



CORPORATE COMPLIANCE POLICY MANUAL	Title: Medicare Part D Fraud, Waste, and Abuse Compliance Plan	
Effective Date: May 1, 2008	Review Date: January 26, 2010	Revise Date: January 26, 2010

Policy: AASC/AICARE for Seniors ensures a comprehensive compliance program to detect, correct, and prevent fraud, waste and abuse in its Medicare Part D Plan.

Purpose: AASC/AICARE for Seniors has adopted this Fraud, Waste and Abuse Compliance Program (“FWA Program”) to fulfill the statutory and regulatory requirement to develop a comprehensive Part D fraud, waste and abuse program.

This Program is intended to follow all relevant guidelines set forth in Chapter 9 of the CMS Prescription Drug Benefit Manual.

AASC’s FWA Program:

- Articulates AASC’s commitment to detecting, correcting and preventing fraud, waste and abuse in the administration of its prescription drug plan;
- Outlines the procedures AASC follows in monitoring and auditing for fraud, waste and abuse, and in addressing any potential improper conduct when identified;
- Provides guidance for AASC employees and contractors in addressing questions relating to fraud, waste and abuse in AICARE for Seniors’ prescription drug plan; and
- Identifies specific risk areas that merit attention and monitoring.

I. Compliance Officer and Compliance Committee

The Compliance Officer will develop, operate and monitor the FWA Compliance Program and will report directly to the Board of Directors on matters related to FWA compliance, as necessary.

The Compliance Officer’s job duties include:

- Developing compliance policies and procedures related to the AICARE for Seniors’ PDP;
- Reporting on a periodic basis to the Board of Directors regarding the status of the AASC’s FWA Program and the identification and resolution of any potential or actual instances of noncompliance;
- Developing and implementing training programs regarding the AASC’s FWA Program;
- Developing and maintaining compliance reporting mechanisms that allow employees and vendors to report suspected fraud, waste and abuse without fear of retaliation;

- Responding to reports of potential instances of fraud, waste and abuse in AASC’s PDP, including coordinating investigations and developing corrective action plans;
- Reporting instances of fraud to the appropriate MEDIC and/or CMS, when AASC determines that such a report is appropriate; and
- Maintaining appropriate documentation regarding the FWA Program

II. Risk Assessment

AASC/AIICARE for Seniors will establish and maintain a risk assessment system to determine where the organization is at risk for FWA and to prioritize (rank) such risks (“Risk Assessment”).

Under this system, the Compliance Officer (or his/her designee) periodically will conduct a FWA Risk Assessment to identify possible FWA risk areas, the safeguards in place to manage those risks, and any areas where additional safeguards might be appropriate. AASC will document the procedures used to implement the risk assessment, and will provide such documentation to CMS or the Medicare Drug Integrity Contractor (“MEDIC”) upon request.

III. Monitoring and Auditing

A. Risk Area Monitoring and Audits

1. AASC will conduct periodic internal monitoring and auditing activities to detect and prevent potential FWA and to ensure compliance with all applicable federal and state laws, the Compliance Program and AIICARE for Seniors’ policies and procedures.
2. The Compliance Officer and Compliance Committee will develop a work plan outlining the planned auditing and monitoring activities, as well as methodologies and scheduling, for each contract year. Any work plans so developed should meet the relevant requirements of Section 50.2.6, Chapter 9 of the CMS Prescription Drug Benefit Manual. *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. *Auditing* refers to a more formal review of compliance with a particular set of internal (e.g., Compliance Program) or external (e.g., laws and regulations) standards.
3. Monitoring and/or auditing will extend to all areas of the PACE Organization vulnerable to potential FWA, including:
 - Subcontractor operations
 - Claims processing
 - Pricing, rebates and other price concessions
 - CMS payments (PDE and other data submission, comparison to the bid, etc.)
 - Other areas identified through the Risk Assessment

4. As part of monitoring and auditing for FWA, the Compliance Officer will engage in regular analysis of data maintained and/or submitted by AASC's PDP. Data will be compiled, sorted and analyzed to identify any anomalies, outliers, or patterns of aberrant and potentially abuse utilization. *Section VII, Data Reporting Compliance*. Data analysis procedures will be provided to CMS upon request.
5. In addition to data analysis, the Compliance Officer may utilize any of the following methods to monitor and audit risk areas:
 - On-site visits with contractors or vendors
 - Unannounced "spot checks" or internal audits on-site at AASC/AllCARE for Seniors or subcontractors
 - Interviews with employees, contractors or vendors involved in various functions pertaining to Part D
 - Examination of the performance of the compliance program including a review of the compliance issues log or complaints
 - Use of objective, independent auditors that are knowledgeable regarding Part D and not employed in the area under review
 - Review of areas previously found noncompliant to determine if corrective actions are being implemented and have fully addressed the underlying problem
6. In addition to the above, the Compliance Officer and Compliance Committee will develop audit and monitoring mechanisms to evaluate the effectiveness of the FWA Program itself. Evaluations of the FWA Program shall include
 - Effectiveness of training;
 - Use of the internal confidential reporting system;
 - Completion of any audit work plans;
 - Effectiveness of internal investigations and disciplinary actions; and
 - AASC responses to particular incidents under the FWA Program.

B. Monitoring Reports of Suspected Noncompliance

1. AASC has a system for reporting confidential reporting of potential FWA.
2. AASC will ensure that any complaints, reports or concerns about FWA in the Medicare Part D program are logged and tracked in accordance with the Compliance Program policies and procedures. The Compliance Officer or his/her designee will address complaints, reports and concerns regarding FWA on an individual basis in accordance with this FWA Program.

C. Audit Reports and Corrective Actions

1. The Compliance Officer or his/her designee, in consultation with the Program Director and/or Board of Directors will arrange for external audits by independent outside auditors or legal counsel when 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 and work product privilege. Upon completion of an external audit, the Compliance Officer or his/her designee will provide a written report to the Executive Director/Board of

Directors. Based on a review of the report the Compliance Officer 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
2. Notice of modification to the FWA Program or other policies and procedures will be disseminated to employees, contractors or vendors 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.

IV. Disciplinary Guidelines

A. Compliance as a Condition of Employment/Contract

AASC's employees, agents, and subcontractors are expected to comply with all organizational policies related to compliance, including but not limited to this FWA Program, as a condition of employment or contract. AASC expects its employees and subcontractors 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.

B. Procedures for Imposing Discipline

1. In a case where an employee or subcontractor has engaged in improper conduct or violated this FWA 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.
2. If the Compliance Officer determines that an employee or subcontractor has materially and willfully violated this FWA Program or other compliance-related policies and the violation is of a serious nature, the Compliance Officer may recommend that the employee be terminated from employment immediately, or that the subcontractor's contract be terminated immediately. Employees and subcontractors 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 AllCARE for Seniors' policies, the Compliance Officer may decide, for a first offense, that a verbal warning be given to the employee or subcontractor. The Compliance Officer may also decide that the employee or subcontractor be re-trained regarding AllCARE for Seniors' compliance and FWA policies and the requirements of Part D. Subsequent offenses by the same employee or subcontractor may warrant more severe disciplinary action.

4. All disciplinary action, including verbal warnings, will be documented in the employee or subcontractor's personnel file by the Human Resources Department/Personnel Manager. In addition, the Compliance Officer or his/her designee will maintain a log of all disciplinary sanctions imposed,

V. Compliance by Third Parties

1. AASC will require all third parties with whom it contracts or does business (including PBMs, TPAs and pharmacies) to comply with all applicable laws and regulations.

NOTE: To the extent any compliance functions are delegated to any third party, AASC 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.

2. AASC will screen contractors and vendors against the OIG List of Excluded Individuals/Entities, the General Services Administration ("GSA") Excluded Parties Listing System and/or any state exclusion lists maintained by state Medicaid programs at the time of contract and annually thereafter. Contractors or vendors found to be excluded will be removed immediately from any work on programs involving Federal Health Care Programs.
3. AASC will make best efforts to ensure that all agreements with contractors and vendors include provisions indicating that the contractor or vendor:
 - Has reviewed AASC'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 AllCARE for Seniors on behalf of the contractor or vendor to comply with such standards, policies and procedures;
 - Will notify AllCARE for Seniors of all subcontractors utilized by the contractor or vendor;
 - Represents that contractor has not been excluded from participation in Federal Health Care Programs
 - Will notify AllCARE for Seniors if it is so excluded from participation; and
 - Agree that its contract with AllCARE for Seniors will terminate automatically if it is excluded in the future.
4. AASC will require contractors and vendors to report immediately to the Compliance Officer any detected errors, possible fraud on the part of beneficiaries, employees or subcontractors, outliers, and other relevant matters related to FWA. AASC will require contractors or vendors found to have violated contractual or regulatory requirements to cooperate with AllCARE for Seniors in implementing additional internal and/or external compliance procedures and cost containment recovery provisions as necessary.

VI. Data Reporting Compliance

A. Monitoring and Safeguards

1. To ensure the truth and accuracy of data submitted to CMS, and to identify areas where data collection and submission practices could be improved, AASC/AIICARE will periodically monitor the following:
 - Prescription Data Event (PDE) information;
 - Cost data;
 - Diagnoses information reported through RAPS
 - Deletion records (generated when a beneficiary fails to pick a prescription for which a plan has already submitted PDE data);
 - Data on direct and indirect remuneration;
 - 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).

2. AIICARE for Seniors will maintain appropriate safeguards to ensure the accuracy, completeness and truth of all data pertaining to the PACE program PDP (including RAPS, PDE data, enrollment data and other Part D required reporting) that is submitted to CMS (or, if a contractor is responsible for collecting, compiling or submitting data on AASC's behalf, that such contractor or vendor maintains appropriate safeguards). Such safeguards may include:
 - Systems configurations that catch 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 internal monitoring or auditing activities, and any issues identified by CMS, the OIG, or other federal or state agencies with FWA oversight or enforcement authority.

3. If a contractor submits data on AASC's behalf, AASC will periodically review the contractor's compliance policies, procedures, and other internal controls of its contractors and vendors to ensure they maintain sufficient mechanisms for monitoring compliance and mitigating risks of FWA.

B. Corrective Actions

The Compliance Officer or his/her designee will review any errors or discrepancies detected with the individual(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).

VII. Monitoring Participant FWA

AASC will monitor the utilization patterns of PACE participants to ensure that participants, or participants' family members, are not improperly using or obtaining prescription drugs. AllCARE for Seniors will periodically review beneficiary complaints and grievances for indications of possible beneficiary fraud and shall follow the additional procedures outlined in this section to meet these responsibilities

A. Establishing Baseline Data

AASC will obtain utilization data from the previous twelve (12) months (January 1 – December 31) 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 that AllCARE for Seniors will use as a benchmark for comparing subsequent periods.

AllCARE for Seniors will compare subsequent data with baseline data to track prescribing and utilization patterns over time and identify aberrant and potentially abusive utilization.

B. Integration into Participant Care Management Process

1. AllCARE for Seniors' initial assessment of a participant will include a review of the participant's prescription drug history and family situation, and identify the appropriate pharmaceutical therapy in the plan of care.
2. During periodic reassessments, participants' prescription drug records will be analyzed, and any changes to pharmaceutical therapies or drugs prescribed (including switches from brand to generics) will be examined to confirm that the changes are appropriate for the participant's condition.
3. The participant's primary care provider in collaboration with the pharmacist will be responsible for monitoring drug-drug interactions and drug changes, but the interdisciplinary team will also regularly review a participant's drug records and highlight any inconsistencies or potential over-utilization.
4. AllCARE for Seniors' social workers, home 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 will be immediately reported to the Compliance Officer. All affected staff members and contractors will be trained on these requirements.

C. Prescription Drug Event Data/Drug Utilization Review

1. AASC 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 VII.A above) 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
 - 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.)
2. To the extent specialized knowledge is required to determine aberrations in any of the above, the Compliance Officer may call on AllCARE's primary care provider and pharmacist for assistance in a review. The Compliance Officer will investigate any potential FWA issues revealed through the review by discussing the participant's condition with the Interdisciplinary Team, reviewing the source data for the PDE (actual prescriptions, etc.), and discussing prescription drug utilization with the Participant (if appropriate).

VIII. **Monitoring Prescriber FWA**

AASC 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, AllCARE for Seniors' PDP will follow the procedures outlined below.

A. Establishing Baseline Data

AASC will obtain utilization data from the previous twelve (12) months 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 that AASC will use as a benchmark for comparing subsequent periods. AASC will compare subsequent data with baseline data to track prescribing patterns over time and identify aberrant and potentially abusive utilization.

B. Procedures

1. AASC will consult with its pharmacist or other professionals involved in pharmaceutical therapy management about any such anomalies in prescribing patterns indicating possible fraud or abuse.
2. The PDE data compiled and submitted by AASC's 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 VI,

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
 - Physicians who prescribe more controlled substances than other physicians
3. If the Compliance Officer identifies outliers or anomalies that he or she believes may suggest improper prescribing patterns, the Compliance Officer may consult with AASC's consulting pharmacist, 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 AASC's PDP's MEDIC. The Compliance Officer and other affected staff members and contractors will cooperate with any MEDIC investigation, in accordance with Section XIV. Cooperating with Government Investigations.
 4. All prescribers who write prescriptions for PACE Participants will be checked against the OIG List of Excluded Individuals/Entities, the General Services Administration ("GSA") Excluded Parties Listing System and/or any state exclusion lists maintained by state Medicaid programs on an annual basis. The PACE Part D Plan shall not pay for medications prescribed by excluded providers.

IX. Monitoring Pharmacies

All pharmacies providing prescription drugs to PACE participants will be checked against the OIG List of Excluded Individuals/Entities, the General Services Administration ("GSA") Excluded Parties Listing System and/or any state exclusion lists maintained by state Medicaid programs, at the time of contract and annually thereafter.

A. Monitoring Pharmacies

1. AASC may monitor pharmacies providing prescription drugs to PACE participants to ensure the pharmacy is complying with all applicable Part D requirements. In particular, AASC may 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," pharmacies 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 AASC's PDP for prescriptions that are never picked up by PACE Participants
 - Pharmacy's dispensing fees must be reasonable and in accordance with any applicable contracts
 - Pharmacy must have standards and protocols to ensure quality of care (monitoring of drug-drug interactions, drug utilization, etc.)

2. AASC may audit pharmacies for compliance periodically through on-site audits, request for reports, or by other means. Auditing strategies may include:
 - 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
 - On a periodic basis, conduct “spot checks” and compare the prescription issued to the beneficiary, the prescription drug claim that was processed by the pharmacy, and the PDE data that was submitted to CMS
3. If auditing and monitoring activities provide clear evidence that a pharmacy is engaged in fraudulent or abusive conduct with respect to prescription drugs, the Compliance Officer will refer the activities to AASC’s MEDIC.

X. Responding to Incidents of Noncompliance

The Compliance Officer or his/her designee shall be responsible for promptly responding to incidents of noncompliance, including violations of AASC’s FWA Compliance Program, AllCARE for Seniors’ policies and procedures, applicable laws and Medicare Part D program requirements, and for developing appropriate corrective action initiatives relating to such offenses.

A. Internal Investigations

1. 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;
 - Consultation with legal counsel.
2. The Compliance Officer or his/her designee will endeavor to initiate all investigations into identified compliance problems within two weeks of receiving the initial complaint or report.
3. If the Compliance Officer has a potential or actual conflict of interest or is otherwise not available to conduct a prompt investigation, the Compliance Officer will appoint another managerial employee to conduct the investigation.

B. Self-Reporting

The Compliance Officer will make an initial determination as to whether the results of a particular investigation should be reported to government authorities, based on the circumstances and nature of the particular incident. If the Compliance Officer initially determines that such self-reporting is appropriate, he or she will refer the matter to the Board of Directors/Executive Director. The Compliance Officer and the Board of Directors/Executive Director shall act promptly to ensure that any self-report is made within a reasonable period of time but no later than sixty (60) days from when it was determined that a violation may have occurred.

The Board of Directors/Executive Director, in consultation with legal counsel as appropriate, will make a final determination as to whether a self-report will be made. In determining whether to self-report, the Compliance Officer/Board of Directors/Executive Director will adhere to the following guidelines:

- Instances of actual fraud perpetrated on or by AllCARE for Seniors' PDP or any of its contractors or agents will be referred to the MEDIC for further investigation and/or potential referral to law enforcement.
- Incidents of criminal misconduct will be reported to appropriate law enforcement authorities.

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 Section 50.2.8.3, Chapter 9 of the CMS Prescription Drug Benefit Manual, and will document all referrals to the MEDIC in accordance with any further CMS instructions.

C. Corrective Action

1. As soon as is practicable after completion of an investigation, the Compliance Officer or his/her designee will establish a corrective action plan if appropriate and will set deadlines by which the prescribed corrective action must be taken. Depending on the nature of the particular compliance problem, corrective action may include the following:
 - Disciplinary action, as prescribed by the Compliance Officer or his/her designee and the individual's immediate supervisor (in accordance with AASC'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 with pharmacies, PBMs or other contracted entities; and
 - Self-reporting to government authorities, in accordance with this policy;

2. If senior management is involved in a compliance violation, the Compliance Officer may elect to refer final authority on the appropriate discipline to the Executive Director and Board of Directors.
3. 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. AASC 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, Compliance Committee, Program Director, Executive Director, the Board of Directors, and legal counsel. Any documents or information protected by the attorney/client privilege will be treated as such.

XI. Cooperating with Government Investigations

AASC will cooperate with CMS, MEDICs and other government auditors and law enforcement agencies.

A. Procedures

1. AASC's employees must notify the Compliance Officer or his/her designee immediately upon being contacted by a law enforcement officer or government agent regarding AASC's business. Any employee served with an OIG or Grand Jury subpoena, summons, court order or complaint in connection with AASC/AIICARE for Seniors' business should contact the Compliance Officer or his/her designee immediately and provide him or her with copies of the served documents.
2. AASC will provide the MEDIC, CMS, 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. AASC will allow access to any government auditor acting on behalf of the federal government or CMS to conduct an audit at the facilities of AASC or any of its subcontractors.

3. In the event AASC refers a case to the MEDIC in accordance with Section X, Policy on 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.
4. AllCARE for Seniors will respond to specific government requests for information as follows:

Search warrants

If a law enforcement officer or government agent presents a search warrant, the Compliance Officer or his/her designee will be notified immediately, and will proceed in accordance with the following guidelines:

- The Compliance Officer or his/her designee will ask the officer or agent for identification, a copy of the warrant, and any affidavit in support of the warrant. The Compliance Officer or his/her designee will immediately check to ensure that the warrant has not expired and is being executed within a time specified in the warrant.
- The Compliance Officer or his/her designee will immediately notify the Program Director of AllCARE for Seniors and legal counsel. The Compliance Officer and/or Program Director will serve as the contact person(s) for the officers or agents during and after the search.
- The Compliance Officer and/or Program Director will accompany officers or agents during a search, and will take notes regarding what officers and agents look at, documents or items they take, people they interview, and questions they ask.
- In the event an officer or agent tries to enter areas or seize things not listed in the warrant, the Program Director of AllCARE for Seniors will ask the officer or agent to wait until legal counsel arrives. If the officer or agent refuses, the Program Director of AllCARE for Seniors will note which officer or agent went into an area not specified in the warrant and whether anything was seized from the area.
- The Compliance Officer will request an inventory of or receipt for any original documents and other materials seized by the agents.
- Employees will be made aware of their rights regarding requests for interviews by law enforcement in the course of executing a search warrant.

Employees will fully cooperate with law enforcement officers and government agents and will not interfere with or prevent investigators from accessing information listed in a search warrant. Employees should not give investigators permission to search an area that is not listed on the warrant, unless advised otherwise by legal counsel. The execution of a search warrant will trigger an immediate investigation by the Compliance Officer.

Service of Subpoenas

- If AASC 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 time-frame for responding.
- AASC will 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 will 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.

Law Enforcement interviews with AllCARE for Seniors employees

The following guidelines apply when a law enforcement officer or government agent contacts or requests an interview of an AASC 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 AASC (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;
- Under no circumstances should any supervisor prohibit an employee from responding to or cooperating with government investigators.

B. Document Retention and Document Destruction

Once AASC 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.

AASC will provide the MEDIC, CMS and law enforcement with access to all requested facilities and any records then existing associated with AASC/AllCARE for Seniors' PDP for ten (10) years from the end of the final contract period or completion of an audit, whichever is later, unless the Compliance Officer or legal counsel specify otherwise.

XII. Training of Employees, Subcontractors and Vendors

A. Compliance Training

1. AASC shall establish a program of regular compliance training that meets the applicable requirements of Section 50.2.3, Chapter 9 of the CMS Prescription Drug Benefit Manual. All employees and subcontractors shall receive training appropriate to their involvement with AASC's PDP.
2. Compliance Training will include updates and current topics reported on the OIG website.
3. PBMs, pharmacies and other third parties retained by AASC to provide services to

the PDP may conduct their own training programs. AASC may require all such vendors to certify (in the contract or otherwise) that its training program meets the applicable requirements of Section 50.2.3, Chapter 9 of the Prescription Drug Benefit Manual.

4. When appropriate, AASC/AIICARE also may educate PACE Participants about prescription drug fraud, waste and abuse. Such education may be included in newsletters, postings in Day Centers or other means of participant communication.

B. Timing and Method of Training

1. Training shall be provided at the time of hire or contracting, and annually thereafter for all current employees and subcontractors. AASC may choose to provide “refresher” training courses to certain employees, subcontractors, or departments in circumstances that indicate additional training may be necessary. Employees may be asked to certify annually that they have received compliance training relating to the Part D Plan.
2. AASC/AIICARE shall utilize the method of training most appropriate to communicate the subject matter, including Power Point 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, topics, and contents.

XIII. Document Retention

AASC’s PDP will maintain the records required by 42 CFR §423.505(d) for a period of ten years. The Compliance Officer or his/her designee is responsible for developing systems to maintain the necessary documentation and for communicating those requirements to affected employees and subcontractors.

All other records shall be maintained in accordance with AASC’s customary document retention and destruction policies.

XIV. Conflict of Interest

See AASC’s Conflict of Interest Policy

XV. Prohibitions on Kickbacks and False Claims

A. Background

As a recipient of federal funds from the Medicare and Medicaid programs, AASC 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 the purpose of AASC's Prescription Drug Plan, the Anti-Kickback Statute prohibits conduct such as:

- A pharmaceutical company's payment of a fee to a physician for every prescription the physician writes for that company's drugs
- A prescription drug plan paying a nursing home to influence all residents to sign up for that prescription drug plan

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.

The False Claims Act prohibits knowingly presenting (or causing to be presented) to the federal government 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 to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor or state Medicaid program. A "claim" could include PDE and other data submitted to CMS, the PACE Organization "bid" and all other reports submitted to CMS for the purposes of receiving federal reimbursement.

For purpose of AASC's PDP, 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 in the RAPS or other systems in order to induce a higher reimbursement or capitation rate
- Submitting data to CMS showing actual costs incurred for purposes of the 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.

There are numerous other federal and state laws that govern AASC's PDP's operations, including the HIPAA Privacy and Security Rules and other state and federal anti-fraud laws. The listing of the False Claims Act and the Anti-Kickback Statute is not intended to suggest that these are the only laws governing AASC's PDP.

B. Procedures

1. Any financial or other business arrangements between AASC's PDP and all physicians, pharmacies, PBMs, pharmaceutical companies and other health care entities 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 AASC 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.
2. When AASC personnel or contractors 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 AASC/AIICARE for Seniors has with contracted providers. AASC's 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, AASC's personnel and contractors must not offer anything of value in order to obtain referrals of patients or services covered under Medicare or Medicaid.
3. The following activities are specifically prohibited by AASC and will not be tolerated within the organization:
 - Submitting false data to CMS for purposes of obtaining reimbursement (including reinsurance and LICS payments) for prescription drugs not dispensed or not provided as claimed, or other costs not incurred as claimed
 - Submitting data for prescription drug claims 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)
 - Knowingly submitting data for prescription drugs dispensed to, or obtained by, individuals not eligible for Medicare Part D
4. AASC's personnel and contractors will receive periodic training on these requirements. The Compliance Officer will monitor the confidential internal reporting system for any allegations regarding kickbacks or bribes received by AASC's personnel, or false claims submitted to CMS.

Appendix A: Glossary

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

Abuse means any activities or practices that are inconsistent with sound fiscal, business or medical practices and either directly or indirectly result in unnecessary costs to federal health care programs. Examples of abuse include:

- Inadequate controls that result in failing to report rebates or discounts;
- Drug-seeking behavior on the part of beneficiaries;
- Issuing refills for a prescription that are not medically necessary

Anti-Kickback Statute (AKS) means the Medicare and Medicaid Patient and Program Protection Act (found at 42 USCA §1320a-7b(b)).

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

Compliance Program means the program adopted by PACE Organization to ensure compliance with all applicable laws, regulations and contractual requirements, headed by the Compliance Officer.

Compliance Officer means the individual appointed by the organization as responsible for the organization's Compliance Program, including the FWA Program, or the individual specifically designated by the organization's Compliance Officer to do so. With respect to fraud, waste and abuse issues, the Compliance Officer reports directly to Appalachian for Agency for Seniors, Inc. Board of Directors.

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

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

Fraud means any knowing and intentional deception for the purpose of receiving undeserved reimbursement from a federal health care program. Examples of fraud include:

- Enrolling, and receiving payments for, fictitious individuals
- Altering PDE data, or submitting fictitious PDE data, to CMS for the purpose of increasing risk-sharing and other CMS subsidies
- 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 (as defined in this Glossary).

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 Departments of Veterans Affairs but excluding the Federal Covered Persons Health Benefit Program (FEHBP).

Formulary means a list of approved drugs included on a PDP's plan of benefits, including but not limited to requirements for generic substitution, step therapy, pre-authorization and the like.

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

Participant means an individual enrolled in the PACE Organization and receiving prescription drug benefits through the PACE Organization's Prescription Drug Plan

Prescription Drug Plan (PDP) means a Medicare Part D Prescription Drug Plan sponsored by a PACE Organization.

Pharmacy Benefits Manager (PBM) means an entity contracted by a Prescription Drug Plan 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.

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.

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 produce.

Third Party Administrator (TPA) means an entity contracted by a Prescription Drug Plan to process claims for the Medicare Part D drug benefit.

Waste means the extravagant, careless or needless expenditure of funds that results from deficient practices, system controls or decisions and results in increased costs to Federal Health Care Programs. Examples of waste include:

- 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
- Failing to adequately differentiate between Part A, Part B and Part D drugs and receiving higher Medicare payments as a result