against the OIG and SAM exclusion lists, the CMS provider preclusion list and/or any state exclusion lists maintained by state Medicaid programs at the time of contract and at least monthly thereafter. Any party found to be excluded will be removed immediately from any work on programs involving Federal Health

Care Programs and the situation will be assessed to determine whether non-compliance must be reported.

(v) Carolina SeniorCare will make its best efforts to ensure that all agreements with FDRs include provisions indicating that the entity:

- has reviewed Carolina SeniorCare's written standards and policies and procedures as they pertain to FWA;
- agrees to comply with such standards, policies and procedures;
- will require others who provide services to Carolina SeniorCare on behalf of the entity to comply with such standards, policies and procedures;
- will notify Carolina SeniorCare of all subcontractors utilized by the entity;
- represents that it is not on the CMS preclusion list and has not been excluded from participation in Federal Health Care Programs and that it screens employees and contractors against the OIG and SAM exclusion lists and/or any state exclusion lists maintained by state Medicaid programs at the time of hire or contract, and at least monthly thereafter;
- will notify Carolina SeniorCare immediately if it is so excluded from participation; and
- agrees that its contract with Carolina SeniorCare will terminate automatically if it is excluded in the future.

(vi) Carolina SeniorCare shall require FDRs to report immediately to the Compliance Officer any detected errors, possible fraud on the part of beneficiaries, employees or contractors, subcontractors, or outliers, and other relevant matters related to FWA. Carolina SeniorCare will require any contractor found to have violated contractual or regulatory requirements to cooperate with Carolina SeniorCare in implementing additional internal and/or external compliance procedures and cost containment recovery provisions as necessary. Carolina SeniorCare shall require FDRs to correct their deficiencies. (*See Section VII.D.7, Monitoring PBMs and Pharmacies*.)

(vii) Carolina SeniorCare shall maintain documentation of all FDR deficiencies identified and corrective action taken by Carolina SeniorCare and/or each FDR.

2. Data Reporting Compliance

(i) Monitoring and Safeguards

a. To ensure the truth and accuracy of data submitted to CMS, and to identify areas where data collection and submission practices could be improved, Carolina SeniorCare will periodically monitor the following:

- Prescription Data Event ("PDE") information;
- Cost data;

- Diagnoses information reported through Risk Adjustment Processing Data System ("RAPS") and include information submitted via the Encounter Data Reporting System (EDRS);

- Information reported on HPMS;

- Deletion records (generated when a prescription for which a plan has already submitted PDE data is not picked up);

- Data on direct and indirect remuneration;

- Information pertaining to formulary development;

- Enrollment and disenrollment data (submitted through monthly attestations);

- Submission of claims under the appropriate reimbursement program (e.g., Medicare Part B claims vs. Medicare Part D claims); and

- All other information required to be reported, including information about vaccines; generic drug utilization; Pharmacy & Therapeutics Committees (if applicable); formulary exceptions (if applicable); overpayments; pharmaceutical manufacturer rebates, discounts and other price concessions; and long-term care ("LTC") rebates.

Carolina SeniorCare will develop specific guidelines for determining how and with what frequency each of these data elements will be reviewed.

b. Carolina SeniorCare will maintain appropriate safeguards to ensure the accuracy, completeness and truth of all data pertaining to the PACE PDP (including all data listed in (1) above) that is submitted to CMS (or, if a contractor is responsible for collecting, compiling or submitting data on Carolina SeniorCare's behalf, that such contractor maintains appropriate safeguards). Such safeguards may include:

- Systems configurations that detect errors;

- Access to source data (e.g., original prescriptions and claims adjudication data from the pharmacy);

- Monitoring and auditing policies and procedures;

- Periodic review of data collection, compilation and submission practices to determine whether such practices comply with all applicable requirements; and

- Review of any issues identified as a result of monitoring or auditing activities, and any issues identified by CMS, the OIG, or other federal or state agencies with FWA oversight or enforcement authority.

c. If an FDR submits data on Carolina SeniorCare's behalf, Carolina SeniorCare will periodically review such entity's compliance policies, procedures, and other internal controls to ensure that it maintains sufficient mechanisms for monitoring compliance and mitigating risks of FWA.

d. The Compliance Officer will arrange for and conduct (or have conducted and documented) regular, random reviews of data both before and after submission of the data to CMS ("pre-submission review" and post-submission review," respectively). Such reviews may include an evaluation of a representative sampling of claims included in a monthly submission of data (e.g., review of ten (10) prescription claims for ten (10) different PACE Participants), "spot checks" of a particular field or data element (e.g., review of all claims for a particular drug or from a particular prescriber to ensure some measure of consistency), and review of any "outlier" claims (e.g., review of non-NCPDP 5.1 data format claims, above-average dispensing fees, etc.).

- Pre-submission Review

The Compliance Officer will direct any questions regarding apparent discrepancies or errors detected via pre-submission review to the individual(s) or entity(s) responsible for gathering, compiling, recording, and/or submitting the relevant data, and will see to it that necessary clarifications and/or amendments to documentation are made prior to submission. The Compliance Officer will ensure that disciplinary action is taken if appropriate.

- Post-submission Review

The Compliance Officer or his/her designee will conduct random audits of data submitted by Carolina SeniorCare or on its behalf over a specified period of time. Methods will include: (i) comparison of submitted data with original source data; (ii) review of reports sent by CMS to Carolina SeniorCare summarizing PDE and other data; and (iii) comparison of data to previously-established thresholds to identify any outliers.

(ii) Corrective Actions

The Compliance Officer or his/her designee will review any errors or discrepancies detected with the individual(s) or entity(s) responsible to determine what actions are necessary to correct the errors (e.g., submission of revised data, refunding of overpayments, reporting to appropriate government or law enforcement authorities) and prevent reoccurrence.

3. Formulary Development and Monitoring

Carolina SeniorCare does not use a formulary however, if it is decided to choose a formulary the following section details how the formulary will be developed and monitored. If Carolina SeniorCare chooses to use a formulary in the design of its PDP, it will ensure that the formulary meets Medicare requirements. The following provisions apply only to PACE organizations that have adopted formularies (whether through a PBM or on their own).

Carolina SeniorCare will adopt the following procedures to prevent and detect FWA in the development and implementation of its Formulary:

(i) Pharmacy and Therapeutics (P&T) Committee

a. All formularies must be developed and overseen by a Pharmacy and Therapeutics Committee ("P&T Committee"). P&T Committee members must complete and submit a conflict of interest questionnaire disclosing economic and other relationships with entities affected by their decisions regarding the Formulary. Prior to convening the P&T Committee, Carolina SeniorCare will undertake reasonable diligence to confirm the integrity, expertise and qualifications of P&T committee members (including checking such members against the CMS provider preclusion list, OIG List of Excluded Individuals/Entities, the SAM exclusion lists and/or any exclusion lists maintained by state Medicaid programs), and submit a listing of committee members to CMS. The P&T Committee shall meet no less frequently than quarterly, and document any decisions regarding drug coverage in writing.

b. Carolina SeniorCare shall ensure that the PBM provides documentation that the P&T Committee meets the above requirements, including providing a listing of P&T Committee members and copies of their completed conflict of interest questionnaires. If Carolina SeniorCare and the PBM have entered into a confidentiality agreement such that the PBM will not disclose its P&T Committee membership to Carolina SeniorCare, Carolina SeniorCare must notify CMS that the PBM will be submitting the P&T Committee listing on Carolina SeniorCare's behalf. Carolina SeniorCare shall require documentation from the PBM that the P&T Committee listing has been submitted to CMS, as required.

(ii) Formulary Establishment

a. Carolina SeniorCare shall ensure that the Formulary meets the requirements of 42 C.F.R. § 423.120(b).

b. If Carolina SeniorCare contracts with a PBM to develop and administer its Formulary, it will receive assurances from the PBM (contractual or otherwise) that the Formulary meets the regulatory requirements.

(iii) Reporting Rebates and Fees

a. Carolina SeniorCare PDP will report to CMS on a quarterly basis all costs it has actually paid to provide prescription drug benefits to PACE Participants. "Actually paid" means that the costs must have been incurred by Carolina SeniorCare PDP, net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) received from any source (including manufacturers, PBMs and pharmacies) that serves to decrease the costs incurred by Carolina SeniorCare PDP for drugs. If Carolina SeniorCare contracts with a PBM, it will report the portion of any such rebates passed along to Carolina SeniorCare PDP by the PBM (but not all rebates received by the PBM itself), as required. (*See Section VII.D.7, Monitoring PBMs and Pharmacies*.)

b. The Compliance Officer or his/her designee will be alerted to any arrangement whereby Carolina SeniorCare PDP receives price concessions, rebates or other discounts in exchange for including particular manufacturers' drugs on its Formulary. To the extent a PBM is responsible for Formulary decisions, the contract with the PBM shall require the PBM to identify all price

concessions, rebates or other discounts it will pass along to the PDP and (if the PBM submits data to CMS on behalf of Carolina SeniorCare PDP), report such information to CMS.

4. Price Concession Generally

The Compliance Officer will be alerted to any arrangement whereby Carolina SeniorCare PDP receives price concessions, rebates or other discounts for drugs generally, even if not in connection with formularies, so proper documentation is maintained and the concessions are reported, if required.

5. Monitoring Participant FWA

Carolina SeniorCare will monitor the utilization patterns of PACE Participants to ensure Participants, or Participants' family members, are not improperly using or seeking to obtain prescription drugs. Carolina SeniorCare will periodically review Participant complaints and grievances for indications of possible Participant fraud, and shall follow the additional procedures outlined in this section to meet these responsibilities.

(i) Establishing Baseline Data

Carolina SeniorCare will obtain utilization data of its PDP and compile it in a manner that outlines the normal range of utilization, number and types of prescriptions, average number of prescriptions per PACE Participant and per prescriber, and other baseline data as Carolina SeniorCare may need for use as a benchmark for comparing subsequent periods. Carolina SeniorCare will compare subsequent data with baseline data to track prescribing and utilization patterns over time and identify aberrant and potentially abusive utilization. Carolina SeniorCare also will review available resources, such as National Association of Boards of Pharmacy's ("NABP") National Specified List of Susceptible Products (drugs determined to be susceptible to adulteration, counterfeiting or diversion) to identify particular drugs that should be monitored for possible abuse.

Carolina SeniorCare will update and redefine baseline data as appropriate to allow for meaningful comparisons over time.

(ii) Integration into Participant Care Management Process

a. Carolina SeniorCare's initial assessment of a Participant will include a review of the Participant's prescription drug history and family situation, and identification of the appropriate pharmaceutical therapy in the plan of care.

b. During periodic reassessments, Participants' prescription drug records will be analyzed, and any changes to pharmaceutical therapies or drugs prescribed (including switches from brand-name-drugs to generics) will be examined to confirm that the changes are appropriate for the Participant's condition.

c. The Participant's [primary care provider/Pharm.D./pharmacist] will be responsible for monitoring drug-drug interactions and drug changes, but the interdisciplinary team also must regularly review a Participant's drug records and highlight any inconsistencies or potential overutilization.

d. Carolina SeniorCare's social workers, home health care providers and other staff members or contractors with regular contact with Participants'

families will report to a member of the interdisciplinary team any observations or suspicions suggesting Participants' family members may be engaged in any improper drug-seeking behavior or other conduct leading to increased utilization. The interdisciplinary team will assess the report as part of the care management process. Clear instances of improper drug-seeking behavior on the part of Participants or family members shall be immediately reported to the Compliance Officer. All affected staff members and contractors, including FDRs, are required to receive training on these requirements.

e. The interdisciplinary team shall report conduct suggesting improper utilization or potential fraud or abuse on the part of Participants or Participants' families to the Compliance Officer, who promptly will investigate the situation.

(iii) Prescription Drug Event Data and Overutilization Review

a. Carolina SeniorCare is required to report prescription drug event (PDE) data to CMS on a regular basis (at least once a month). On a periodic basis, the Compliance Officer or his/her designee will review the PDE data (and the benchmark data compiled as noted in Section VII.D.2. above) as well as reports from the Medicare Part D Overutilization Monitoring System to monitor for potential Participant FWA by looking at, among other factors, the following:

- Significant outliers (i.e., Participants whose drug utilization patterns far exceed those of the average PACE Participant, in terms of cost or quantity);

- Disproportionate utilization of controlled substances for individuals or groups; and

- Use of prescription medications for excessive periods of time (e.g., multiple refills for drugs commonly prescribed for short-term pain, prescriptions refilled prior to the end of the 30- or 90-day prescription, etc.).

b. To the extent specialized knowledge is required to determine aberrations in any of the above, the Compliance Officer may call on the pharmacist, members of the P&T Committee or the PBM for assistance in this review. The Compliance Officer will investigate any potential FWA issues revealed through this review by discussing the Participant's condition with the participant's primary care provider or interdisciplinary team, as appropriate, reviewing the source data for the PDE (actual prescriptions, etc.), and discussing prescription drug utilization with the Participant (if appropriate).

(iv) Reporting Participant FWA

If after the investigation, the Compliance Officer determines that a Participant or a Participant's family member has engaged in improper drug-seeking behavior or other conduct potentially leading to FWA, the Compliance Officer will report the instance to the Carolina SeniorCare's MEDIC. The Compliance Officer and other affected staff members will cooperate, and Carolina SeniorCare's contracts with FDRs shall require such entities to cooperate, with any MEDIC investigation, in accordance with Section X. Cooperating with Government Investigations. The Compliance Officer will document the results of the investigation and the referral to the MEDIC in the Participant's medical record. Carolina SeniorCare will not disenroll a PACE

Participant for improper drug utilization unless the Participant has been counseled by Carolina SeniorCare regarding such behavior, and he or she continues to refuse to comply.

6. Monitoring Prescriber FWA

Carolina SeniorCare will track and monitor prescribing patterns to guard against FWA on the part of prescribers. Aberrations or unwarranted changes in a prescriber's prescribing patterns may indicate that other factors (such as pharmaceutical company marketing efforts or the fact of Part D payment) have influenced the prescriber's medical judgment. To guard against such conduct, Carolina SeniorCare PDP will follow the procedures outlined below.

(i) Establishing Baseline Data

Carolina SeniorCare will obtain utilization data of its PDP and compile it as necessary to outline the normal range of utilization, number and types of prescriptions, average number of prescriptions per PACE Participant and per prescriber, and other baseline data that Carolina SeniorCare may need to use as a benchmark for comparing subsequent periods. Carolina SeniorCare will compare subsequent data with baseline data to track prescribing patterns over time and identify aberrant and potentially abusive utilization. Carolina SeniorCare also will review available resources, such as the NABP's National Specified List of Susceptible Products (drugs determined to be susceptible to adulteration, counterfeiting or diversion) to identify particular drugs that should be monitored for possible abuse. Carolina SeniorCare will update and redefine baseline data as appropriate to allow for meaningful comparisons over time.

(ii) Procedures

a. Carolina SeniorCare will consult with its Pharm.D, pharmacist or other professionals involved in pharmaceutical therapy management about any anomalies in prescribing patterns indicating possible fraud or abuse (such as sudden switches to a particular company's drug without therapeutic justification, significantly increased numbers of prescriptions or prescriptions for drugs on the National List of Susceptible Products). The Pharm.D or pharmacist will notify the Compliance Officer or his/her designee if prescribing patterns suggest a prescriber may be engaged in fraud or abuse.

b. The PDE data compiled and submitted by the PACE PDP (or by a PBM or other third-party submitter on the PDP's behalf) will be reviewed periodically by the Compliance Officer or other designated individual in accordance with *Section VII.D.2. Data Reporting Compliance*. Such data will be sorted by prescriber and compared against benchmark data and other resources. The Compliance Officer will review the data for anomalies such as:

- High-volume prescribing of a particular manufacturer's drugs or of drugs particularly susceptible to addiction or abuse;
- Excessive prescriptions for off-label uses; and/or
- Physicians who prescribe more controlled substances than other physicians.

c. If the Compliance Officer identifies outliers or anomalies that he or she believes may suggest improper prescribing patterns, the Compliance Officer may consult with Carolina SeniorCare's consulting pharmacist, Pharm.D, Medical Director or others to determine whether there may be therapeutic reasons for the

prescribing pattern. If the Compliance Officer discovers clear evidence that a prescriber is engaged in fraudulent or abusive conduct with respect to prescription drugs, he or she will report the instance to Carolina SeniorCare's MEDIC. The Compliance Officer and other affected staff members will cooperate, and Carolina SeniorCare will require FDRs to cooperate, with any MEDIC investigation, in accordance with *Section X. Cooperating with Government Investigations*.

d. All prescribers who write prescriptions for PACE Participants will be checked against the OIG List of Excluded Individuals/Entities, the GSA Excluded Parties Listing System, the CMS Preclusion List, and/or any state exclusion lists maintained by state Medicaid programs on an annual basis. Carolina SeniorCare PDP shall not pay for medications prescribed by excluded providers.

7. Monitoring PBMs and Pharmacies

If Carolina SeniorCare has delegated any of its responsibilities as a PDP sponsor to a PBM or a pharmacy, Carolina SeniorCare must monitor those entities and must obtain adequate contractual assurances that both PBMs and pharmacies will comply with all applicable laws. Carolina SeniorCare also will obtain, when possible, contractual provisions requiring PBMs or pharmacies to indemnify Carolina SeniorCare for any harm resulting from the PBM's/pharmacy's failure to comply with legal requirements.

All PBMs and pharmacies with which Carolina SeniorCare contracts will be checked against the CMS Preclusion List, the OIG List of Excluded Individuals/Entities, the GSA Excluded Parties Listing System and/or any state exclusion lists maintained by state Medicaid programs, at the time of contract and monthly thereafter. *See Section VII.D.1, Compliance by First Tier, Downstream, and Related Entities*.

(i) Monitoring PBMs

a. Through its contract or otherwise, Carolina SeniorCare will ensure that the PBM meets the following requirements relating to auditing and compliance:

- PBM shall provide access to all facilities and records associated in any manner with Carolina SeniorCare's PDP for ten (10) years from the end of the final contract period. Access shall be provided to any government auditor, agency or contractor acting on behalf of the federal government to conduct an onsite audit (including, but not limited to, CMS, OIG and the MEDIC), as well as to a designated representative of Carolina SeniorCare for purposes of monitoring compliance.

- PBM shall report all instances of potential or actual fraud identified in the PACE PDP and all complaints received by the PBM alleging or demonstrating potential fraud to the Compliance Officer or his/her designee at Carolina SeniorCare.

- PBM shall furnish all information (including claims data) requested from Carolina SeniorCare to respond to the MEDIC or other government auditors within twenty (20) days of the request, unless

Carolina SeniorCare must receive the information under a more immediate timeframe.

- PBM and Carolina SeniorCare will establish a coordinated reporting structure whereby PBM and Carolina SeniorCare regularly communicate regarding any FWA concerns, active internal investigations, outliers, and other matters. PBM should designate a contact person responsible for FWA issues, and the Compliance Officer or his/her designee at Carolina SeniorCare should speak regularly with the PBM contact.

- Carolina SeniorCare will conduct regular audits of PBM's performance through "spot checks" of the data submitted to CMS; comparison of data to actual drug claims; reviewing PBM's efforts to distinguish between Part B and Part D drugs; and auditing PBM's compliance with other Part D requirements.

Even if all of the above requirements are specifically set forth in the PBM agreement, the contract between the PBM and Carolina SeniorCare at the least must contain provisions relating to the following:

- PBM must have an effective compliance program in its own right, and must provide information about that compliance program to Carolina SeniorCare on request;

- The PBM must allow Carolina SeniorCare to conduct ongoing audits to ensure PBM is meeting all applicable Part D requirements;

- PBM must agree to implement cost containment and recovery measures to make Carolina SeniorCare and/or CMS whole in the event there are infractions or errors by PBM in meeting contractual obligations;

- To the extent PBM has negotiated rebates or other discounts with pharmaceutical manufacturers or other entities, the contract must specify which portion of those rebates will be passed on to Carolina SeniorCare; and

- The contract must allow termination by Carolina SeniorCare in the event the PBM's right to provide services under Part D is revoked by CMS.

b. Carolina SeniorCare will exercise any audit rights it has under the contract and consider retaining a third-party auditor if Carolina SeniorCare has any concerns regarding PBM's performance. Audits will be conducted regularly, and the frequency of the audits should be determined and agreed to at the inception of the agreement. Carolina SeniorCare's audit rights will extend to any subcontractor or affiliate performing services for PBM relating to the PACE PDP. Carolina SeniorCare may also seek indemnification from the PBM for any FWA occurring as a result of the PBM's actions or inaction. All audits of PBMs will be documented.

c. To the extent Carolina SeniorCare's auditing and monitoring activities identify any potential FWA on the part of the PBM, such FWA shall be reported and handled in accordance with Carolina SeniorCare policy and Medicare requirements. (*See Section IX, Responding to Incidents of Non-Compliance*.)

(ii) Monitoring Pharmacies

a. Carolina SeniorCare shall monitor the pharmacy (ies) it has contracted to provide prescription drug benefits to PACE Participants to ensure the PACE pharmacy is complying with all applicable Part D requirements. In particular, Carolina SeniorCare shall monitor to ensure the following:

- Pharmacy must bill for name-brand drugs only when a name-brand drug is dispensed;
- If a prescription is a "partial fill," Pharmacy must not bill for the complete fill amount (i.e., billing for a 30-day prescription when only 28 tablets are dispensed);
- Pharmacy must accurately credit the PACE PDP for returned prescriptions and for prescriptions that are never picked up (e.g., prescriptions left in the "will-call" bin at the pharmacy) or delivered;
- Pharmacy shall not solicit or receive payment from pharmaceutical companies or others for effecting drug switches;
- Pharmacy may not bill for expired drugs, drug samples, or drugs diverted from other locations (e.g., nursing homes, hospitals, etc.);
- Pharmacy's dispensing fees must be reasonable and in accordance with any applicable contracts;
- Pharmacy must have sufficient inventory controls to prevent theft or spoilage of prescription drugs, and controls relating to drug pedigree to ensure only drugs from valid sources are dispensed to PACE Participants; and
- Pharmacy must have standards and protocols to ensure quality of care (monitoring of drug-drug interactions, drug utilization, etc.).

b. To the extent Carolina SeniorCare contracts directly with pharmacy (ies), the contract should allow Carolina SeniorCare to audit the pharmacy for compliance regularly, whether through on-site audits, requests for reports or other means. In addition, Carolina SeniorCare will:

- Regularly review PDE data submitted to CMS and compare it to the actual claims data to confirm accuracy and completeness;
- Review any Participant complaints or grievances relating to prescription drugs to ensure Participants are receiving the prescription drugs prescribed for them; and

- On a periodic basis, conduct "spot checks" and compare the prescription issued to the Participant, the prescription drug claim that was processed by the pharmacy, and the PDE data that was submitted to CMS.

c. To the extent Carolina SeniorCare's auditing and monitoring activities identify any potential FWA on the part of a pharmacy, such FWA shall be reported and handled in accordance with Carolina SeniorCare policy and Medicare requirements. (*See Section IX, Responding to Incidents of Non-Compliance*.)

(iii) Monitoring Third-Party Submitters

a. To the extent a PBM, pharmacy or other third-party compiles and submits PDE or other data to CMS on Carolina SeniorCare's behalf, Carolina SeniorCare will ensure, through its contract or otherwise, that the third party meets the following requirements relating to compliance:

- The third-party submitter must certify to CMS regarding the accuracy, completeness and truthfulness of the data and acknowledge that it is being submitted on behalf of Carolina SeniorCare's PDP for purposes of obtaining federal reimbursement.

- The third-party submitter must have the capability to maintain audit trails that link the submitted data to the source data (i.e., individual claims transactions).

- The third-party submitter must allow Carolina SeniorCare to monitor the accuracy of the data it submits by any reasonable mechanism (conducting "spot checks," comparison to reports received back from CMS, etc.).

b. To the extent Carolina SeniorCare's auditing and monitoring activities identify any potential FWA on the part of a third-party submitter, such FWA shall be reported and handled in accordance with Carolina SeniorCare policy. *See Section IX, Responding to Incidents of Non-Compliance*.

VIII. INTERNAL REPORTING OF WRONGDOING

A. Duty to Report Actual or Suspected Violations

Each employee, each member of the Board, each contractor, and each of such contractor's employees shall immediately report any suspected violations of the Standards of Conduct, the Compliance Program, and any laws or regulations. The individual making such report may do so anonymously if he/she chooses. To the extent feasible, all communications shall be kept confidential. Carolina SeniorCare shall not tolerate intimidation of or retaliation against any person making such report of suspected violations. Under no circumstances will an employee, contractor, contractor employee, or Board member be discharged, demoted, suspended, threatened, harassed or in any manner discriminated against for reporting in good faith any actual or suspected violation of the Standards of Conduct or applicable laws or regulations.

B. Reporting the Actual or Suspected Violations

An employee must report the actual or suspected violation to his/her manager, the Compliance Officer**]**, a member of the Compliance Committee or the Integrity Hotline 1-800 826-6762. Board members must report actual or suspected violations to the Compliance Officer, a member of the Compliance Committee or the Integrity Hotline 1-800 826-6762.

C. Contractor Reporting

Contractors and their employees are expected to report actual or suspected wrongdoing to the Compliance Officer. This obligation will be included in a written agreement with the contractor as appropriate. The Compliance Officer, with assistance from the Compliance Committee, shall widely publicize and ensure that contractor and their employees are made aware of the Compliance Line and of the obligation to report actual or suspected wrongdoing.

D. Compliance System

The Compliance Officer, with assistance from the Compliance Committee, shall establish and maintain a system to receive, record, respond to, and track compliance question or reports from employees, members of the Board, contractors, and contractors' employees. This system shall allow for anonymous, confidential reporting and shall emphasize policies of non-retaliation and non-intimidation for persons making reports of suspected or actual compliance violations.

1. Integrity Hotline [1.800.826.6762]

The Compliance Officer, with assistance from the Compliance Committee, shall establish and maintain a telephone line for receiving reports of potential violations, which may be anonymous (the "Integrity Hotline"). To the extent feasible, all calls to the Compliance Line shall be kept confidential. The Integrity Hotline shall be accessible 24 hours a day, 7 days a week, 365 days a year.

2. Guidelines

The Compliance Officer shall develop appropriate guidelines for operation of the Compliance Line, which shall address procedures for receiving and logging calls, follow-up and response to calls and confidentiality safeguards.

3. Reporting

The Compliance Officer shall make regular reports to the Compliance Committee, the Board, and other senior management on the reporting system, including the number of calls received and the status and disposition of any resulting investigations.

4. Compliance Officer Accessibility

The Compliance Officer shall maintain an "open door" policy for questions and concerns that employees, contractors, or Board members may have concerning adherence to legal standards and organizational policies.

5. Documentation of Questions

The Compliance Officer shall document all compliance questions raised other than through the Compliance Line, including the nature of the question raised and how it was answered/resolved.

IX. RESPONDING TO INCIDENTS OF NONCOMPLIANCE

The Compliance Officer or his/her designee shall be responsible for promptly responding to incidents of noncompliance, including violations Carolina SeniorCare's Compliance Program, Carolina SeniorCare policies and procedures, applicable federal and state laws and PACE program requirements, and for developing appropriate corrective action initiatives relating to such offenses.

A. Internal Investigations

1. Commencement of Investigation

The Compliance Officer or his/her designee will review all identified potential compliance problems to determine the severity of the potential violation and the extent of further investigation deemed necessary, if any. The appropriate response will be determined based on the nature and severity of the potential violation. Investigative techniques may include:

- Interviews with persons who report, witness, or have knowledge or information regarding a potential violation. To the extent reasonably practicable, interviews will take place in private and will be conducted in as confidential a manner as possible;
- Review of relevant documents (e.g., contracts, claims, reports, clinical documentation);
- Review of applicable policies and procedures; and
- Consultation with legal counsel.

The Compliance Officer coordinates investigations and works with the EveryAge Chief Quality and Compliance Officer and other members of the Compliance Committee, to investigate compliance violations as promptly as possible, and no later than two weeks of receiving the initial complaint or report. If the Compliance Officer has a potential or actual conflict of interest or is otherwise not available to conduct a prompt investigation, the EveryAge Chief Quality and Compliance Officer will conduct the investigation.

2. Responsibilities/Procedures

Based on the severity of the potential violation, it may be determined that further internal investigation is appropriate and/or necessary. The depth of the internal investigation will depend on the nature and extent of the potential violation; not all instances of potential compliance problems identified may merit further internal investigation. Prior to commencing an internal investigation, the Compliance Officer, EveryAge Chief Quality and Compliance Officer, and/or Chief Human Resources Officer shall consult with the Executive Director and Compliance Committee, as appropriate, to:

- Identify and assemble the investigative team;
- Establish the lines of responsibility, supervision and reporting;
- Define the factual and legal issues to be resolved;

- Determine whether the organization should engage legal counsel and/or consultants to conduct the investigation and review the steps necessary to protect the attorney-client and work product privilege; and

- Implement mechanisms to ensure that relevant documents are not destroyed and to ensure the comprehensiveness, integrity and control of all documents collected during the investigation.

The Chief Human Resources Officer should be consulted/involved in any investigation to ensure consistency with employment policies and procedures.

In conducting the internal investigation, the Compliance Officer shall ensure that the investigative team follows the following guidelines and procedures. These general guidelines are utilized when investigating reports of potential compliance violations. The guidelines may need to be altered for cases which are reported anonymously or through an integrity hotline, or as otherwise deemed appropriate. The extent of the investigation will vary depending upon the issues and circumstances.

- Interview the complainant as soon as possible after the report of the alleged violation. Interviews can be held over the telephone or in person and should be private and confidential. Encourage the complainant to disclose all facts and other relevant information regarding this or any other alleged violation. If appropriate, request a signed written summary of his/her complaint. Remind the complainant that the organization will not tolerate any form of retaliation for having made the complaint, and that the complainant should immediately report any retaliation or threatened retaliation to the Compliance Officer or to the Human Resources department. Even if the Complainant states that he/she does not want anyone to "get in trouble," or does not want an investigation to occur, the investigator should explain to the complainant that the organization has a legal responsibility to investigate any allegation that is other than trivial.

- Interview and/or request written statements from any witnesses or other persons with knowledge regarding the alleged violation, which based on the circumstances may include residents, vendors and other providers, as appropriate. Interviews should take place in as confidential manner as possible. Explain to the witnesses that the organization will not tolerate any form of retaliation for having participated in the investigation, and that the witness should immediately report any retaliation or threatened retaliation to the Compliance Officer or to the Human Resources department. Encourage the witnesses to disclose all facts and relevant information to enable the organization to make an informed decision. Non-employee witnesses should not be compelled to talk. When appropriate, witnesses who are employees should be required to submit a written statement. Refusal by an employee to cooperate with an investigation will be subject to disciplinary action up to and including termination. Carefully document interviews. If no witnesses are named, the Compliance Officer should make a determination as to whether the scope of the investigation should be broadened. The Compliance Officer also should make a determination as to whether it is appropriate at that time to refer the matter to a criminal and/or civil law enforcement agency. The Compliance Officer shall document all interviews conducted and maintain copies and/or a log of all pertinent documents reviewed.

- Investigate the alleged compliance violation in a confidential manner. Explain to those being interviewed or being asked to submit written statements that a complaint has been made concerning a possible compliance violation, and that no conclusions or decisions have been made by the organization. Advise any personnel involved in the investigation that disciplinary action up to and including termination will occur if he/she is not truthful or makes any material omissions. Carefully document interviews and/or obtain written statements.

- Make an initial determination as to whether the alleged compliance violation occurred, and the appropriate disciplinary action that should result if an employee is involved in the compliance violation.

3. Presentation of Findings

Upon completion of the internal investigation, the Compliance Officer shall present the findings of the investigation to the Compliance Committee, the Executive Director and other senior management, and the Board of Directors, as appropriate.

The Compliance Officer shall consult with outside counsel if involved, on the appropriate means of documenting the findings of any internal investigation and on guidelines to follow in the event a written report is prepared.

4. Response to Findings of Internal Investigation

The Compliance Offer will review the findings of the investigation with the Chief Human Resources Officer. If the Chief Human Resources Officer agrees that a violation has occurred after reviewing the Compliance Officer's investigation, he/she should make a final determination as to appropriate discipline. If a senior manager has engaged in a compliance violation, the Compliance Officer may elect to refer final authority on the appropriate discipline to the President and CEO or the Board of Directors.

For significant compliance infractions, the Compliance Committee shall include the Executive Director, President and CEO, Board, and other senior management in determining what action should be taken in response.

If the investigation indicates that illegal or unethical conduct has occurred, at a minimum, the Compliance Committee must:

- Ensure that the conduct is stopped and institute any corrective action necessary (*See Section IX.C., below*);

- Work with human resources to discipline personnel involved;

- Institute appropriate measures to ensure that the conduct does not reoccur (e.g., revise policies and procedures or deploy additional auditing mechanisms);

- As further detailed in Section IX.B below, determine, in consultation with legal counsel, whether the incident should be reported to the government, whether any refunds should be made to the government or a third-party payor and whether other notices or disclosure are required;

- Review the effectiveness of the Compliance Program and procedures in light of the incident and make recommendations to the Board as appropriate concerning any necessary modifications to the Compliance Program; and

- If a complainant is involved, report to the complainant that the complaint was investigated, that findings were made and that appropriate action was taken in response. The communication should emphasize the organization's anti-retaliation policy.

5. Documentation of Investigation

The Compliance Officer, in consultation with any outside counsel involved, shall ensure that an appropriate record is maintained of the internal investigation (*e.g.*, description of matter investigated, activities undertaken, log of persons interviewed, and documents reviewed, results of investigations, disciplinary and corrective action taken).

B. Self-Reporting

The determination of whether to report the results of an investigation to government authorities depends on the circumstances and nature of the particular incident. Likewise, the method of self-reporting will depend on the type of non-compliance at issue.

Incidents of criminal misconduct should be reported to appropriate law enforcement authorities. Incidents of significant Medicare program noncompliance should be reported to CMS, and the SAA, as appropriate, as soon as possible after their discovery.

Carolina SeniorCare will consider, in consultation with counsel, whether fraudulent conduct or overpayments should be reported to other government authorities, such as the Office of the Inspector General (through the Self-Disclosed Protocol) or the Department of Justice.

With regard to non-compliance concerning FWA associated with the PACE PDP in particular, if a preliminary investigation uncovers potential fraud or abuse in the following areas, Carolina SeniorCare will report the matter promptly to MEDIC:

- Suspected, detected or reported criminal, civil, or administrative law violations;

- Allegations that extend beyond the PDP involving multiple health plans, multiple states, or widespread schemes.

- Allegations involving known patterns of fraud; and

- Pattern of fraud or abuse threatening the life or well-being of beneficiaries.

- A scheme with large financial risk to the Medicare program or Participant.

If a determination is made to refer an incident of noncompliance to the MEDIC, the Compliance Officer or his/her designee will develop a referral package that meets the requirements of Sections 50.7.3 through 50.7.5, Chapter 9 of the CMS Prescription Drug Benefit Manual/Chapter 21 of the CMS Medicare Managed Care Manual and will document all referrals to the MEDIC in accordance with CMS instructions.

Lastly, Carolina SeniorCare shall consider reporting instances of regulatory non-compliance to its CMS account manager and SAA. If non-compliance occurring during an audit

review period is reported, corrected and risk to participants was mitigated, CMS will not apply the ICAR condition classification to that condition on a subsequent audit.

The Compliance Officer and the Board of Directors/Executive Director, with assistance from legal counsel as appropriate, shall act promptly to ensure that any self-report is made within a reasonable period of time from when it was determined that a violation may have occurred.

C. Corrective Action

1. As soon as practicable after completion of an investigation, the Compliance Officer will establish a corrective action plan if appropriate and will set deadlines by which the prescribed corrective action must be taken. The Compliance Officer shall involve the Executive Director, members of the Compliance Committee other senior management, President and CEO, legal counsel, and/or auditors, as appropriate. Depending on the nature of the particular compliance problem, corrective action may include the following:

- Disciplinary action, as prescribed by the Compliance Officer and human resources, and the individual's immediate supervisor (in accordance with Carolina SeniorCare's personnel policies and procedures and/or any applicable contractual requirements);
- Mandatory education and training;
- Modification of existing policies and procedures and/or implementation of new policies and procedures;
- Correction of erroneous data;
- Refunding any overpayment received;
- Focused reviews for individual departments and/or employees to ensure that the prescribed corrective action is being followed and is effective;
- Termination or suspension of any applicable contracts; and
- Self-reporting to government authorities, in accordance with this policy.

2. The Compliance Officer will monitor corrective actions after implementation to be sure that the plan is effective at remedying the problem identified.

D. Documentation

1. The Compliance Officer or his/her designee will maintain a record of all investigations, including:

- All relevant facts and information concerning the reported compliance problem;
- A summary of the investigation process;
- Interview notes and copies of key documents;

- A list of individuals interviewed, and documents reviewed;
- The results of the investigation, including any disciplinary action taken; and
- The prescribed corrective action plan.

2. Carolina SeniorCare will maintain such records for a minimum of ten (10) years. Under no circumstances should such records be distributed or released outside of the organization by anyone other than legal counsel. Access to such records by individuals within the organization shall be limited to the Compliance Officer, the Compliance Committee, the Executive Director, the Board, and legal counsel. Any documents or information protected by the attorney/client privilege will be treated as such.

X. COOPERATING WITH GOVERNMENT INVESTIGATIONS

Carolina SeniorCare will cooperate with CMS, MEDICs, the SAA, and other government auditors and law enforcement agencies.

A. Procedures

1. Carolina SeniorCare employees must notify the Compliance Officer or his/her designee immediately upon being contacted by a law enforcement officer or government agent regarding Carolina SeniorCare's business. Any employee served with an OIG or Grand Jury subpoena, summons, court order or complaint in connection with Carolina SeniorCare business should contact the Compliance Officer or his/her designee immediately and provide him or her with copies of the served documents.

2. The Board, Executive Director, and other senior management shall be notified of all governmental compliance enforcement activity from Notices of Non-compliance to formal enforcement actions.

3. Carolina SeniorCare will provide the MEDIC, CMS, the SAA, and law enforcement with any requested information, including claims data, within thirty (30) days from the date of the request, unless some other timeline is specified. Carolina SeniorCare will allow access to any government auditor acting on behalf of the federal or state government, CMS or the SAA to conduct an audit at the facilities of Carolina SeniorCare or any of its FDRs. To the extent the information requested is maintained by a contractor, the Compliance Officer or his/her designee will contact such party immediately and invoke any contractual rights to require it to provide the requested information in the necessary timeframe.

4. Carolina SeniorCare shall comply with requests by law enforcement, CMS, or the SAA regarding monitoring of providers within Carolina SeniorCare's network that CMS has identified as potentially abusive or fraudulent.

5. In the event Carolina SeniorCare refers a case to the MEDIC in accordance with Section IX, Responding to Incidents of Noncompliance, the Compliance Officer or his or her designee will track all aspects of the case as specified by the MEDIC and will provide updates to the MEDIC as needed.

6. Carolina SeniorCare will respond to specific government requests for information as follows:

a. <u>Search warrants</u>

If a law enforcement officer or government official/investigator arrives to conduct a search on Carolina SeniorCare property with a warrant, the Executive Director or the highest-level manager on duty should review the warrant to verify the scope and location of the search.

As soon as possible, the Executive Director must be advised of the nature and scope of the search warrant. The Executive Director will notify the EveryAge President and CEO, Chief Operating Officer, Chief Quality and Compliance Officer and Chief Financial Officer immediately.

Request an investigator who is on the organization's premises to wait until the arrival either of an Executive Director, Chief Operating Officer, Chief Financial Officer, Chief Quality and Compliance Officer or Corporate Risk Manager. (One will be designated as the employee in charge).

The following guidelines should be followed closely and will be led by the employee in charge:

- Do not interfere with the search. If the investigator(s) present a search warrant, the investigators have the authority to enter private premises, search for evidence of criminal activity, and seize those documents listed in the warrant.
- Get the name of the lead agent, the agency for which he or she works, address, telephone number, business cards and reason for the visit. List the names and positions of all investigators with date and time.
- Request a copy of the search warrant and the affidavit providing reasons for the issuance of the warrant. Note the areas the agents can search and the items they can seize. If the agents begin to search places or seize items not identified in the search warrant, bring it to the lead agent's attention.
- Staff should request an opportunity to consult with the organization's legal counsel before the search commences. Provide a copy of the warrant to legal counsel immediately. If counsel can be reached by phone, put counsel directly in touch with lead investigator.
- Cooperate with investigators, **but do not consent to the search**
- The employee in charge should instruct the lead investigator that the organization objects to the search; the search is unjustified because the organization is willing to voluntarily cooperate with the government and the search violates the rights of the organization and its employees.
- Under no circumstances should staff obstruct or interfere with the search. Employees must not alter remove or destroy permanent documents or records of the organization. Once there is a notice of an investigation, the destruction portion of any policy on record retention is suspended.
- Identify attorney-client and other privileged information. The agents are permitted to seize this information but should keep it segregated.
- Request permission to have an employee accompany agents to monitor the search. Tell these employees not to make any substantive statements to the agents. Have employees take notes on the following:
    - areas searched;
    - documents or items seized;

- questions asked by agents; and
- names of employees interviewed by agents.

- The agents may detain all persons on the premises while the warrant is being executed. Ask permission to send nonessential employees home. If permission is granted, advise employees to take home only personal possessions and not to take any company documents or files with them, including electronic files. Advise employees who do leave that they will be contacted regarding when to return to work or that they should contact a designated individual at a certain time and date to find out when to return to work.
- Develop an employee announcement to advise employees that the premises are being searched pursuant to a search warrant, the company is cooperating with officials executing the warrant, and employees are not to interfere with the search.
- Explain rights to employees:
- Employees have the right not to be interviewed by the government. It is the individual's choice whether or not he or she agrees to be interviewed. If employees agree to be interviewed, they can have counsel to represent them at the interviews.
- Advise employees that they may be contacted at home by government agents and that the same rights to be interviewed or to decline apply there as well. Also advise employees that even if they choose not to be interviewed, they could still be subpoenaed to testify before a grand jury.
- The company should not instruct employees to decline to be interviewed. That choice belongs fully to each employee.
- The company should determine whether it is willing to pay for representation of its employees. If so, it should inform employees.
- Have employees inform the company if they have been contacted by a government agent, been interviewed, or received a grand jury subpoena.
- Provide a name and telephone number of a company representative employees can contact if they have questions.
- Get a "receipt" for items seized from the officials conducting the search.
- If possible, videotape the search. A videotape may provide evidence of undue disruption or misconduct on the part of the investigators. If the investigators claim the taping interferes with the search, the employee in charge should make a record of the refusal. Do not persist if the agents have warned that they regard the taping as an interference.

b. <u>Service of Subpoenas</u>

If Carolina SeniorCare is served with an OIG, Grand Jury or other government subpoena, the Compliance Officer will be notified immediately, and will proceed in accordance with the following guidelines:

- The Compliance Officer will contact legal counsel immediately, who will attempt to contact the government, clarify the scope of the subpoena and establish a timeframe for responding.

- Carolina SeniorCare should identify a records custodian who will be responsible for producing the documents and maintaining a log and copies of documents provided to the government. The custodian must be someone who is prepared to testify under oath about the steps taken to gather the information called for in the subpoena.

- The Compliance Officer will issue a directive to employees that a subpoena has been served, instructing employees not to discuss the subpoena or any other aspect of the investigation with other employees or anyone else.

The service of an OIG, Grand Jury or other government subpoena will trigger an immediate investigation by the Compliance Officer.

c. Law enforcement interviews with Carolina SeniorCare employees

The following guidelines apply when a law enforcement officer or government agent contacts or requests an interview of Carolina SeniorCare employee:

- Employees are not required to consent to an interview by government investigators but may volunteer to do so;

- Employees are entitled to their own individual legal counsel, and may request that an interview be stopped at any time and resumed only after legal counsel is present;

- Employees may request that another representative of Carolina SeniorCare (other than legal counsel) be present with them during any interview;

- Employees should obtain the name, title, agency affiliation, and business telephone number of any investigator involved in an interview, and should ask for an explanation of the nature of the investigation and the reason for the interview; and

- Under no circumstances should any supervisor prohibit an employee from responding to or cooperating with government investigators.

- The employee should not release any documents to the investigators unless first reviewed by Management or legal counsel. This is not possible under a search warrant.

- Any staff member contacted by an investigator should immediately notify his or her supervisor and provide this individual with as much information and documentation about the investigation as is known. The request should be reported to the Compliance Officer,

Executive Director, the Chief Quality and Compliance Officer, and Corporate Risk Manager.

B. Document Retention and Document Destruction

Once Carolina SeniorCare has received notice of an investigation, the Compliance Officer will communicate with employees as necessary to ensure that any routine document destruction is stopped and that documents are retained as appropriate. Carolina SeniorCare will provide the MEDIC, CMS, the SAA, and law enforcement with access to all requested facilities and any records as required by law and consistent with any CMS contractual obligations.

XI. DISCIPLINARY GUIDELINES

A. Disciplinary Standards

Carolina SeniorCare shall publicize its disciplinary standards to its Board, employees, and contractors. The following are examples of methods of publication that may be used:

- Newsletters;
- Regular presentations at department staff meetings;
- Communication with contractors;
- General compliance training;
- Intranet site;
- Posters prominently displayed throughout employee work and break areas; and
- Cafeteria table tents.

The disciplinary standards shall identify noncompliant or unethical behavior by using examples of violative conduct employees may encounter in their jobs. Such examples may be publicized by way of compliance training materials or any of the above methods of publication.

B. Compliance as a Condition of Employment/Contract

All Carolina SeniorCare employees, contractors and are expected to comply with the applicable provisions of Carolina SeniorCare's Compliance Program and related compliance policies as a condition of employment or contract. Carolina SeniorCare expects its employees and contractors to meet the highest ethical standards, and comply with all applicable laws. Failure to do so may result in appropriate disciplinary action, up to and including termination.

C. Procedures for Imposing Discipline

1. In a case where an employee has engaged in improper conduct or violated this Compliance Program in any way, the Compliance Officer or his/her designee, in conjunction with the individual's supervisor, is responsible for determining the appropriate discipline. All discipline will be imposed in a timely and consistent manner and in accordance with the terms of any applicable collective bargaining agreements, union rules, requirements of law, and Carolina SeniorCare policies governing the discipline of employees. In a case where a contractor has engaged in improper conduct or has acted in a manner that is inconsistent with applicable provisions of this Compliance Program, the Compliance Officer or his/her designee, in

conjunction with the Executive Director**,** is responsible for determining the appropriate course of action.

2. If the Compliance Officer determines that an employee or contractor has materially and willfully violated this Compliance Program or other compliance-related policies and the violation was of a serious nature, the Compliance Officer may recommend that the employee be terminated from employment immediately, or that the contractor's contract be terminated immediately. Employees and contractors should be aware that violations of a serious nature may result in notification of law enforcement officials and licensure authorities.

3. If the Compliance Officer determines that the violation resulted from carelessness or inadequate understanding of Carolina SeniorCare's policies, the Compliance Officer may decide, for a first offense, that a verbal warning be given to the employee or contractor. The Compliance Officer may also decide that the employee or contractor be trained/re-trained regarding Carolina SeniorCare's compliance policies and applicable legal requirements. Subsequent offenses by the same employee or contractor may warrant more severe disciplinary or remedial action.

4. All disciplinary and remedial actions, including verbal warnings, will be documented in the employee personnel file by Human Resources or, in the case of a contractor, in the contractor's file. In addition, the Compliance Officer or his/her designee shall maintain a log of all disciplinary sanctions imposed and remedial actions taken. All disciplinary records for compliance violations shall be maintained for ten (10) years and shall include:

- the date of the report of the violation;
- a description of the violation;
- the date of investigation;
- a summary of findings;
- the disciplinary action taken; and
- the date it was taken.

XII. TRAINING

Carolina SeniorCare shall establish a program of regular compliance training.

A. General Compliance Training

1. Process

Carolina SeniorCare's employees, including temporary workers and volunteers, and members of the Board shall receive general compliance training within 90 days of initial hiring, and annually thereafter. Carolina SeniorCare shall review and update, if necessary, the general compliance training whenever there are material changes in regulations, policy or guidance, and at least annually.

2. Content

The compliance training shall consist of, among other things:

- A description of the compliance program, including a review of compliance policies and procedures, the Standards of Conduct, and Carolina SeniorCare's commitment to business ethics and compliance with legal requirements;

- An overview of how to ask compliance questions or report suspected or detected noncompliance. Training should emphasize non-retaliation and non-intimidation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;

- The requirement to report to Carolina SeniorCare actual or suspected noncompliance or potential FWA;

- Examples of reportable noncompliance;

- A review of the disciplinary action for non-compliant or fraudulent behavior, including mandatory retraining or termination;

- A review of conflicts of interest and Carolina SeniorCare's system for managing conflicts of interest;

- HIPAA/HITECH obligations and the importance of maintaining the confidentiality of personal health information; and

- An overview of the monitoring and auditing process.

B. PDP FWA Compliance Training

1. Process

All employees shall receive training appropriate to their involvement with Carolina SeniorCare's PDP, including ensuring that employees are aware of the Medicare requirements related to their jobs. In addition, appropriate compliance training concerning FWA and Carolina SeniorCare PDP shall be provided to Carolina SeniorCare managers and members of Carolina SeniorCare's Board of Directors within 90 days of initial term and annually thereafter.

All FDRs (e.g., PBMs and pharmacies) must confirm that they have implemented FWA training. Any FDR may participate in Carolina SeniorCare's training programs if feasible and reasonable or may (i) elect to use the CMS standardized FWA training materials to conduct its own training program, (available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html, or (ii) receive Part D training from another PDP sponsor or other organization acceptable to Carolina SeniorCare. Carolina SeniorCare may provide its own Part D compliance training materials to a FDR to ensure the quality of the training received. (*See Tabs I and J* for the relevant Carolina SeniorCare's training.) Carolina SeniorCare may require any FDR to certify (in the contract or otherwise) that relevant employees, agents and subcontractors of the FDR have received appropriate FWA training. Carolina SeniorCare shall recognize that FDRs who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse and have thereby met Carolina SeniorCare's FWA compliance program training requirements. In the case of chain pharmacies, each individual location must be enrolled in Medicare Part A or Part B to be deemed as having met the training requirement.

2. Content

Carolina SeniorCare shall ensure that all employees and all FDRs are aware, at a minimum, of the following:

- Laws and regulations related to Part D fraud, waste, and abuse (e.g., Anti-Kickback Statute, False Claims Act, etc.);
- Part D FWA risk areas/vulnerabilities;
- Obligations of FDRs to have appropriate policies and procedures to address FWA;
- The obligation of FDRs and their employees to report to Carolina SeniorCare actual or suspected Medicare program noncompliance or potential FWA;
- Mechanisms available for Carolina SeniorCare and FDR employees to anonymously and confidentially report suspected fraud, waste, and abuse or Medicare program noncompliance to Carolina SeniorCare (or, as to FDR employees, either to Carolina SeniorCare directly or to their employers who must then report it to Carolina SeniorCare;
- Examples of types of FWA that can occur in the settings in which Carolina SeniorCare and FDR employees work;
- Protections for individuals and entities who in good faith report suspected fraud, waste and abuse; and
- Potential consequences of non-compliant or fraudulent conduct, including, but not limited to, termination of employment or the relevant contract.

When appropriate, Carolina SeniorCare also may educate PACE Participants about prescription drug fraud, waste, and abuse. Such education may be included in newsletters, postings in Carolina SeniorCare's facilities or other means of Participant communication.

C. Timing and Method of Training

1. Training shall be provided within ninety (90) days of hire and annually thereafter. Carolina SeniorCare should provide additional or "refresher" training courses to certain employees or departments when additional or new job functions are assigned, when the compliance program requirements change, when employees are found to be noncompliant, as corrective action to address a noncompliance issue, when an employee works in an area with past FWA issues and in any other circumstance that indicates additional training may be necessary. Carolina SeniorCare shall document training of employees through a written certification signed by the employee or other document evidencing that the employee has received compliance training.

2. Carolina SeniorCare shall utilize the method of training most appropriate to communicate the subject matter, including PowerPoint presentations at staff meetings, reminders in staff newsletters, individual one-on-one sessions with particular employees, regular quizzes or distribution of written materials.

3. The Compliance Officer or his/her designee shall be responsible for documenting all training sessions, including attendance, topic, and results of training and maintaining those records for ten (10) years.

4. FWA training for FDRs should occur prior to the time of contract with Carolina SeniorCare's PDP, and at least annually thereafter. FDRs must, at the time of contract, provide assurances that FWA training occurred at least within the last year, or within a shorter period (e.g., six months). The Compliance Officer or his/her designee shall be responsible for maintaining documentation evidencing that each FDR has received appropriate FWA training, that such training is current, and that each FDR maintains records of attendance, topic of training, certificate of completion (if applicable), test results (if test is given) for its employees for ten (10) years.

XIII. DOCUMENT RETENTION

As required by 42 CFR § 460.200, Carolina SeniorCare will retain records including, but not limited to, medical records, personnel records, and financial books and records for the longest of the following periods:

1. Ten years from the last entry date; or

2. For medical records of disenrolled participants, ten years after the date of disenrollment.

As required by 42 CFR § 423.505(d), Carolina SeniorCare's PDP will maintain, for a period of at least ten (10) years, books, records, documents and other evidence of accounting procedures and practices that:

1. Are sufficient to do the following:

   - Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid for the PDP);

   - Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of Carolina SeniorCare's services and facilities;

   - Enable CMS to audit and inspect any books and records of the PDP that pertain to the ability of Carolina SeniorCare to bear the risk of potential financial losses, or services performed or determinations of amounts payable under the contract;

   - Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of Carolina SeniorCare's bid for the PDP and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs; and

   - Establish the basis for the components, assumptions, and analysis used by Carolina SeniorCare's PDP in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in 42 CFR. § 423.265(c)(3); *and*

2. Include records of the following:

   - Ownership and operation of Carolina SeniorCare's financial, medical, and other record keeping systems;

   - Financial statements for the current Part D contract period and ten (10) prior periods;

- Federal income tax or informational returns for the current Part D contract period and ten (10) prior periods;
- Asset acquisition, lease, sale, or other actions;
- Agreements, contracts, and subcontracts;
- Franchise, marketing, and management agreements;
- Matters pertaining to costs of operations;
- Amounts of income received by source and payment;
- Cash flow statements;
- Any financial reports filed with other Federal programs or state authorities;
- All prescription drug claims for the current Part D contract period and ten (10) prior periods; and
- All price concessions (including concessions offered by manufacturers) for the current Part D contract period and ten (10) prior periods accounted for separately from other administrative fees.

The Compliance Officer or his/her designee is responsible for developing systems to maintain the necessary books, records, and other documentation, and for communicating those requirements to affected employees and contractors. All other records and documentation shall be maintained in accordance with Carolina SeniorCare's customary document retention and destruction policies.

APPENDIX A

Deficit Reduction Act
Information on Federal and State Laws Concerning False Claims

Pursuant to the Deficit Reduction Act of 2005, Carolina SeniorCare is required to provide to employees contractors and agents, educational information on the Federal and State False Claims Acts and whistleblower protection laws aimed at preventing and detecting fraud, waste and abuse in health care programs. Annual compliance training shall address False Claims Act provisions and whistleblower protections, and such information shall appear in the Employee Handbook.

1. FEDERAL CIVIL FALSE CLAIMS ACT

The federal civil False Claims Act, 31 U.S.C. § 3729, *et seq.*, ("FCA") was originally enacted in 1863 to combat fraud perpetrated by defense contractors against the United States Government during the Civil War. The current version of the FCA was enacted in 1982 and was amended in 1986; however, the FCA's purpose, to protect the United States government from fraud, waste and abuse, remains unchanged.

The FCA prohibits any "person" from:

A. Knowingly submitting a false or fraudulent claim for payment to the federal government or causing such a claim to be submitted;

B. Knowingly making or using a false record or statement to secure payment from the federal government for a false or fraudulent claim or causing such a false record or statement to be made or used; or

C. Conspiring to get a false or fraudulent claim paid by the federal government.

The FCA specifically states that a person acts "knowingly" when that person: (1) has actual knowledge of the information, (2) deliberately ignores the truth or falsity of the information, or (3) recklessly disregards the truth or falsity of the information. The FCA also defines the term "claim" as any request or demand for money or property where the United States government provides any portion of the money or property which is requested or demanded. A person who has violated the FCA must repay all of the falsely obtained reimbursement and is liable for a civil penalty of up to $11,000 and three times the amount of actual damages the federal government sustained for each false claim that was submitted. In addition, a person who has violated the FCA may be terminated from participation in federal health care programs, including the Medicare and Medicaid programs.

Both the United States Attorney General and private citizens may bring lawsuits alleging a violation of the FCA. When brought by private citizens, these actions are known as *qui tam* lawsuits, and the citizens who file these suits are known as "relators" or "whistleblowers." When a relator brings a *qui tam* action, the United States government may choose to intervene in the lawsuit and exercise primary responsibility for prosecuting, dismissing, or settling the claim. If the government declines to intervene, the relator can pursue the suit individually. As a reward for filing the action, a *qui tam* relator may receive between fifteen and thirty percent of the sum recovered for the government, in addition to attorneys' fees and other expenses. Alternatively, if a court determines that a relator's suit was frivolous, clearly vexatious, or brought primarily to harass the defendant, the relator will have to reimburse the defendant for the fees and costs it spent defending the lawsuit.

The FCA offers "whistleblower protection" to employees who bring suit pursuant to the FCA. If these employees are discharged, demoted, suspended, threatened, harassed, or discriminated against because of their involvement in an FCA claim, the employee may bring suit against his or her employer. A court may then determine that the employee is entitled to reinstatement, twice the amount of back pay plus interest, attorneys' fees, and other costs and expenses.

2. FEDERAL PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. § 3801, *et seq.*, ("PFCRA") imposes administrative remedies against a person who presents or causes to be presented a claim or written statement that the person knows or has reason to know is false to certain federal agencies, including the United States Department of Health and Human Services. The PFCRA states that a person "knows or has reason to know" that a claim or statement is false if the person: (1) has actual knowledge that the claim or statement is false, fictitious, or fraudulent, (2) deliberately ignores the truth or falsity of the claim or statement, or (3) acts in reckless disregard of the truth or falsity of the claim or statement. The PFCRA, like the FCA, defines a "claim" as any request or demand for money or property where the United States government provides any portion of the money or property which is requested or demanded.

A person who violates the PFCRA may be assessed civil money penalties of up to $5,000 per false claim and as much as twice the amount of each claim. The PFCRA generally applies to claims valued at less than $150,000. Alleged violations of the PFCRA are investigated by the agency to which the false claim was submitted, and enforcement actions may be brought only with the approval of the United States Attorney General.

3. NORTH CAROLINA MEDICAL ASSISTANCE PROVIDER FALSE CLAIMS ACT

The North Carolina Medical Assistance Provider False Claims Act, N.C.G.S. § 108A-70.10, *et seq.*, ("NC FCA") forbids North Carolina Medical Assistance Program providers (e.g., Medicaid providers) from:

A. Knowingly submitting a false or fraudulent claim for payment or approval to the Medical Assistance Program or causing such a claim to be submitted, or

B. Knowingly making or using a false record or statement to secure payment from the Medical Assistance Program for a false or fraudulent claim or causing such a false record or statement to be made or used.

The NC FCA specifically states that a provider acts "knowingly" when that provider: (1) has actual knowledge of the information, (2) deliberately ignores the truth or falsity of the information, or (3) recklessly disregards the truth or falsity of the information. The NC FCA defines the term "claim" as an application for payment or approval that is submitted to the Medical Assistance Program and that identifies a service, good, or accommodation as reimbursable under the Medical Assistance Program.

A provider who has violated the NC FCA may be liable for a civil money penalty of up to $11,000 plus three times the amount of damages sustained by the Medical Assistance Program for each false claim that was submitted. The provider will also be liable for investigatory and court costs, as well as interest on the damages amount.

Lawsuits brought pursuant to the NC FCA can only be instituted by the North Carolina Attorney General. Thus, unlike the federal FCA, private citizens may not file actions against providers under the NC FCA.

The NC FCA, like its federal counterpart, does provide "whistleblower protection" to employees who assist in the investigation or pursuit of an NC FCA claim. If these employees

are discharged, demoted, suspended, threatened, harassed, or discriminated against because they aided in the furtherance of an NC FCA investigation or suit, the employee may bring a claim against his or her employer. A court may determine that the employee is entitled to reinstatement, twice the amount of back pay plus interest that the employee is due, attorneys' fees, and other costs and expenses.

4. PROHIBITIONS AGAINST SUBMISSION OF FALSE CLAIMS TO INSURERS

Section 58-2-161 of the North Carolina General Statutes levies civil and criminal penalties against any person who, with the intent to injure, defraud, or deceive an insured or insurance claimant:

A. Presents or causes to be presented a statement or claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains false or misleading information concerning a material fact, or

B. Assists, solicits, or conspires with another person to prepare or make a statement or claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains false or misleading information concerning a material fact.

Examples of a possible false claim

A. Making false statements regarding a claim for payment;
B. Falsifying information in the medical record;
C. Double-billing for items or services;
D. Billing for services or items not performed or never furnished.

What should be done if a possible false claim has been made?

A. If an employee discovers an event that is similar to one of the examples of a false claim above, an employee is encourage to:

   1. Report to the Compliance Officer (336) 746-3500 for further investigation. If the employee is not comfortable doing this;

   2. The Employee should contact the hotline (800) 826-6762

B. An employee is not required to report a possible FCA violation to Carolina SeniorCare first. A report may be made directly to the Department of Justice or applicable state authorities. However, in many instances Carolina SeniorCare believes that the use of its internal reporting process is a better option because it allows our compliance office to quickly address potential issues. Carolina SeniorCare encourages employees to consider first reporting suspected false claims to the Compliance Officer but the choice is up to the employee.

C. Carolina SeniorCare will not retaliate against any employee for informing us or the federal or state government of a possible FCA violation.

APPENDIX B
Carolina SeniorCare
Standards of Conduct

Introduction

Carolina SeniorCare has adopted a Corporate Compliance Program to help ensure that Carolina SeniorCare operates in full compliance with applicable laws. An important component of the program is the Standards of Conduct, which sets out basic principles which Carolina SeniorCare, directors, officers, employees (personnel) and agents must follow. These Standards apply to all business operations and personnel. Non-personnel representatives of Carolina SeniorCare such as contractors or external advisors and consultants, should also be directed to conduct themselves in a manner consistent with these Standards when they are acting on behalf of Carolina SeniorCare. If you have any questions about the Standards or its applicability to a particular situation, please contact your supervisor or the Compliance Officer.

The Corporate Compliance program and these Standards are not intended to and shall not be deemed or construed to provide any rights, contractual or otherwise, to any personnel or to any third parties. The Standards of Conduct is comprised of the following principles:

STANDARDS OF CONDUCT – Principle 1

Our employees and agents strive for honesty and integrity while delivering quality services that are necessary to attain or maintain the Participants' physical, psychosocial, mental, and spiritual well-being.

- A fundamental principle on which Carolina SeniorCare will operate its business is full compliance with applicable laws. Carolina SeniorCare will also conduct its business in conformance with sound ethical standards. Achieving business results by illegal acts or unethical conduct is not acceptable. Our employees and agents should act in compliance with the requirements of applicable law and these Standards in a sound ethical manner when conducting business and operations.
- Our employees and agents should respect a person's dignity and will treat him or her with consideration, courtesy and respect, with recognition of the needs of the aged, cognitively impaired and dying.
- Our employees and agents should maintain the integrity and reputation of our organization and maintain truthful communications with those we serve.
- Our employees and agents should observe appropriate standards of informed consent and refusal of treatment.
- In order to make intelligent decisions, the individuals we serve should receive information about our organization, policies and procedures, charges, and who will provide services on behalf of our organization.
- Our employees and agents should strive to provide appropriate and sufficient treatment and services based on an accurate comprehensive assessment and plan of care that address their conditions.
- Our employees and agents should have sufficient education, licenses, background experience, on the job training and supervision to render services to those we serve.
- No deficiency or error should be ignored or covered up. A problem should be brought to the attention of those who can properly assess and resolve the problem.

- Employees and agents should receive clear instructions about what is expected of them.
- Our employees and agents should strive to do their jobs so that no harm is caused to those we serve, ourselves, or the public.
- Our employees and agents should protect each person we serve from neglect; verbal, mental or physical abuse (including Participant-on-Participant abuse); exploitation; misappropriation of personal property; corporal punishment and involuntary seclusion. Any such incident should be reported to the Center Executive and other officials of our organization for investigating and reporting, as required by law. Employees and agents are responsible for reporting reasonable suspicions of a crime against a Participant to the designated state agency and law enforcement.
- Our employees and agents should protect individuals against the inappropriate use of physical or chemical restraints.
- Our employees and agents should provide individuals with personal privacy and access to their personal records and should respect and protect the confidentiality of medical, financial and other personal information records. Employees and agents should refrain from revealing any personal or confidential information unless supported by legitimate business or individual care purposes in accordance with the law.
- Our employees and agents should safeguard financial affairs of each person we serve.

STANDARDS OF CONDUCT - Principle 2

Our employees and agents strive to comply with all applicable laws and regulations that affect our various businesses.

- Employees and agents should promptly report all suspected violations of the Standards of Conduct, compliance policies, operational policies, laws or regulations.
- Our employees and agents should not pursue any business opportunity that requires engaging in unethical or illegal activity.
- Neither our organization, nor our employees or agents should pay employees, physicians, or other healthcare professionals, directly or indirectly, in cash or by any other means, for referrals. Every payment to a referral source must also be supported by proper documentation that the services contracted for were in fact provided.
- No employee or agent is authorized to enter into any joint venture, partnership or other risk sharing arrangement with any entity that is a potential or actual referral source unless the arrangement has been reviewed and approved by our legal counsel.
- Our employees and agents shall be completely honest in all dealings with government agencies and representatives.
- Employees or agents who perform billing and/or coding of claims must take every reasonable precaution to help ensure that their work is accurate, timely and in compliance with federal and state laws and regulations and our policies.
- No misrepresentations shall be made and no false bills or requests for payment or other documents shall be submitted to government agencies or representatives. No falsification of medical, time or other records that are used for the basis of submitting claims will be tolerated.
- Our employees and agents should bill only for services that are medically indicated, ordered by the person's physician, actually rendered and which are fully documented in the person's clinical records. If the services must be coded, then only billing codes that accurately describe the services provided should be used.

- Personnel certifying the correctness of records submitted to government agencies, including bills or requests for payment, shall have knowledge that the information is accurate and complete before giving such certification. Team members should act promptly to investigate and correct the problem if errors in claims that have been submitted are discovered. Complete and thorough clinical and billing records should be maintained. All drugs or other controlled substances should be maintained, dispensed and transported in conformance with all applicable laws and regulations.
- By and through our employees and agents we should comply with all applicable laws, regulations, standards and other requirements imposed by any level of government. Without limiting the generality of that statement, our employees and agents should comply with applicable requirements of the PACE and Part D requirements, HIPAA/HITECH; Identify Theft Protection laws, the Deficit Reduction Act, OSHA, the False Claims Act, nondiscrimination requirements under Section 504 of the Rehabilitation Act of 1973, Section 1557 of the Affordable Care Act, and state licensure requirements.
- Our employees, agents and business associates have a responsibility to safeguard protected health information in compliance with HIPAA and HITECH Act requirements. Protected Health Information (PHI) violations should be reported to the Compliance Officer or IT Director immediately so required breach notifications can be issued.

STANDARDS OF CONDUCT – Principle 3

Our employees and agents strive to engage in ethical business relationships and practices.

- Our organization strives to not employ or contract with any person or entity ineligible to participate in federally funded healthcare programs. We conduct pre-engagement and periodic screening.
- Employees or agents should not use or reveal any confidential information concerning our organization or use, for personal gain, confidential information obtained as an employee or agent of our organization.
- Employees and agents should be honest in doing their jobs; should safeguard passwords, user ID codes, electronic signatures and any other authorization they have that allows access to protected information.
- Employees and agents should be honest and forthright in any representations made to Participants vendors, payers, other employees or agents and the community.
- All reports or other information required to be provided to any federal, state or local government agency should be accurate, complete and filed on time.
- The source or amount of payment should not determine the quality of care that we deliver.
- During nonworking time, employees are not permitted to provide any services for compensation to participants or their representatives.
- Employees and agents should refrain from entering into any type of arrangement with program Participant in which Participants receive compensation for services or products provided to CSC or CSC staff, without prior approval by the Executive Director.
- Employees and agents shall not offer or give any bribe, payment, gift or thing of value to any person or entity with whom Carolina SeniorCare has or is seeking any business or regulatory relationship except for gifts of nominal value which are legal and given in the ordinary course of business. Personnel must promptly report the offering of gifts above a nominal value to the Executive Director.

- Employees and agents shall not offer or transfer to a Participant any remuneration that is cash or cash-equivalent. Non-cash items having a retail value of no more than $15 per item or $75 in the aggregate per Participant on an annual basis, are permitted, as long as they are not offered as inducements.
- Employees and agents may not request or accept any gift or gratuity in any amount from a Participant, Participant's family member or representative, that is cash or a cash equivalent including a check, a gift card, a credit or discount for a service or product, a personal loan, or payment for a service or product received by the employee or agent. Gifts, which are not cash or a cash equivalent, may be accepted from a Participant, Participant's family or representative only if they have not been requested and do not exceed $25.00 in value in any calendar year. Any gift accepted by an employee or agent must be reported to the Executive Director and documented immediately.
- Employees and agents shall not directly or indirectly authorize, pay, promise, deliver or solicit payment, gratuity, or favor for the purpose of influencing any political official or government employee in the discharge of that person's responsibilities. Employees and agents shall not entertain government personnel in connection with the Organization's business.

STANDARDS OF CONDUCT – Principle 4

Our employees and agents strive to avoid either conflicts of interest or the appearance of an impropriety.

- Employees and agents should not have other jobs that interfere with their ability to perform their duties at our organization.
- Employees and agents should avoid any activity that conflicts with the interests of our organization or its Participants. They should try to avoid even the appearance of an impropriety. If an employee or agent suspects that a conflict may exist or be created, then he or she should consult with management.
- Placing business with any firm in which there is a family relationship may constitute a conflict of interest. Employees and agents must report any potential conflicts of interest concerning themselves or their family members to management.
- Employees and agents shall not engage in any financial, business or other activity which competes with EveryAge business which may interfere or appear to interfere with the performance of their duties that involve the use of EveryAge property, facilities, or resources, except to the extent consistent with the conflict of interest policies. Personnel should not become involved, directly or indirectly, in outside commercial activities that could improperly influence their actions. For example, an employee or agent may not be an officer, director, manager or consultant of a potential competitor, customer, or supplier of our organization without first disclosing that relationship to management.
- There should not be any business activities conducted between Carolina SeniorCare and other entities, which would give the appearance of corruption, bribery, facilitation payments or other types of inappropriate inducement. Other than compensation from Carolina SeniorCare and as consistent with the conflict of interest policies, personnel shall not have a financial or other personal interest in a transaction between Carolina SeniorCare or any of its business operations and a vendor, supplier, provider or customer.
- Employees and agents should not accept or provide benefits that could be seen as creating conflict between their personal interests and our organization's legitimate business interests, or could be seen as inducing or rewarding the referral or generation of business. This includes accepting expensive meals, gifts, refreshments, transportation, lodging or entertainment

provided or received in connection with the job. The value of free passes for educational sessions, conferences, expositions and related lodging provided by an individual vendor may not exceed $50.00 per year.

- Gifts and benefits given to or received from clinicians or referral sources are not appropriate. Occasional gifts that are limited to reasonable meal expenditures or entertainment or that are of nominal value are discouraged, although not prohibited. Gifts of cash or can be converted to cash are prohibited.
- Employees may not be appointed to serve as a Participant's agent in a general power of attorney or a healthcare power of attorney, unless the employee is an immediate family member of the Participant or has been appointed to serve as the Participant's agent through legal proceedings. Employees may not serve as a notary or as a witness in executing a healthcare power of attorney for any Participant. Employees may not serve as a witness for a Participant in executing a general power of attorney, or any other document where there is potential for a conflict of interest.
- All political activities relating to Carolina SeniorCare shall be conducted in full compliance with applicable law. No Carolina SeniorCare funds or property shall be used for any political contribution or purpose unless first approved by the Political Action Committee. Personnel may make direct contributions of their own money to political candidates and activities, but these contributions will not be reimbursed.
- Employees and agents shall comply with applicable antitrust laws. There shall be no discussions or agreements with competitors regarding price or other terms for product sales, prices paid to suppliers or providers dividing up customers or geographic markets, or joint action to boycott or coerce certain customers, suppliers or providers.
- Carolina SeniorCare and its employees and agents shall not engage in unfair competition or deceptive trade practices including misrepresentation of Carolina SeniorCare products or operations.

STANDARDS OF CONDUCT – Principle 5

Our employees and agents strive to protect our property and respect the property rights of others with whom we do business.

- All employees and agents are personally responsible and accountable for the proper expenditure of our funds and for the proper use of company property. All employees and agents must obtain authorization prior to committing or spending our organization's funds.
- Medical waste or other hazardous materials should be disposed of properly.
- Employees and agents may not use our resources or resources of a person we serve for personal or improper purposes, or permit others to do so.
- Surplus, obsolete or junked property should be disposed of in accordance with our procedures.
- Books and records shall be created, maintained, retained or destroyed in accordance with the schedule outlined in the Carolina SeniorCare record retention policy.
- Employees and agents have a duty to be productive during the time that is paid for by our organization.
- Employees and agents may only use computer systems, networks and software consistent with our license(s) and/or rights. They should take all reasonable steps to protect computer systems and software from unauthorized access or intrusion.

- Any improper financial gain to the employee through misconduct involving misuse of our property or the property of a person we serve is prohibited, including the outright theft of property or embezzlement of money. Employees and agents should report any observed misuse of property to management.
- Drugs and other pharmaceuticals should be safely stored, secured, inventoried, and missing supplies should be promptly reported to a supervisor.
- Employees and agents shall maintain confidentiality of Carolina SeniorCare business information and of information relating to our vendors, suppliers, providers and customers. Our confidential and proprietary information is valuable and personnel shall not use any confidential or propriety information except as appropriate for business. Personnel shall not seek to improperly obtain or to misuse confidential information of our competitors.

STANDARDS OF CONDUCT – Principle 6

Our employees and agents strive to respect each other as human beings and professionals.

- All employees and agents should show proper respect and consideration for each other, regardless of position or station. All employees and agents are responsible for ensuring that the work environment is free of discrimination or harassment due to age, race, gender, gender identity, color, religion, national origin, disability, sexual orientation, genetic information including family history, or covered veteran status. Discriminatory treatment, harassment, abuse or intimidation will not be tolerated.
- All employees and agents should maintain confidentiality in the workplace among themselves, Participants, family members and guests in an effort to maintain a harmonious work environment. Personal information about self or others should not be disclosed to individuals who do not have a "need to know" for conducting business in the workplace. When requesting or providing personal information, it should be limited to the minimum amount necessary to get the job done.
- Quality care can only be delivered through the use of qualified, competent staff. Our organization will contribute to an employee's or agent's competence by making available continuing job-related education and training, and employees are responsible for completion of assigned training and education.
- Applicants and employees should be afforded equal employment and advancement opportunities, pursuant to our policies.
- Employees and agents should conform to the standards of their respective professions and exercise sound judgment in the performance of their duties in a way that promotes the public's trust in our organization. No employee or agent should subordinate his or her professional standards, judgment or objectivity to any individual. Any differences of opinion in professional judgment should be referred to appropriate management levels for resolution in accordance with standard grievance procedures.
- Employees and agents are expected to provide only truthful and accurate information when reporting a compliance concern for investigation and/or providing information to investigators during an investigation.
- Employees and agents shall follow safe work practices and comply with all applicable safety standards and health regulations.
- We strive to maintain a working environment free from all forms of sexual harassment, including the creation of a hostile working environment or intimidation. By way of example, unwelcome

sexual advances, requests for sexual favors and other verbal or physical conduct of a sexual nature are prohibited and will not be tolerated.

- We promote a tobacco-, drug- and alcohol-free workplace in accordance with our policies which employees and agents are required to follow.
- We do not permit any action of retaliation or reprisal to be taken against any employee who reports a violation of law, regulations, standard, procedure, or policy.

These Standards have been distributed to all personnel and sets forth general standards applicable to all business and operations. In addition, there are a number of more detailed and specific policies covering particular programs or subject matters. EveryAge will communicate those specific policies to personnel who are particularly affected by and who must comply with them in the course of EveryAge business. A current set of such policies is available at EveryAge worksites (and on the EveryAge computer network). A person may review them by contacting his/her supervisor or the Compliance Officer.