2023 Compliance Program
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2023 Compliance Program
Introduction

Astiva Health, LLC., its Board of Directors, the management, staff, and contracting providers are committed to honoring and complying with all applicable Federal and State standards including, but not limited to guidance and regulations promulgated and distributed by the Centers for Medicare and Medicaid Services (CMS). Following is the Compliance Program Description for Astiva Health (**AH or "the Plan").**

This compliance plan (program) applies to Medicare Part C and Part D.

The Compliance Program Description indicates how the Plan works to ensure compliance to meet the regulatory requirements set forth at 42 CFR§422.503(b)(4)(vi) and 423.504(b)(4)(vi)(A). Astiva Health monitors and ensures the prompt implementation of HPMS memos, Call Letters, Best Practices, and any other guidance released by CMS.

Minimum Seven Core Elements

The Astiva Health Compliance Program includes the minimum seven core requirements listed below:

1. Written Policies, Procedures, and Standards of Conduct
2. Compliance Officer, Compliance Committee, and High-Level Oversight
3. Effective Training and Education
4. Effective Lines of Communication
5. Well Publicized Disciplinary Standards
6. Effective System for Routing Monitoring and Identification of all Compliance Risks
7. Procedures and System for Prompt Response to Compliance Issues.

Resources, Roles, and Responsibilities

Astiva Health understands the need and requirement to dedicate appropriate resources to ensure the Program's success in achieving and maintaining compliance. The following AH staff members are responsible for working with the Compliance Officer and have accepted responsibility to implement and oversee the following main areas of compliance:

#	Responsibilities / Duties	Responsible Party	With Assistance from:
1.	Distribute, promote, and enforce Standards of Conduct	Compliance Officer	Compliance staff and/or Human Resources
2.	Promote and enforce the AH Compliance Program	Compliance Officer	Board of Directors, Executive Officers, and Department Leadership
3.	Effectively train and educate its governing body members, employees, and FDRs	Compliance Officer/Delegation Oversight Committee	Compliance Dept.; Human Resources; Provider Relations; and the Plan's website: www.astivahealth.com and the ICE website: www.ICEforHealth.org
4.	Establish effective lines of communication within AH and between AH and its First Tier and Downstream Related Entities (FDRs)	Compliance Officer, Chief Information Officer (CIO), VP Provider Relations	Provider Relations; and Dir. Delegation Oversight
5.	Oversee FDR compliance with Medicare Part C and D requirements	Compliance Officer/ Operations	Compliance Internal Auditor; Delegation Oversight Director and Auditors; and / Operations
6.	Establish and implement an effective system for routine auditing and monitoring	Compliance Officer / Operations	Compliance Internal Auditor/ Internal Operational areas perform monitoring
7.	Identify and promptly respond to risks and findings	Compliance Officer	Compliance staff

First Tier and Downstream Related Entities (FDRs) and Delegated Functions

Part D Delegation:

Astiva Health utilizes a Pharmacy Benefit Manager (**PBM**), currently Elixir, to help manage its formulary and the administration of its pharmacy benefits. Some functions are delegated to the PBM, and some functions are retained. Prior to the start of each

year AH and the PBM meet on multiple occasions to discuss which functions will be delegated and how they are to be performed in accordance with the AH Plan Benefit Packages (based on next year's Bid). Delegation details are documented in signed "Information Questionnaires," referred to as IQs. Whenever changes in delegation occur, they are documented in an updated IQ. The annual contract between the PBM and AH includes some of the major delegated functions as well. AH requests and reviews the PBM's program descriptions (policies and procedures/**P&Ps** or standard operating policies and procedures/**SOPs**) as requirements change annually at a minimum. AH Subject Matter Experts (**SMEs**) review the PBM P&Ps/SOPs, and the enterprise Compliance Committee (**CC**) gives final approval. The AH Compliance Officer and AH subject matter experts/leadership meet with the PBM weekly or bi-weekly to review new CMS guidance, communications with Pharmacies, and to discuss and track any issues and requests. AH conducts desk review audits of the PBM to monitor and help ensure its compliance. AH requests corrective action plans (**CAPs**) as needed from the PBM and re-measures later to determine the effectiveness of the CAP. AH may conduct an onsite audit of the PBM as needed.

The Plan may utilize a specialized pharmacy to assist with medication adherence and medication therapy management (**MTM**) tasks.

Part C Delegation to Providers and Vendors:

Astiva Health (**AH**) has a network of direct contracting physicians, independent physician associations (**IPAs**), contracting medical groups (**CMG**s), ancillary providers, hospitals, and other providers as needed. AH also contracts with some vendors and intervention companies for some services. The Plan requests completion of information forms for the purpose of conducting due diligence for new company relationships. At the time of writing, the Plan *may* "out-source" the following Part C activities/functions: Information Technology (**IT**) services, Credentialing, Administrative /Management Services Organization (**MSO**) services, Human Resources (**HR**), dialysis services, field marketing organization (**FMO**) services, etc. The Plan understands that it can delegate services and functions, but it can *never* delegate the "responsibility" of ensuring compliant performance. Therefore, AH ("**the Plan**") has an active Delegation Oversight Committee (**DOC**) that reviews monitoring reports and delegation oversight audit results to ensure ongoing compliance and member satisfaction. Initial Delegation Audits (**IDA**s) take place to ensure the ability of the entity to accept delegation. At the time of the IDA, the contracting entity does not have credentialing or claims files belonging to AH, therefore IDAs involve review of the delegated entity's standard operating policies and procedures (**SOPs** or **P&P**s). IDAs take place prior to or as soon after contracting as possible. Ongoing Annual Delegation Audits (**ODA**s) also take place to ensure ongoing compliance. IDAs and ADAs are scored element by element. Based on IDA/ODA information and scores, the Plan may require a corrective action plan (**CAP**) be implemented. A Follow-up or Focused Audit (**FA**) may take place depending on the severity of an issue. A FA (scheduled or a surprise audit) may take place at any time the Plan has concerns. The DOC sends reports to the Compliance Committee routinely with substantial audit findings and/or other issues.

The DOC makes recommendations regarding delegation status (delegation, limited or provisional delegation, revocation of delegation, etc). The Plan may decide to delegate but be part of the decision-making process until such time as the Plan is sure the entity is capable and able to sustain compliance.

The Compliance Committee (**CC**) is responsible for the final delegation decisions and ratifies recommendations (or not) to grant final delegation approval. Delegation agreements are signed by both parties identifying duties and functions to be delegated and notating functions that are *not* delegated. AH requires delegates to submit reports (monitoring reports, self-reported by the entity) at specific intervals (monthly, quarterly, and annually) and additionally whenever required by AH.

Additionally, the Plan conducts Joint Operation & Utilization Meetings (**JOUM**s) with delegated entities. They are at scheduled intervals by the Plan. JOUMs are scheduled, conducted, and documented by staff from the Provider Relations (**PR**) department with other Plan representatives as may be needed at any given meeting. This could include a Medical Director, MSO representative, compliance staff person, delegation oversight staff person, etc. The frequency of JOUM meetings is determined based on the experience of the delegated entity, utilization data, and compliance issues. JOUMs may be onsite or virtual. CAPs may be required as a result of reviews during the JOUMs. The Manager/Director of Provider Relations reports to the CC any issues from JOUMs or from any other source that are non-compliant (substantively), that need actions and/or follow up.

Retention of Ultimate Responsibility:

Although AH delegates functions and duties to other entities, AH always retains full responsibility for the actions, lack of action, and inappropriate actions of its delegates. AH works to train, monitor, and audit the delegates to ensure they learn, understand, and implement all Medicare requirements to ensure the beneficiaries have good experiences, good care, and good outcomes.

Chapter One

Written Policies, Procedures, and Standards of Conduct

Written Policies and Procedures:

Astiva Health has written standard operating policies and procedures (**SOPs** or **P&Ps** or "policies"). Every policy statement includes a commitment to comply with all applicable State and Federal requirements. Policies are routinely reviewed and updated as regulations change, as departmental procedures change, and bi-annually at a minimum. Policies are reviewed by impacted departments. Leadership of the departments discuss the policies and when agreement is reached, they jointly submit policies to the compliance committee for final review and approval prior to Board approval. Between meetings the policies may be adopted and implemented if approved by impacted department leadership and the Compliance Officer (**CO**), CEO, and/or Chief Medical Officer (**CMO**) as appropriate.

The Compliance Officer or designee maintains a tracking log of all policies including review dates, authors, and important historical information such as policy number changes, revisions, replacement policies, etc. Policies are stored in a central location (such as Drop Box), where all staff can access the most recent policies, use them, or recommend changes as needed. Some policies are on the website, and some are in the Provider Manual (**PM**).

Policies are developed by each department regarding how they comply with Federal and State requirements and regulations. Policies generally include important information such as standards for timeliness, responsible parties, actions or process steps required for compliance, and steps to prevent and detect potential fraud, waste, and abuse, and monitoring and auditing of functions within a department or critical system of the Plan.

Changes are tracked with redlines (when possible) to enable ease in identifying the modifications. Retired versions and retired policies are stored in the Archives.

<u>Distribution of Policies to AH Employees</u>

Policies are posted on the Astiva Health SharePoint for easy access by all staff. This ensures that the staff all always have the most current versions available. Policies are shared with Providers in the Provider Manual and through other electronic media depending upon the provider's ability to view electronic media. New and changed policies are sent by the Compliance Dept. staff with an impact analysis and training opportunities when needed.

Distribution of Policies to the Board of Directors:
Policies are available to the Board of Directors upon request to the Compliance Officer, and via the Astiva Health SharePoint.

Distribution of Policies to FDRs and their Employees:
AH distributes policies to its First Tier and Downstream Related Entities (**FDRs**) and their employees via one or more of the following methods:

- Some policies are posted on the Plan's website;
- Some policies are restated or summarized in the Provider Manual (**PM**) which is referenced in the provider contract, indicating the requirement for compliance with the policies;
- New and changed policies may be sent by email or by SFTP site to providers as needed;
- Policies that have been confusing or which providers are not following may be sent individually or collectively to providers by email or by SFTS; and
- Providers may at any time request additional copies of any policy.

Demonstrating Delivery of the Provider Manual (**PM**) and Standards of Conduct to FDRs and their Employees:
AH maintains a tracking log of dates when PM and Standards of conduct were mailed or posted for providers, vendors, the Board, etc. Providers are asked to attest that they received and will abide by the Code of Conduct and policies (or an equivalent thereof) and attest that they were delivered to the employees, staff, and any downstream contracting providers. Additionally, the Astiva Health Code of Conduct appears (ongoing) on the internet. Providers and others may be required to review and attest via the AH website.

Monitoring Compliance Policies:
Astiva Health reviews its own Compliance policies annually or as needed. Additionally, the Compliance Department conducts periodic auditing of 10% of its FDRs annually, based on the volume of members and/or any noted risk factors. The audit includes a review of the FDR's compliance policies, compliance program, sanction list checks, Standard of Conduct, and required training attestations. The Compliance Department reviews to ensure compliance with Medicare and state requirements. The PBM policies are reviewed annually due to the high beneficiary impact.

Standards of Conduct / Code of Conduct:

Approved by the Board of Directors:
The Astiva Health "Code of Conduct" is the company's statement of its ethical business expectations for all Board members, all staff, and all First Tier and Downstream Related Entities (**FDRs**) and their staff. Therefore, the Code of Conduct is presented to the Board of Directors of AH for review and adoption annually. The Board is committed to

adhering to ethical standards as set forth in the Code of Conduct. The Board of Directors are asked to sign the Code of Conduct and lead by example.

Shared with Employees:

The Astiva Health Code of Conduct is shared with all new employees upon hiring or contracting. Employees and contractors must sign an acknowledgement of receipt (this may be done on the Plan' website, or via paper copy sent to Compliance@astivahealth.com). Additionally, the Code of Conduct is delivered and discussed with staff during the "New Hire Orientation" by a designated staff person from the Human Resources Department. Annual training (including the Code of Conduct review and signature) is tracked by the Human Resources Department and/or the Compliance Department. Failure to comply with the standards results in disciplinary action up to and including potential termination of services.

Shared with FDRs:

The Code of Conduct is shared with Providers during the New Provider Orientation and is posted on the Plan's website. Providers may use their own equivalent standard/code of conduct or may use the Astiva Health Code of Conduct. Astiva Health is committed to doing business with ethical individuals and entities only. The Annual Provider Training includes the Code of Conduct in addition to other mandated training like Compliance, Model of Care, Fraud/Waste/Abuse, and HIPAA training. Providers are asked to attest to training their staff. The Plan also utilizes the ICE website for this purpose as well as the Plan's website, www.astivahealth.com .

Internal Tracking of Training / Distribution of the Code of Conduct:

The HR Director tracks the initial training, and the Compliance staff tracks ongoing training (including review and signature on the Code of Conduct). The Plan website tracks completion of the training and reports are available for the Compliance Department.

Oversight of Employee and Contractor

The Director of Human Resources provides to the Compliance Department designee, a listing of all employees added to or deleted from company each month. The Provider Contracting Manager or designee produces a list of the contracting entities added or deleted from the network each month. These lists are for the purpose of comparing who was hired and which of them completed the training. The listings are delivered to the Compliance Department monthly and/or upon request including the "Hire/Start Date and End Date." The Compliance Internal/External Auditor (**IEA**) audits periodically to validate the HR Director and Contract Manager files to ensure the staff and contractors are completing the Code of Conduct attestation timely upon orientation and that documents are available to validate the completion of a random sample of New Hires.

Annually the Compliance Department distributes (or posts on the website) materials for self-study (either electronically or in hard copy). Department Leadership may request the Compliance Officer to schedule a training meeting or webinar with the department/s for which the leader is responsible. Leadership is trained (Train the Trainer) during a Compliance Committee meeting annually (at a minimum). An attestation accompanies the training materials requiring the staff member to acknowledge receipt and to complete the training, understand, and abide by information in the training materials. No testing takes place at that time, but random (and possibly selective) testing by the Compliance Department may take place to audit for understanding and retention.

Shared with the Public:
The Code of Conduct is placed on the Astiva Health website to ensure the public that Astiva Health has ethical standards to which it is committed.

Monitoring / Auditing:
The Compliance Department conducts full or random sample audits to ensure compliance as follows:

- ★ ***New Hire Training:*** The HR Director maintains tracking logs to monitor compliance and reports any compliance training or non-compliance to the compliance committee. When needed, the Compliance Officer addresses non-compliance by sending non- compliance notices including warnings of suspension to staff who have not completed the training as required. A link is also provided to the self-training modules on the Plan's website where newly hired / newly contracted staff and others may complete the training. The website tracks completion of the training.
- ★ ***Staff Annual Training Log:*** The Compliance Internal Auditor (CIA) maintains tracking logs to monitor compliance and reports any non-compliance issues to Compliance Committee (CC). The Compliance Officer addresses non- compliance by sending non-compliance notices including warnings of suspension to staff who have not completed the training as required. A link is also provided to the self-training modules on the Plan's website where existing staff, contractors, and other FDRs and their staff may complete the training. The website tracks completion of the training. Reports can be run by the Compliance department staff.
- ★ ***Provider Orientation:*** The Provider Relations Department provides a link to the self-training modules on the Plan's website where existing staff, contractors, and other FDRs and their staff may complete the training. The website tracks completion of the training. Reports can be run by the Compliance department staff. The Plan also recommends the ICE website for FDR training. Reports can be run to determine who has and hasn't completed the training. Follow up is required by the Provider Relations staff and Delegation (vendors) Oversight staff

with the FDRs. Issues of non-compliance are reported to the Compliance Committee, and the Compliance Officer addresses non-compliance by sending notices of non-compliance (NONCs) including warnings of actions to be taken with providers who have not completed the training as required.

- ★ ***FDR Compliance P&Ps Audited:*** Plan auditors request copies of FDR policies for compliance with Medicare standards during pre-delegation and annual audits. They report their findings to the Delegation Oversight Committee (**DOC**) which is under the Compliance Department. DOC reviews and approves corrective action plans CAPs required of non-compliant FDRs and reports any non-compliance and CAPs to the compliance committee. The Compliance Officer issues notices of non-compliance, and the Committee decides if the FDR contract should be terminated based on this and other instances of ongoing non-compliance.
- ★ ***FDR Codes of Conduct:*** The Plan collects and reviews attestations regarding Codes of Conduct from delegated contracting medical groups annually. AH makes several attempts to collect these. Non-compliance is reported to the Compliance Committee (CC) and the Compliance Officer sends notices of non-compliance or completes other follow-up actions to gain compliance.

Chapter Two

Compliance Officer, Compliance Committee, and High-Level Oversight

Compliance Officer

(Medicare Managed Care Manual, Part C, Chapter 21.50.2.1; Prescription Drug Manual, Chapter 9.50.2.1)

Unfiltered Reporting to the Governing Body

Compliance Officer is a full-time employee of the Plan and is able to deliver unfiltered, unfettered reports directly to the senior-most leader (the CEO) and to the governing body (the Board of Directors) at the discretion of the Compliance Officer. The Compliance Officer attends the Board of Director meetings on a regular basis. If needed, the Compliance Officer (CO) may request and meet with the Board of Directors in Executive Session. The CO's reports are not routed through the CEO or other executives for approval. The Compliance Officer furnishes reports regarding the status and the activities of the compliance program. The CO is responsible for sharing with the Board any areas at risk of substantial non-compliance and any substantial fraud, waste, or abuse uncovered. The CO is free to raise compliance issues without fear of retaliation or intimidation. The Board must be knowledgeable about and oversee the compliance program and its effectiveness.

Overall Responsibilities

The Compliance Officer is responsible for developing and implementing the health plan's compliance program. The CO defines the program structure, mandated training requirements, reporting, complaint mechanisms, response and corrective action procedures, and compliance expectations of all FDRs, all of which is approved by the Board of Directors. Therefore, the CO is required to have training and experience in working with the Medicare Advantage and Prescription Drug programs and must communicate well with peers, leadership, and regulatory authorities. The CO is a member of the senior management team.

Duties

The basic duties of the Compliance Officer (CO) are as follows:

- Routine Compliance Reports: Ensure that regular compliance reports are developed and delivered to the CO, the Board of Directors (BOD), CEO, and Compliance Committee;
- Reports of Oversight & Potential Non-compliance: Ensure that reports include existing and potential areas of non-compliance, oversight, and audit activities;
- Operational Interactions: Maintain awareness of daily business activities by interacting with operational areas;
- Compliance Training: Develop and implement compliance training modules regarding compliance program elements and compliance expectations for the Board of Directors, management, employees, contractors, and FDRs; Ensure that AH staff and FDRs know

where and how to report potential or suspected compliance issues to Compliance@astivahealth.com or to Hotline@astivahealth.com, including but not limited to fraud, waste, and abuse;

- Regulations Training: Ensure training regarding applicable and federal and state statutory regulations, reporting, and requirements;
- Prevent Retaliation for Reporting: Develop and implement programs and methods for the reporting of program non-compliance and potential Fraud, Waste, or Abuse (FWA) without fear of retaliation (which includes the opportunity to report to the CO anonymously) via Hotline@astivahealth.com or a hotline phone extension. Confidentiality is maintained to the greatest extent possible);
- Prompt Investigation & Response: Develop and implement programs to ensure triage, investigation (as appropriate), and documentation regarding potential FWA via close coordination with and oversight of internal and external investigations;
- Exclusion List Monitoring: Ensure that the Department of Health and Human Services (**DHHS**) Office of the Inspector General (**OIG**), Government Services Administration (**GSA**), and/or other lists are reviewed and documented monthly for any sanctioned or excluded personnel of Astiva Health or its FDRs;
- Preclusion List Download and Distribution: Download and distribute the Preclusion List monthly and ensure the provider contracts are termed; ensure that any members using providers on the Preclusion List are moved timely to their new provider selections;
- Non-Compliance Documentation: Maintain tracking documentation and timely completion of potential noncompliance or potential FWA received from any source;
- CAP Implementation & Tracking: Oversee the development, implementation, tracking, monitoring, and effective completion of any necessary corrective action plans (CAP)

Authority:

The Compliance Officer recommends participation in the CMS Healthcare Fraud Prevention Partnership (HFPP) and collaborates with other sponsors (health plans and Prescription Drug Plans), State Medicaid programs, the California Department of Managed Health Care (DMHC), Medicaid Fraud Control Units (MCFUs), the MEDIC, the OIG, commercial payers, and other organizations, where appropriate, when a potential FWA issue is discovered that involves multiple parties.

The Compliance Officer has the authority to:

- Interview (or delegate the responsibility to interview) the sponsor's employees and other relevant individuals regarding compliance issues;
- Review company contracts and other documents pertinent to the Medicare program;
- Review (or delegate the responsibility to review) the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements;
- Independently seek advice from legal counsel;
- Report significant potential FWA to CMS, HFPP, California Department of Managed Health Care, I-MEDIC, or law enforcement as appropriate per case; and to any delegating or other entities as required;
- Conduct and/or direct audits and investigations of any FDRs;
- Conduct and/or direct audits of any area or function involved with Medicare Parts C or D plans; and
- Recommend policy, procedure, and process changes

Compliance Committee
(Medicare Managed Care Manual, Part C, Chapter 21.50.2.2; Prescription Drug Manual, Chapter 9.50.2.2)

The primary Astiva Health Compliance Committee (**CC**) is a multidisciplinary team of departmental leadership, chaired by the Compliance Officer, that meets quarterly at a minimum and preferably monthly. The CC (referred to hereafter as "The Committee" or "CC") reviews compliance data and reports from the IT department and other leadership and informs the Compliance Officer (**CO**) and CC regarding monitoring reports from the various departments and FDRs. The Committee is accountable to and provides regular compliance reports to the Chief Executive Officer (**CEO**) and Board of Directors (**BOD**) through the CO especially regarding non-compliant areas, or areas with high risk of becoming non-compliant. The Committee may designate a workgroup/subgroup to meet regarding matters that require greater expertise and extreme confidentiality. Subgroups at the time of writing include:

- Special Investigation Unit (SIU): is comprised of the Compliance Officer (CO), designated Compliance staff appointed by the CO and other Subject Matter Experts (SMEs) as needed. They meet as needed to investigate matters of potential FWA, or other non-compliance that require the strictest confidentiality. Minutes are not maintained. They use an FWA tracking log and/or case summaries as the basis for discussions.
- FDR Delegation Oversight Committee): This team is comprised of the Plan's subject matter auditors and key stakeholders who review all matters related to the delegation oversight of contracting medical groups (**CMGs**), independent physician associations (**IPAs**), and **vendors**. The DOC reviews pre-contractual audits, focused audits, annual audits, required reporting, corrective action plans, and other issues that may arise. This committee works under the direction of the Director of Delegation Oversight, Compliance Officer, and the Compliance Committee.
- PBM Oversight: The Compliance Officer (and/or designees) meet telephonically with the PBM at scheduled intervals. They usually meet weekly but may determine that bi-weekly or monthly meetings are appropriate, depending on the number of issues or matters of delegation to discuss. The Compliance Officer is present and invites Plan SMEs to participate in the meetings (some ongoing and some as needed).
- Compliance Internal Audit (CIA) Team: This team consists of the Compliance Internal Auditor (**CIA**), the Compliance Officer, leadership from the area being audited, and other leadership sometimes including senior management. They meet on an ad hoc basis as needed, for example to review results of an audit.

Duties of the Compliance Committee:

The basic duties of the Compliance Committee are as follows:

- Oversee the Compliance Program: All aspects of the compliance program are under the Compliance Committee;
- FWA Prevention: Develop strategies to detect, report, and correct any FWA issues;
- Training Program: Review and approve all CMS-required Training materials (and Code of Conduct) ensuring that the education is appropriately completed and effective;
- Preventive Plans: Develop prevention strategies and actions to reduce violations;
- Risk Assessment: Review and approve the annual risk assessment, developing and implementing work plans to mitigate risk;
- Audit Results: Review and implement corrective actions as needed to resolve issues detected during audits (internal or external);
- CAP Tracking: Monitor CAPs to ensure completion and effectiveness;

- Resource Monitoring: Monitor the effectiveness and completeness of internal controls to ensure that adequate staff and other resources are available to the Compliance Department to enable its ability to complete required tasks and duties;
- Policies and Procedure Maintenance: Monitor policies and procedures to ensure that compliance policies are up to date;
- System for Questions and Answers: Ensure that Astiva Health has a process in place by which members, FDRs, employees, and contractors can ask compliance questions and report potential issues of non-compliance in a confidential / anonymous manner without fear of retaliation. This is done in a variety of ways but primarily by sending email to Compliance@astivahealth.com or by calling the CO or a compliance department staff member.
- Monitoring Compliance / Non-compliance: Review and ensure that appropriate corrective actions are taken to address audits and other reports of non-compliance;
- Reports to the CEO and Board of Directors: The Compliance Committee provides quarterly and ad hoc reports to the Board of Directors via the Compliance Officer, with recommendations regarding improving compliance.

Composition of the Compliance Committee:
The multi-disciplinary compliance committee is chaired by the Compliance Officer and includes compliance department staff, clinicians, non-clinicians, auditors, departmental leadership, and senior management. Departmental leaders in attendance are to be ones with decision making authority.

Governing Body
(Medicare Managed Care Manual, Part C, Chapter 21.50.2.3; Prescription Drug Manual, Chapter 9.50.2.3)
42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The AH, Inc., (parent company) Board of Directors (**BOD**) oversees the implementation and effectiveness of the Astiva Health Compliance Program throughout the enterprise of the health plan. The Compliance Officer's written report advises the BOD of compliance issues and/or risk and makes recommendations to the BOD. The BOD may request additional actions and/or resources to ensure the issues are resolved. They may follow up to ensure actions are completed and effective.

The Compliance Officer provides information to educate the BOD regarding the structure, operations, risks, and strategies of the Compliance so the BOD is able to judge the outcome measurements to determine the effectiveness of the Compliance Program.

Oversight:
The BOD oversees the following at a minimum:

- Code of Conduct: Review and approve annually;
- Compliance Program Structure: Understand the program and approve it annually or upon significant changes;
- Monitoring: Be informed regarding program outcomes, and results of internal and external audits; Review Compliance Committee / Officer's reports and updated information; Have the ability to review minutes from various committees;
- State Enforcement Activities: audit results, CAPs, penalties, and other enforcement actions;
- CMS Enforcement Activities: Be informed regarding:
    - CMS Notices of Non-Compliance
    - Warning Letters
    - Corrective Actions
    - Formal Actions
- Assessments: Review results of performance and effectiveness assessments of the compliance program including (but not limited to) the following:
    - Annual Risk Assessment (required by CMS)
    - Annual Compliance Program Effectiveness (CPE) Audit (required by CMS)
    - Annual Model of Care Evaluation
    - and others.

Involvement or Delegation

At their discretion, the BOD may be involved in, may delegate to senior management, or may delegate to the ECC the following activities:

BOD Delegated Activities

The BOD has chosen to delegate the following activities to the Compliance Committee:

- Policies and Procedures: development, implementation, annual review, and approval of P&Ps
- Compliance and FWA Training: development, implementation, annual review, and approval of training materials (including the Code of Conduct)
- Compliance Risk Assessment: review and approval
- Internal and External Audit Work Plans and Results: review and approval
- Corrective Action Plans: review and approval
- Compliance Dashboards and Self-Assessment Tools: review and assess program based on outcomes

BOD Involved Activities

The BOD is responsible for the following activities:

- Compliance Officer: only the BOD has the authority to oversee, hire, or fire the Compliance Officer (CO); the CO is obligated by law to report to authorities any significant matters of non-compliance with or without the Board's approval;
- Compliance Officer's Job Description: only the BOD has the authority to determine, review duties of, and approve performance goals for the Compliance Officer
- Senior Management's Commitment: the BOD is involved in the evaluation of the senior management's commitment to ethics and the compliance program, and may seek input from others as needed
- Monitoring Evidence: the BOD may review summary information and/or measurable evidence to determine if the compliance program is detecting and correcting issues of non-compliance in a timely manner. The BOD requests data showing that the Compliance Program has reduced the risks of Program non-compliance and FWA. Some indicators it monitors are:
    - Enrollment and Disenrollment data;
    - Appeals and Grievance data;
    - PDE Errors data;
    - Claims timeliness and accuracy data;
    - FDR Delegation Oversight Audit data;
    - Compliance Internal Audit (CIA) data;
    - External Audit data;
    - Sales Allegation data;
    - Tracking HPMS memos to ensure the timely, complete implementation of new or changing CMS regulations;
    - Tracking submission of CMS required reports and monitoring analysis;
    - Tracking CMS notices of non-compliance, warning letters, etc.
    - Tracking to determine if root causes were found and corrected; and
    - Ensuring there was timely, appropriate, and consistent disciplinary action as needed.

BOD Minutes

The BOD maintains contemporaneous minutes which can be shared with CMS auditors as evidence of the BOD's active engagement in oversight of the Medicare Compliance Program. The BOD asks questions, takes actions, and follows up as needed.

Senior Management Involved in Compliance Program
(Medicare Managed Care Manual, Part C, Chapter 21.50.2.4; Prescription Drug Manual, Chapter 9.50.2.4)
42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The Chief Executive Officer (CEO), Chief Operations Officer (COO), the Chief Medical Officer (CMO), Chief Information Officer (CIO), the Chief Financial Officer (CFO), and other senior management understand the importance of the compliance program. They are involved in oversight of the Compliance Program. They ensure that the Compliance Officer is given the respect, credibility, authority, and resources needed to maintain a robust and effective compliance program. The Compliance Officer updates them regarding areas in which Astiva Health is at risk of non- compliance. The Compliance Officer is free to discuss issues, audit results, and strategies to improve compliance. The CEO and COO are advised of all compliance enforcement notices and activities in a timely manner.

Chapter Three

Effective Training and Education

(Medicare Managed Care Manual, Part C, Chapter 21.50.3; Prescription Drug Manual, Chapter 9.50.3)
42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

Astiva Health ensures training at the onset (orientation) of employment or contracting and again annually thereafter. The chief executives and senior administrators or managers; as well as members of the governing body are also trained upon orientation and annually thereafter. The HR Department and the Compliance Department track completion of attestations from staff indicating they have read, understand, and will abide by the training and Code of Conduct. Effective training is designed to ensure higher rates of compliance with all Medicare and other program requirements. Astiva Health Compliance Department staff and departmental leadership spend time training employees in various departments regarding how their work impacts the Compliance Program and how the Medicare requirements apply to their job functions.

General Compliance Training

(Medicare Managed Care Manual, Part C, Chapter 21.50.3.1; Prescription Drug Manual, Chapter 9.50.3.1)
42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The Compliance Officer develops the required training materials annually. Astiva Health (AH) mails, emails, faxes, or posts training materials on the website and has training available via monthly video/phone teleconferences, in paper, and other methods and mediums. The website is the primary vehicle for training, and it tracks the names, dates, and other information about those who complete the training. The Compliance Dept. tracks completion by other methods. The Plan accepts training certificates from those who complete their training on the CMS website. When completed they are asked to furnish a copy of their certificates of completion. The Compliance Officer or designee follows up as needed on delinquent training attestations or other evidence.

The FDRs are asked to complete training and testing with their staff. AH requests the FDRs to submit an annual attestation stating they have completed training with their staff and that they maintain records available for audit. AH accepts FWA Certifications and other training certification from those who completed requirements through Medicare or another credible source. Marketing agents, for example submit AHIP training certificates annually.

Model of Care Training and Code of Conduct Training must be completed as well. The training is available: on the Plan website, can be mailed by email or by paper upon request, conducted in virtual meetings, face-to-face meetings, and via one-to-one meetings with the Compliance Officer. FDRs may use their own Code of Conduct or the AH Code of Conduct. The same tracking and follow up occurs as needed by the Compliance Officer.

New Employee Training:
The Director of Human Resources (HR) is responsible to ensure orientation includes training and access to the Plan website where training can also be completed.

Annual Employee Training:
The Compliance Officer sends an all staff email annually requiring completion of the annual training via the website and provides alternative training methods available.

Contracting Providers:
Provider Relations and Representatives ensure that contracting Providers are trained upon orientation and annually thereafter. Some providers may complete the annual provider training on the ICE website, or on the AH website. Those sites have reports available that the Compliance staff download and use to develop reports. The Plan's Provider Service Representatives follow up with providers who are not compliant.

Vendors:
The Compliance staff responsible for Vendor Oversight assists the Compliance Officer with ensuring the training of all vendors upon orientation and annually thereafter. The primary training tool for vendors is the Plan website.

Board of Directors
The Compliance Officer (CO) ensures that members of the Board of Directors are trained upon orientation and annually thereafter. The CO usually conducts a training at a Board Meeting and gains approval of the materials at the same time.

Updating Content of Compliance Training Materials
The Compliance Officer reviews and updates training materials annually at a minimum and/or when there are substantive changes in regulations, policies, or guidance.

Content of Compliance Training Materials:
Astiva Health compliance training materials must include at a minimum:

- Compliance Program, related policies & procedures
- Code of Conduct
- Fraud, Waste, and Abuse Training – including how to report suspected non-compliance or Fraud, Waste or Abuse (FWA) including some examples of non-compliance employees might witness;
- Non-compliance in any area;
- Assurance of confidentiality, anonymity, and non-retaliation for reporting;
- The requirement to report indicating it is against federal law to not report;
- Review of Disciplinary Guidelines (including potential termination of services);
- Training is mandatory and a condition of continued employment;
- Review policies related to contracting with government (no gifts);
- Review of potential Conflicts of Interest (COI) and requirement to report it to the

Astiva Health Director of Human Resources;

- HIPAA security and confidentiality;
- Compliance monitoring and auditing;
- Laws that govern employee conduct in the Medicare program

Fraud, Waste, and Abuse Training
(Medicare Managed Care Manual, Part C, Chapter 21.50.3.1; Prescription Drug Manual, Chapter 9.50.3.1)
42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)
HPMS memo of May 8, 2012, regarding CMS FWA Training and Education Guidance

Like the Compliance Training, the FWA Training is conducted by the Human Resources Department with staff for New Hires upon orientation of employment / contracting and annually thereafter. As needed The Plan may conduct ad hoc training focusing on specific issues regarding FWA risks, non-compliance, or when requirements change. The Plan conducts the same training during the New Hire and Annual training, but ad hoc training may be department specific. Department-specific training is conducted with individuals depending on their functions within the company. FDR Training is the general training, but ad hoc training may be more specific.

If FDRs have completed the training available through the CMS Medicare Learning Network (MLN) at http://www.cms.gov/MLNProducts or via the ICE or another credible training option, they are not required to complete the Plan training. They can submit the training certificate from MLN or another credible entity instead and be deemed "trained."

FWA Training includes:

- Laws and regulations related to MA and Part D FWA (False Claims Act, Anti-Kickback statute, HIPAA/HIGHTECH, etc.);
- FDR obligation to have FWA policies and procedures;
- Processes for reporting FWA to FDR or Astiva Health;
- Protections for FDR employees and others who report FWA (no retaliation policy);
- Types of FWA that can occur in the FDR setting;
- How to report potential FWA to AH via email to: Hotline@astivahealth.com; or by telephone to the Compliance Officer at 909-630-2031; or by email to Compliance@astivahealth.com.

Record Retention – Evidence of Training
Medicare requires health plans and providers (FDRs) to retain *all records* for a minimum of ten (10) years. This includes records as proof of training and training materials must be retained for the ten-year period to enable CMS to audit training records. Plans and providers must be able to demonstrate evidence of training via: attestations, sign-in sheets, tests, test scores, certificates, etc. AH accepts FWA Certifications from those who

completed requirements through Medicare websites. They are deemed to have met the training and educational requirements for FWA.

Chapter Four

Effective Lines of Communication

(Medicare Managed Care Manual, Part C, Chapter 21.50.3; Prescription Drug Manual, Chapter 9.50.3)
42 CFR §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

The Plan has established lines of communication that ensure confidentiality between the Compliance Officer, Compliance staff, members of the compliance committee, employees, managers, the Board of Directors, FDRs, and the public or other interested parties. The Plan has a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to, reporting potential issues, conducting self-evaluations, audits, and remedial actions, and reporting to appropriate officials.

Matters of non-compliance (compliance issues) or reports of potential fraud, waste, or abuse (**FWA**) can be reported via a confidential and anonymous toll free "Hot Line" 866-860-0008. The Plan has an email box available to those who wish to report via confidential email, Hotline@astivahealth.com. Documentation is maintained in a confidential shared drive, "Hotline." The Plan also accepts online reports at www.lighthouse-services.com/astivahealth. Only the Compliance Officer or Special Investigation Unit (**SIU**) staff have access to receive these confidential reports.

Effective Lines of Communication Among the Compliance Officer, Compliance Committee, Employees, Governing Body, and FDRs

(Medicare Managed Care Manual, Part C, Chapter 21.50.4.1; Prescription Drug Manual, Chapter 9.50.4.1)
42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

Compliance Officer and Compliance Committee:

The Compliance Officer (**CO**) is the Chair of the Compliance Committee (**CC**) and sets the agenda. The agenda includes changes and new information from CMS via the sharing of HPMS memos, audit findings, monitoring reports, issues of significant non- compliance, FWA summary reports and closed cases of significant non-compliance, etc. Decision-making leaders from each department are given opportunities to openly discuss issues, barriers to compliance, or concerns they may have. The CO communicates changes in regulations, requirements, company policies and procedures, and the Code of Conduct. The committee approves many compliance-related training materials, reports, etc. Contemporaneous minutes are maintained and approved.

Chief Compliance Officer (**CO**) and Employees:

The CO is available to all employees via an "open door policy." Employees can come to the

CO with any issues, concerns, or barriers to compliance. CO is available by cell phone 24/7. They may also share any concerns regarding suspicious activities, potential fraud, waste, or abuse. The CO issues memoranda, Medicare Alerts, and other written communications to employees and contracting staff, as required. Each memo includes the Compliance Officer's name, email address, and contact information. The CO and/or Compliance Department staff conduct training meetings with employees, leadership, contracting staff, and consultants as needed from time to time. The CO and staff receive and answer compliance questions for staff and FDRs daily.

Compliance Officer and Compliance Committee with the Board of Directors:

The CO is invited to the quarterly meetings of the Board of Directors (BOD). The CO shares with the board compliance risks, issues of compliance, audit findings, and recommendations to improve compliance through new processes or the addition of needed resources. The CO shares FWA trends and summary information as well as any significant fraud uncovered and corrected. The CO shares appeals and grievance trends and interventions with the BOD. The BOD may recommend additional activities and interventions they wish to have carried out. The CO is responsible for ensuring the effective oversight of implementation of such activities and interventions. The CO communicates requests / required actions from the Board of Directors. The CO communicates to the Board of Directors regarding activities and compliance issues during quarterly meetings, or as needed by email or memo. The HPMS Memo Tracking Log is posted in the AH SharePoint where staff can access any memo at any time to view or review the details. They may also request additional training from the Compliance Officer.

50.4.2 – Communication and Reporting Mechanisms
(Medicare Managed Care Manual, Chapter 21. 50.4.2; Prescription Drug Manual, Chapter 9. 50.4.2)

42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

Mandated Reporting

AH / The Plan requires employees to report possible ethical issues. The Plan offers several channels by which employees and others may report ethical concerns or incidents, including, without limitation, concerns about violation of this code, Plan policies, accounting, internal controls, or auditing matters. The Plan provides an anonymous Compliance Hotline telephone number and voice mail that is available 24 hours a day, seven days a week. The Plan prohibits retaliatory action against any individual for raising concerns or questions regarding ethical matters, or for reporting suspected violations done so in good faith.

Communication and Reporting Mechanisms

The Plan communicates and reminds staff and FDRs regarding the importance of reporting and how to report potential compliance issues including but not limited to fraud, waste, and

abuse; HIPAA violations; other ethical concerns. Information about "how to report" is included in but not limited to the following:

- New employee and annual mandated training materials and discussion
- Code of Conduct, Compliance Program, related Compliance Policies & Procedures
- Reminders included in meetings or sent by email.

Reporting information is as follows:

By toll free telephone: **Compliance Hotline: 866-860-0008**

By cell phone to the Compliance Officer: 909-630-2031

By mail: Compliance Officer:
_____
3200 Bristol Street, Suite 640, Costa Mesa, CA 92626

By email: Compliance@astivahealth.com or
anonymous reporting:
Hotline@astivahealth.com

Communications with the FDRs takes place in a variety of ways:
Providers receive information and communication from AH in many ways including but not limited to the following:

- "**Astiva Health Alerts**" – are posted on the website: www.astivahealth.com;
- **Email Blasts –** information and non-PHI documents are blasted by email;
- **JOUM** – Joint Operations/Utilization Management meetings are scheduled monthly, bi-monthly, quarterly, or semi-annually depending on the performance of the group and the length of time they have been with the Plan;
- **Letters –** individual letters of non-compliance or disciplinary action are sent by mail and or email.
- **Mail and Faxes –** of Individual Care Plans, Predictive Modeling Reports, Listings of preventive services due, Incentive bonuses, etc.
- **Newsletters –** regarding QI Program and results
- **Outbound phone calls** – from Provider Services and/or other Plan departments;
- **SFTP –** sensitive documents including member specific data are posted on Secure File Transfer Protocol (SFTP);
- **Training Materials –** sent by various methods;

- **Webinars –** training and topics of interest may be conducted by webinar by various departments;
- **Website –** posting information on the AH website: www.astivahealth.com.

50.4.3 – Enrollee Communications and Education

(Medicare Managed Care Manual, Chapter 21.50.4.3; Prescription Drug Manual, Chapter 9.50.4.3)
42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

The Plan communicates with members in multiple ways such as but not limited to the following:

- **Letters –** individual letters of non-compliance or disciplinary action are sent by mail and or email.
- **Mail –** of Individual Care Plans;
- **Newsletters –** regarding QI Program and results; educational articles; and encouragement;
- **Outbound phone calls** – from Care Managers and other nurses and staff;
- **Educational Materials –member-level materials for ease in understanding;**
- **Fraud Scam Alerts –** sent by various methods;
- **Webinars –** training and topics of interest may be conducted by webinars; and
- **Website –** posting information on the AH website: www.astivahealth.com.

Chapter Five

Well-Publicized Disciplinary Standards

(Medicare Managed Care Manual, Part C, Chapter 21.50.5; Prescription Drug Manual, Chapter 9.50)
42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

The Plan has a Code of Conduct that includes the company's expectations / requirement regarding reporting compliance issues. The Code of Conduct clarifies the need to identify and report noncompliance and unethical behavior. AH includes the fact that disciplinary actions will be taken, up to and including termination of employment for violating the Code of Conduct. The Plan ensures timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

50.5.1 – Disciplinary Standards

(Medicare Managed Care Manual, Part C, Chapter 21. 50.5.1; Prescription Drug Manual, Chapter 9. 50.5.1)
42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

The Plan has published disciplinary policies and procedures that reflect clear and specific disciplinary standards. The disciplinary policies describe the sponsor's expectations for the reporting of compliance issues including noncompliant, unethical, or illegal behavior, that employees participate in required training, and the expectations for assisting in the resolution of reported compliance issues.

The policies have some examples of noncompliant, unethical, or illegal behavior, through examples of violations. Disciplinary action is determined based on the seriousness of the violation.

Methods to Publicize Disciplinary Standards

(Medicare Managed Care Manual, Chapter 21. 50.5.2; Prescription Drug Manual, Chapter 9. 50.5.2)
42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

The Plan publishes its expectation of reporting Compliance, FWA, and other Ethical concerns via some of the following:

- Regular discussions in committees and in department staff meetings;
- Communications with FDRs such as the Provider Manual and sharing the AH Code of Conduct;
- General compliance training;

- Internet website;

The Plan investigates each report to identify non-compliant or unethical behavior.

Enforcing Disciplinary Standards
(Medicare Managed Care Manual, Chapter 21. 50.5.3; Prescription Drug Manual, Chapter 9. 50.5.3)
42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Highest Priority
Astiva Health considers unethical behavior and fraudulent activities or other violations of the Code of Conduct to be serious offenses. These issues are of highest priority. The Plan expects members to be treated and spoken to respectfully and kindly. The Plan expects truthfulness from employees and contractors.

Records of Issues and Actions
The Compliance Department and/or the Human Resources Department documents compliance violations and disciplinary actions, noting the date the violation was reported, details of the violation, dates of investigations, investigator's name and job title, findings, disciplinary action taken and the date it was taken. All Medicare records are maintained for a period of 10 years.

Monitoring for Consistent and Timely Actions
The Compliance Officer is to be copied on any such discipline for tracking purposes at a minimum. They are reviewed to ensure that disciplinary actions are appropriate to the seriousness of the violation, fairly and consistently administered, and imposed within a reasonable timeframe. The Compliance Officer sends reports to the Human Resources director / staff regarding non-compliance, fraud, waste, or abuse with a request that the notation be placed in the employee's personnel files and considered during the individual's annual performance review. The Plan may or may not (due to the small size of the company) publish de-identified disciplinary action in employee publications, such as a by email or in a committee report, in order to demonstrate to employees that disciplinary action is imposed for violations.

Chapter Six

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

(Medicare Managed Care Manual, Chapter 21. 50.6; Prescription Drug Manual, Chapter 9. 50)
42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Committee Monitoring

The Plan conducts routine monitoring to identify areas of deficiency, poor performance and compliance risks. The Plan accomplishes this by reviewing data in standing committees and work groups such as but not limited to the following:

- Compliance Committee (CC);
- Quality Committee (QC);
- Utilization Management Committee (UMC);
- FDR – Delegation Oversight Committee (DOC)
- Vendor Oversight Team (VOT)
- Special Investigations Unit (SIU)
- SNP Directors Committee
- Credentialing and Peer Review Committees
- Provider Relations meetings

Additionally, AH conducts internal and external audits to evaluate the Plan's and FDR's compliance with CMS requirements and the overall effectiveness of the compliance program.

Routine Monitoring and Auditing

(Medicare Managed Care Manual, Chapter 21. 50.6.1; Prescription Drug Manual, Chapter 9. 50.6.142 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Internal Auditing

The Plan conducts internal audits to measure the company's compliance with State and Federal regulations, and company policies and procedures to ensure timely, quality care for its members, and to identify noncompliance and potential FWA.

Monitoring

Per CMS, "Monitoring activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective." Monitoring can be self-reported by a department.

Auditing

Per CMS, "An audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures." Auditing is performed by a qualified person who is not part of the specific area being audited.

The Plan has a "Compliance Internal Audit" (CIA) auditing schedule. Barring unexpected, unavoidable other events (such as audits from CMS or other external entities). The initial audit schedule is developed considering the scores in the annual risk assessment. AH adheres to the CIA auditing schedule as much as possible. The schedule may be altered when a "hot topic" is reported or discovered. The Compliance Officer may reorder the audit schedule to expedite auditing of more critical areas as priorities. When the schedule must be adjusted, it is done so to ensure that areas of greater risk are audited and areas of lesser risk are the ones postponed.

Auditing Team

The Compliance Department has a designated Compliance Internal Auditor (CIA). The CIA reports audit findings to the Compliance Officer and compliance committee preferably after sharing them privately with the department leadership. Senior management is involved during review of findings. The Compliance Officer may request specific department leaders to conduct "self-audits," as a first step or corrective action. Compliance staff may review (over-read) their work for accuracy.

Responsibility

The auditing schedule is developed by the Compliance Officer with the CIA and the Director of Compliance. The compliance department staff assists and conducts actual audits. Consultants may be hired to conduct audits as well. The Compliance Officer (CO) may personally conduct some audits. Results and "findings" (deficiencies) from audits are reported to the CO and summary reports are shared with the Compliance Committee. Corrective actions may be required and tracked by the Enterprise Compliance Committee (ECC) and the CO or a designated party. The CO also reports audit results to the CEO, CMO, COO, senior leadership and the Board of Directors as appropriate and required.

External Auditing

The Plan conducts external audits of its FDRs that have been delegated functional duties such as Contracting, Credentialing, Utilization Management, Claims, Pharmacy Benefit Management (**PBM**), Management Service Organization (**MSO**), Administrative Services Organizations (**ASOs**), Transition of Care (**TOC**) Protocol, Model of Care (**MOC**) standards, Medication Therapy Management (**MTM**) vendors, Field Marketing Organizations (**FMOs**), etc. Ideally, Auditing is conducted "pre-delegation" or as soon thereafter as a contract is signed with the entity, and annually thereafter. There may also be focused audits (**FAs**) when there is a deficiency that could put members at risk. Corrective Action Plans (**CAPs**) are required when performance does not meet required thresholds and when there are deficiencies noted during the audit (unless an extension is given to enable the audited area to regain compliance within the next month).

Delegation may be revoked at any time due to repeated inadequate performance by the delegate. External auditing is monitored by the Delegation Oversight Committee (**DOC**) and

its auditors and key stakeholders. The DOC reports to the Enterprise Compliance Committee (**ECC**) and seeks guidance from them. Some vendors are also audited.

Development of a System to Identify Compliance Risks
(Medicare Managed Care Manual, Chapter 21.50.6.2; Prescription Drug Manual, Chapter 9. 50.6.2)
42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)
The Plan conducts an annual overall risk assessment (annually at a minimum) to identify areas of potential risk. The assessment includes all business operational areas. Each operational area must be assessed for the types and levels of risks the area presents to members and to the company. Factors considered in determining the risks associated with each area include, but are not limited to:

- Size of department;
- Complexity of work;
- Volume of work;
- Amount of training that has taken place;
- Completeness and current maintenance of Policies and Procedures;
- Timeliness and accuracy of work;
- Competency of leadership of the area;
- Recent compliance issues;
- Etc.

Areas of Special Concern
Medicare has indicated that areas of particular concern for Medicare Parts C and D sponsors are areas with a high beneficiary impact. This would include, but is 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 also of concern to AH.

National Medicare Program Audit results are published annually on the CMS website and can indicate the common areas of deficiencies and non-compliance. The Compliance Officer (**CO**) reviews the CMS report and considers those areas to be "high-risk" as well. Other Medicare alerts and memos from CMS may indicate areas in which non-compliance is prevalent. The Plan also received information from its Regional Office Manager regarding areas to be watched carefully. The CO considers these high-risk areas when completing or updating the Annual Risk Assessment.

Scoring and Prioritizing Risks
The risk tool assigns a score to each element to indicate which risk areas will have the

greatest impact on the company. The tool includes a "weight" (multiplier) based on the impact that non-compliance would have on beneficiaries (beneficiary impact). AH prioritizes its auditing strategy based to some degree on the Annual Risk Assessment, and heavily considers areas of non-compliance that appear throughout the year.

Re-evaluations

Because laws, regulations, staff, resources, and other factors are always changing, there must be ongoing review and re-evaluation of potential risks of noncompliance and FWA. Risk areas identified through CMS audits and oversight, as well as through the sponsor's own internal monitoring, audits and investigations are priority risks.

Development of the Monitoring and Auditing Work Plan / Schedule

(Medicare Managed Care Manual, Chapter 21 .50.6.3; Prescription Drug Manual, Chapter 9.50.6.3)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Results of the risk assessment help develop the Compliance Internal Auditing (CIA) audit schedule. AH prioritizes (and reprioritizes, adjusting the CIA audit schedule as needed throughout the year. Not all audits scheduled will be completed based on varying factors including staffing which is a challenge in a small health plan. The high-risk areas are of greatest concern and will be audited unless they are bumped out of the schedule by urgent and higher priority risks that appear throughout the year. Issues with high beneficiary impact are of greatest concern. AH schedules re-audits when an area is found to have multiple findings that put members and the company at risk. Corrective actions are required for deficiencies. Corrective action and follow-up are overseen by the Compliance Officer with compliance department staff.

Audit Schedule and Methodology

(Medicare Managed Care Manual, Chapter 21. 50.6.4; Prescription Drug Manual, Chapter 9. 50.6.4)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

The CIA Auditing Schedule includes a schedule that lists all of the internal operational monitoring and compliance auditing activities for the calendar year. (Adjustments are made as needed.) Monitoring is completed by operational areas and reported to Compliance. AH uses a combination of desk and on-site audits.

AH utilizes audit tools (including but not limited to the CMS audit tools). The scored audit tool may serve as the audit report or a Final Report may be drafted. For the FDRs, a written letter/report the FDR explains the findings, recommendations, and requirements for corrective actions. AH conducts follow up audits as appropriate to re-audit areas previously found non-compliant to determine the effectiveness of the corrective actions taken.

CMS requires Internal Auditing, Internal Operations Monitoring, and FWA cases to be reported in the CMS Medicare Program Audit universes for Compliance Oversight Activities (**COA**) as required.

Audit of the Sponsor's Operations and Compliance Program
(Medicare Managed Care Manual, Chapter 21. 50.6.5; Prescription Drug Manual, Chapter 9. 50.6.5)
42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Audit of Operations
The Compliance Officer and compliance committee take into consideration the small size of the health plan when developing the CIA Audit Schedule. Monitoring must be performed by the department being audited and then spot checked for accuracy by the Compliance Department. Audits conducted as required or if need arises due to non-compliance noted within monitoring efforts by operations. Auditors must be knowledgeable about CMS operational requirements for the areas under review. Auditors may include SMEs such as pharmacists, nurses, physicians, certified public accountants, fraud investigators, and compliance staff. Final audit results are from the Compliance staff who may not engage in self-policing. Auditing confirms the effectiveness of the compliance program, and the results must be shared with the Compliance Committee and the Board of Directors.

Auditing the Compliance Program Effectiveness
Audits of the compliance program are to occur at least annually. In order to avoid self- policing, the plan outsources the audit to external third-party auditors.

Monitoring and Auditing FDRs
(Medicare Managed Care Manual, Chapter 21.50.6.6; Prescription Drug Manual, Chapter *9.* 50.6.6*)*
42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

AH audits and monitors its first-tier entities (**FTEs**) to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first-tier entities are monitoring the compliance of the entities with which they contract (the sponsors' "downstream" entities).

AH has a unit to monitor delegated first tier, downstream, and related entities (**FDRs**). AH is responsible and must conduct specific monitoring of first tier entities to ensure they fulfill the compliance program requirements. Monitoring the first-tier entities for compliance program requirements must include an evaluation to confirm that the first-tier entities are applying appropriate compliance program requirements with downstream entities with which the first-tier contracts.

AH requests data as part of reports that FDRs must submit routinely to the Plan. Data from the FDRs may include some or all of the following;

• **Payment Reports** that detail the amount paid by both the sponsor and the enrollee; in addition, payment reports identifying the provider, the enrollee, and a description of the drug (including dosage and amount) or service provided. These reports should be used to identify over and under payments, duplicate payments, timely payments, and pricing aberrances, and to help verify correct pricing;

• **Drug Utilization Reports** that identify the number of prescriptions filled by a particular enrollee and in particular, numbers of prescriptions filled for suspect classes of drugs, such as narcotics, to identify possible therapeutic abuse or illegal activity by an enrollee. Enrollees with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports. Likewise, Drug Utilization Management reports from FDRs may be a useful tool in identifying FWA;

• **Provider Utilization Reports** that identify the number and types of visits and services submitted for payment to identify possible spikes and/or irregularities such as a provider submitting claims for services that would not normally be performed by the provider's specialty;

Prescribing and Referral Patterns by Physician Reports that identify the number of prescriptions and referrals written by a particular provider and typically focus on a class or particular type of drug, such as narcotics, or a specific type of DME, such as scooters. These reports should be generated to identify possible prescriber and referral/provider, pharmacy fraud and DME fraud; and

• **Geographic ZIP Reports** can identify possible doctor shopping schemes or script mills by comparing the geographic location (ZIP code) of the patient to the location of the provider that wrote the prescription and should include the location of the dispensing pharmacy. These reports should generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (for example, 30 miles). "Normal distance" should consider where the enrollee resides (i.e., enrollees in rural areas would typically have longer trips to a doctor or pharmacy than enrollees living in urban areas).

When corrective action is needed, AH meets (by webinar usually) with the FDR and requires that corrective actions are taken by the entity. AH is obligated to perform its auditing of first tier entities regardless of any self-auditing the FDR may conduct.

Tracking and Documenting Compliance and Compliance Program Effectiveness
(Medicare Managed Care Manual, Chapter 21. 50.6.7; Prescription Drug Manual, Chapter 9. 50.6.)
42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

The Plan tracks and documents its compliance efforts. Ideally, dashboards showing the compliance rates of various departments and functions enable the Compliance Officer, the Compliance Committee, and the Board of Directors to identify trends of non-compliance and dedicate resources to areas of greater risk any given month. The Dashboard of "Key Performance Indicators" (**KPIs**) are reviewed and discussed monthly during the compliance committee. Dashboards are available to the Board of Directors.

OIG/GSA Exclusion

(Medicare Managed Care Manual, Chapter 21.50.6.8; Prescription Drug Manual, Chapter 9.50.6.8)

The Act §1862(e)(1)(B), 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901

The Plan is committed to ensuring that no one on any OIG or GSA Exclusion List or Preclusion List is able to participate in any AH or FDR program. Medicare payment may not be made for items or services furnished or prescribed by an excluded provider or entity. Precluded provider payments must be stopped within 90 days of the provider being added to the Preclusion List. AH must ensure it does not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the DHHS OIG or GSA.

Identifying Excluded Individuals, Providers, and Entities

The Human Resources Director reviews the DHHS OIG List of Precluded and Excluded Individuals and Entities (LEIE list) and the GSA Excluded Parties Lists System (EPLS) prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, to ensure that none of these persons or entities are excluded from participation in any Medicare funded program. Monthly the exclusion listings are reviewed to ensure that no individuals, providers, or entities have recently become excluded from participation in federal programs. If so, their services are terminated immediately, and members are transferred to other providers. The AH PBM (Elixir) is also responsible for monthly screening of providers and pharmacies to ensure no prescriptions are filled from Precluded or Excluded Providers. This is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to exclusions lists since the last time the list was checked. After entities are initially screened against the entire LEIE and EPLS at the time of hire or contracting, sponsors need only review the LEIE supplement file and Preclusion List provided each month, which lists the entities added to the lists that month. The EPLS updates provided during the specified monthly time frame are also reviewed.

Reporting

Should a Precluded or Excluded Provider be identified as participating their services are terminated immediately and the matter is reported promptly to the Compliance Officer for action. If a payment is found the payment is to be recovered.

Use of Data Analysis for Fraud, Waste and Abuse Prevention and Detection
(Medicare Managed Care Manual, Chapter 21.50.6.9; Prescription Drug Manual, Chapter 9.50.6.9)
42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Monitoring through Data Analysis
Astiva Health conducts monitoring in order to prevent and detect FWA by pulling data reports specifically designed to help identify potential FWA. Data analysis may include the comparison of claims' information against other data (e.g., provider, drug or medical service provided, diagnoses or beneficiaries) to identify *unusual patterns* suggesting potential errors and/or potential fraud and abuse. Data analysis may factor in the particular prescribing and dispensing practices of providers who serve a particular population (e.g., long term care providers, assisted living facilities, etc.). Duplicate billing is monitored and recovered monthly. Use of data analysis may include monitoring pharmacy and medical billing to detect *unusual patterns*.

Responsibilities
Identifying potential FWA is the responsibility of every employee, contractor, provider, and member, but some have better skills and the ability to pull and analyze data. The information technology department is key in developing and generating ad hoc and monthly reports to assist various departments and the Compliance Department in identifying possible areas of concern.

The PBM also generates and shares reports that assist AH in identifying providers that should be monitored closely due to *unusual patterns* of prescribing.

Data Analysis Is Valuable Because:

• It Establishes baseline data to enable AH to recognize unusual trends, changes in drug utilization over time, physician referral or prescription patterns, and plan formulary composition over time;

• It enables AH to analyze claims data to identify potential errors, inaccurate TrOOP accounting, and provider billing practices and services that pose the greatest risk for potential FWA to the Medicare program;

• It identifies items or services that are being over utilized;

• It identifies problem areas within the plan such as enrollment, finance, or data submission;

• It identifies problem areas at the FDR (e.g., PBM, pharmacies, pharmacists, physicians, other health care providers and suppliers); and

• AH can use findings to determine where there is a need for a change in policy.

Special Investigation Units (SIUs)
(Medicare Managed Care Manual, Chapter 21.50.6.10; Prescription Drug Manual, Chapter

9.50.6.10)

SIU

The Plan has policies and procedures and some statistical norms used to identify and address FWA at both the Plan and FDR levels in the delivery of Parts C and D benefits. Within the Compliance Department there is a Special Investigations Unit (SIU) to prevent, detect, and correct fraud. For each case, the Compliance Officer appoints subject matter experts (**SME**s) as needed for SIU investigations.

Teams are overseen by the Compliance Officer (**CO**). The CO also appoints a Team or Case Lead for each case to ensure case documentation, and appropriate investigative steps as well as to answer questions related to compliance. The SIU team is responsible for conducting surveillance, interviews, data mining, and other investigation relating to the potential FWA. AH is not responsible to perform law enforcement activities and may refer all matters indicative of FWA to the CMS I-MEDIC, OIG, DOJ, or law enforcement.

SIU Responsibilities Include:

- Reducing or eliminating inappropriate Medicare Parts C and D benefit costs due to FWA;
- Reducing or eliminating fraudulent or abusive claims paid for with federal dollars;
- Preventing illegal activities;
- Identifying enrollees with overutilization issues;
- Identifying and recommending providers for exclusion, including those who have defrauded or who may have abused the system. Reporting to the NBI-MEDIC, I-MEDIC, OIG, CMS Program Integrity, and/or other agencies and law enforcement;
- Referring suspected, detected or reported cases of illegal drug activity, including drug diversion, to the I-MEDIC and/or law enforcement and conducting case development and support activities for I-MEDIC and law enforcement investigations; and
- Assisting the OIG with case investigation upon request.
- Assisting law enforcement by providing information needed to develop successful prosecutions.

Mandatory Reporting of Suspected FWA

Anyone can and must report suspected FWA. Suspicious activities and unethical behavior possibly related to FWA are to be reported immediately as follows:

By toll free telephone: **Compliance Hotline: 866-860-0008**
By cell phone to the Compliance Officer: 909-630-2031

By mail: Compliance Officer:
Astiva Health
3200 Bristol Street, Suite 640

Costa Mesa, CA 92626

By email: Compliance@astivahealth.com or
Hotline@astivahealth.com

Issues must be reported the same day or next day at the latest, whenever possible, but no later than 60 days after the occurrence of non-compliance. The Plan also reports FWA as quickly as possible to any entities that are delegating services to Astiva Health and other entities with whom Astiva Health subcontracts. The Plan additionally submits monthly reports to delegating entities that require it, per their schedule.

Anonymity

FWA can be reported anonymously to the Compliance Officer (or other compliance staff), to a supervisor, to Human Resources, to a Board Member, or to senior management. Unless the Compliance Officer (**CO**) is suspected to be involved, the CO is notified by the person receiving the report. Anonymity is preserved to the greatest extent possible. Must be reported in good faith.

Auditing by CMS or its Designee

(Medicare Managed Care Manual, Chapter 21.50.6.11; Prescription Drug Manual, Chapter 9.50.6.11)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 422.504(e)(2), 423.505(e)(2)

The Plan and its FDRs understand that CMS has the discretionary authority to perform audits under 42 C.F.R. 44 422.504(e)(2) and 423.505(e)(2), which specify the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of sponsors or FDRs that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract.

Audits

The Plan and its FDRs allow access to any auditor acting on behalf of the federal government or CMS to conduct an on-site audit. (Delegated entities have the right to inspect books and operations at any time.) On-site audits require a thorough review of required documentation. Such reviews include any information needed to determine compliance with the Medicare Parts C and D regulations and contracts, such as copies of prescriptions, invoices, provider and pharmacy licenses, claims records, signature logs, records documenting delivery status by postal carrier, long-term care delivery notice to nursing staff, other forms of documentation of medication delivery, purchase records, contracts, rebate and discount agreements, as well as interviews of the staff. The interviews gauge whether control activities are practiced as dictated by the company's policy and applicable Parts C and D requirements are being followed. On-site audits are based on sampling or results of desk audits. In most cases, CMS or its designee provides reasonable notice to the sponsor of the time and content of the audit. Reasonable notice is also expected from any

delegating entities.

Additionally, the OIG has independent authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement.

Document Requests

The Plan and its FDRs provide records to CMS or its designees and cooperates in allowing access as requested. CMS hires contractors at times to conduct their audits. Requests for audits may come from the I-MEDIC, OIG, FBI, and other contractors. Contractors trained by CMS and engaged to conduct CMS data validation audits, and other audits are acting on behalf of the federal government and are not required to sign the sponsor's confidentiality statement prior to the start of an on-site audit. The Plan and FDRs are required by contract to cooperate with CMS and CMS contractors by providing CMS and their contractors access to all requested records associated in any manner with the Parts C or D program.

Turnaround Time Expectations

When CMS or its designee (e.g., the I-MEDIC) requests information that will be used for an audit, CMS or its designee notifies the sponsor of the time period within which AH or the FDR must provide the requested information.

Chapter Seven

Procedures and System for Prompt Response to Compliance Issues

(Medicare Managed Care Manual, Chapter 21.50.7 Prescription Drug Manual, Chapter 9.50.7 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

The Plan promptly responds to compliance issues as they are raised. The Compliance Department tracks each compliance issue brought to its attention to ensure timely processing. The Compliance Officer and/or designated staff investigate potential compliance problems that may be identified by any means. The Plan corrects such any non-compliance promptly and thoroughly to reduce the potential for reoccurrence, and to ensure ongoing compliance with CMS requirements.

1. If AH discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

2. AH must also conduct appropriate and timely corrective actions (for example, repayment of overpayments, disciplinary actions against responsible individuals) in response to the potential violation referenced above.

3. AH voluntarily self-reports potential fraud or misconduct related to the Medicare program to its appointed CMS Regional Office Account Manager (**ROAM**) and/or to the MEDIC as appropriate or as requested by the ROAM.

Conducting a Timely and Reasonable Inquiry of Detected Offenses

(Medicare Managed Care Manual, Chapter 21.50.7.1; Prescription Drug Manual, Chapter 9.50.7.1)
42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Inquiry / Investigation

The Compliance Department conducts timely and well-documented reasonable inquiry into any compliance incident or issue involving potential Medicare program noncompliance or potential FWA. Program noncompliance and FWA may occur at the level of the sponsor or its FDRs. Every report is taken seriously and investigated.

Timely Investigation

AH initiates a reasonable inquiry as quickly as possible. The goals are to acknowledge most cases and appoint a case Lead within five (5) business days and start the investigation within two (2) weeks after the date the potential noncompliance or potential FWA incident was identified or reported. Because the Plan is small and its resources are limited, the Compliance Officer (CO) prioritizes cases and works with those with the greatest beneficiary impact first. CMS MEDICs must close every case within 180 days, even if the case was not resolved. The Plan follows the same guidelines.

Responsibility to Monitor and Report

The Plan monitors FWA and Medicare program noncompliance within its own departments. When serious noncompliance or waste occurs, AH refers the matter to its appointed CMS Regional Office Account Manager (**ROAM**). When significant and appropriate, AH refers the matter to the appropriate I-MEDIC or other agency or law enforcement, as appropriate in each case.

Corrective Actions

(Medicare Managed Care Manual, Chapter 21.50.7.2; Prescription Drug Manual, Chapter 9.50.7)

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Root Cause Analysis and Resolution

AH is committed to correcting any and all noncompliance and FWA. AH conducts root cause analysis, and any corrective actions must be designed to correct the underlying problems identified that resulted in program violations in order to prevent future noncompliance. Corrective actions must include timeframes for specific achievements. Reaudits are ideal to determine the effectiveness of the CAP after it is fully implemented.

FDR Oversight

The Plan must ensure that FDRs have corrected their deficiencies. This is best accomplished by re-measuring after the CAP has been fully implemented. Requests / requirements for FDR Corrective Action Plans (CAPs) for FWA or program noncompliance must be in writing and must include ramifications if the FDR fails to implement the corrective action satisfactorily. Some FWA cases also include required corrective actions.

AH Contract Language with FDRs

The AH contract with an FDR should include language that details the ramifications if the FDR fails to maintain compliance or engages in FWA. This may result in contract termination depending on the infraction.

Monitoring FDR's CAP Effectiveness

AH conducts independent audits or reviews the FDR's monitoring or audit reports and continues to monitor corrective actions after their implementation to ensure that they sustain compliance.

FWA Committed by Employees

If AH identifies employees involved in FWA and decides not to terminate the employment, AH must retrain the employee and monitor the employee closely. The CAP must address the noncompliance or FWA committed by the employee(s) or FDRs and must include ramifications should the sponsor's employee(s) or its FDRs fail to satisfactorily implement the corrective action. AH will enforce effective correction through disciplinary measures, including employment or contract termination, if warranted.

Thorough documentation must be maintained of all deficiencies identified and corrective

actions taken.

50.7.3 – Procedures for Self-Reporting Potential FWA and Significant Non Compliance
(Medicare Managed Care Manual, Chapter 21.50.7.3; Prescription Drug Manual, Chapter 9.50.7.3)
42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Self-Reporting
The Plan is committed to self-reporting of FWA and Medicare program noncompliance to its CMS Regional Office Account Manager although such reporting is voluntary. AH will self-report potential FWA discovered at the plan level, and potential fraud and abuse by FDRs, as well as significant waste and significant incidents of Medicare program noncompliance.

The Plan also reports FWA to the Congressionally approved, CMS sponsored "Healthcare Fraud Prevention Partnership" (**HFPP**). The Plan voluntarily send data to HFPP for analysis and detection of potential fraud schemes. Additionally, the plan reports to the HFPP any FWA it has found or suspects. This is bumped against data from other health plans to see if other health plans are finding the same issues with certain providers, etc. There is no cost to join the HFPP. CMS sponsors the cost because if finds and stops FWA so effectively.

When appropriate, AH will notify the MEDICs of potential FWA in accordance with the guidelines described below, the MEDICs refer potential FWA to law enforcement when appropriate. AH understands that issues that are referred to the MEDIC may require the Plan's cooperation in the investigation.

Timely Investigation
The Plan investigates potential FWA activity to decide whether potential FWA has occurred. The Plan makes every effort to conclude investigations of potential FWA within a reasonable time period, as soon as possible after the activity is discovered.

Reporting to the MEDIC
If after conducting a reasonable inquiry, the sponsor (e.g., the Compliance Officer or SIU) determines that potential FWA related to the Medicare Parts C or D programs has occurred, the matter will be referred to the MEDIC promptly. Sponsors should also refer potential FWA at the FDR levels to the MEDIC so that the MEDIC can help identify and address any scams or schemes.

Other Reporting
The Plan also considers reporting potentially fraudulent conduct to government authorities such as the Office of Inspector General (**OIG**) (through the OIG's Provider Self- Disclosure Protocol) or to the Local OIG office, or to the Department of Justice as may be appropriate.

Who Can Report
All health care providers doing business with Medicare that want to disclose violations of law are eligible to disclose fraudulent conduct under the Provider Self-Disclosure Protocol. The Protocol offers a detailed step-by-step explanation of how a provider should proceed in reporting and assessing the extent of potential fraud and how the OIG will go about

verifying irregularities.

If AH discovers an incident of significant noncompliance with the Medicare program the SIU or the Compliance Officer reports the incident to CMS as soon as possible after its discovery. CMS will provide guidance regarding mitigation of the harm caused by the incident of noncompliance. The AH Compliance Officer uses his/her best judgment to determine what is a "significant" or "serious" incident that should be reported. AH will err on the side of over-reporting rather than under-reporting.

The Plan understands that self-reporting offers the opportunity to minimize the potential cost and disruption of a full-scale audit and investigation, to negotiate a fair monetary settlement, and to potentially avoid an OIG permissive exclusion preventing the AH from doing business with Federal health care programs.

The MEDIC

(Medicare Managed Care Manual, Chapter 21.50.7.4; Prescription Drug Manual, Chapter 9.50.7.4)

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

What are MEDICs

Medicare Drug Integrity Contractors (**MEDICs**) are organizations that CMS contracts with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program.

What Is the Role of a MEDIC

The MEDIC's primary role is to identify potential fraud and abuse in Medicare Part C and Part D. The I-MEDIC investigates referrals from sponsors, develop the investigations, and make referrals to appropriate law enforcement agencies or other outside entities when necessary. The MEDICs must close all cases 180 days after the case is opened, regardless of whether or not the case has been resolved. The Plan can submit a new case identifying the MEDIC investigator on the previous case to continue an investigation when significant and appropriate. The *MEDIC will keep the sponsor apprised of the development and status of the investigation.* The Plan has the right to call and request the status of the case at any time. If the MEDIC determines a referral to be a matter related to noncompliance or mere error rather than fraud or abuse, the matter will be returned to CMS and/or the sponsor for appropriate follow-up.

Referral Criteria – What to Report to the MEDIC

Cases involving potential fraud or abuse that meet any of the following criteria are to be reported to the MEDIC:

- Suspected, detected, or reported criminal, civil, or administrative law violations;
- Allegations that extend beyond the Parts C and D plans, involving multiple health plans, multiple states, or widespread schemes;
- Allegations involving known patterns of fraud;

- Pattern of fraud or abuse threatening the life or wellbeing of beneficiaries; and
- Scheme with large financial risk to the Medicare Program or beneficiaries.

Referrals to the MEDIC

(Medicare Managed Care Manual, Chapter 21.50.7.5; Prescription Drug Manual, Chapter 9.50.7.5)

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

What to Include in a Referral to the MEDIC

Referrals to the NBI MEDIC are to contain as many specifics as possible to enable an investigator to follow-up on a case including basic identifying information and contacts as well as a description of the allegations.

If available, a referral should include:

- Name of the AH Compliance Officer;
- Organization name;
- Contact information for follow up;
- Summary of the Issue: (who, what, when, where, why, and how)
- Include any potential legal violations;
  - ✓ Specific Statutes and Allegations:
  - ✓ List civil, criminal, and administrative code or rule violations, state and federal; and
- Provide detailed description of the allegations or pattern of fraud, waste, or abuse;
- Incidents and Issues (List incidents and issues related to the allegations);
- Background information: (Contact information for the complainant, the perpetrator or subject of the investigation, and beneficiaries, pharmacies, providers, or other entities involved);
- Additional background information that may assist investigators, such as names and contact information of informants, realtors, witnesses, websites, geographic locations, corporate relationships, networks;
- Perspectives of Interested Parties: o Perspective of Plan, CMS, enrollee;
- Data: Existing and potential data sources;
- Graphs and trending;
- Maps; and
- Financial impact estimates; and
- Recommendations in Pursuing the Case: o Next steps, special considerations, cautions.

MEDIC Requests for Additional Information / TAT

The MEDIC may request additional information in order to fully investigate and resolve the matter. AH will make every attempt to furnish additionally requested information within 30 days, unless the NBI MEDIC specifies otherwise. In instances where the MEDIC requires information *in less than 30 days, all parties involved will be notified* as soon as possible.

The Plan will provide updates to the MEDIC whenever new information regarding the matter is identified.

Responding to CMS-Issued Fraud Alerts
(Medicare Managed Care Manual, Chapter 21.50.7.6; Prescription Drug Manual, Chapter 9.50.7.6)
42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Actions to be Taken
When AH receives Fraud alerts issued by CMS concerning fraud schemes identified by law enforcement officials, AH takes action (including denying or reversing claims) in instances where the sponsor's own analysis of its claims activity indicates that fraud may be occurring. A sponsor's decision to deny or reverse claims should be made on a claim- specific basis.

Considering Contract Termination
AH reviews its contractual agreements with the parties identified in the CMS Alert and considers terminating the contract(s) with the identified parties if law enforcement has issued indictments against particular parties and the terms of the sponsor's contract(s) authorizes contract termination in those circumstances.

AH is also obligated to review past paid claims from entities identified in a fraud alert. With the issuance of a fraud alert, CMS has placed sponsors on notice (see 42 CFR 423.505(k)(3)) that they should review claims involving identified providers. To meet the "best knowledge, information, and belief" standard of certification, sponsors should make their best efforts to identify claims that may be or may have been part of an alleged fraud scheme and remove them from their sets of prescription drug event data submissions.

PBM Assistance
The Plan works with its PBM to identify and reverse pharmacy claims involved in schemes.

Identifying Providers with a History of Complaints
(Medicare Managed Care Manual, Chapter 21.50.7.7; Prescription Drug Manual,(Chapter 9.50.7.7)
42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G), 422.504(d)-(e)

Record Retention
The Plan maintains *all* Medicare records for a period of 10 years. This includes but is not limited to both in-network and out-of-network providers who have been the subject of complaints, investigations, violations, and prosecutions. This includes enrollee complaints, MEDIC investigations, OIG and/or DOJ investigations, US Attorney prosecution, and any other civil, criminal, or administrative action for violations of Federal health care program requirements.

AH considers maintains records including but not limited to any files that contain:
- Documented warnings (i.e., fraud alerts);

- Educational contacts;
- Results of previous investigations;
- Allegations reported; at a minimum.

The Plan always complies with requests by law enforcement, CMS, and CMS' designee regarding monitoring of providers within the sponsor's network that CMS has identified as potentially abusive or fraudulent.

Appendix A

Resources

- **Chapter 21 - Rev. 110, Rev. 110, 01-11-13** *(or a more recent version if released)*
- **Chapter 9 - Rev. 16, Rev. 110, 01-11-13** *(or a more recent version if released)*

Government Resources:

1. Investigations MEDIC (I-MEDIC) Complaint Form https://www.qlarant.com/wp-content/uploads/2020/03/Qlarant_I-MEDIC_Complaint_Form_2020_03_13.pdf

2. Stop Medicare Fraud:
https://www.stopmedicarefraud.gov

3. The Patient Protection and Affordable Care Act: http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf

4. Compliance Guidance for Medicare Organizations:
http://oig.hhs.gov/fraud/docs/complianceguidance/111599.pdf

5. Office of the Inspector General, Compliance Program Guidance for the Healthcare Industry:
http://oig.hhs.gov/compliance/compliance-guidance/index.asp

6. Federal Sentencing Guidelines:
https://www.ussc.gov/guidelines

7. Fraud Alerts, Bulletins and Other Guidance from the OIG:
http://oig.hhs.gov/compliance/alerts/index.asp

8. False Claims Act:
http://www.justice.gov/jmd/ls/legislative_histories/pl99-562/pl99-562.html

9. Health Insurance Portability and Accountability Act (HIPAA):
http://aspe.hhs.gov/admnsimp/pl104191.htm

10. Anti-Kickback Statute (see section 1128B(b)):
http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f

11. Stark Law (Physician Self-Referral):
https://www.cms.gov/PhysicianSelfReferral/

12. TRICARE Fraud & Abuse:
http://www.tricare.osd.mil/fraud

Other Resources:

1. Health Care Administrators Association (HCAA): http://www.hcaa.org/

2. Heath Care Compliance Association (HCCA): http://www.hcca-info.org

3. Society of Corporate Compliance and Ethics (SCCE):
http://www.corporatecompliance.org

4. American Health Lawyers Association (AHLA): http://www.healthlawyers.org

5. National Health Care Anti-Fraud Association (NHCAA): http://www.nhcaa.org

6. Institute for Health Care Improvement (IHI): http://ihi.org

7. Corporate Responsibility and Health Care Quality – A Resource for Health Care Boards of Directors, U.S. Dept. of Health and Human Services Office of the Inspector General and The American Health Lawyers Assn.:
http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf

8. Healthcare Fraud Prevention Partnership
https://www.cms.gov/hfpp

Links to OIG and GSA Exclusions Databases
• OIG LISTSERV via the OIG Website: http://exclusions.oig.hhs.gov/

• General Services Administration (GSA) database of excluded individuals/ entities:
https://www.epls.gov/

Appendix B

Laws and Regulations to Consider in Standards of Conduct and/or Training

(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

- Title XVIII of the Social Security Act

- Medicare regulations governing Parts C and D found at 42 C.F.R. §§ 422 and 423 respectively

- Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)

- Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)

- False Claims Acts (31 U.S.C. §§ 3729-3733)

- Federal Criminal False Claims Statutes (18 U.S.C. §§ 287,1001)

- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- The Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))

- Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))

- Physician Self-Referral ("Stark") Statute (42 U.S.C. § 1395nn)

- Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act

- Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal Government (42 U.S.C. §1395w-27(g)(1)(G)

- Fraud Enforcement and Recovery Act of 2009

- All sub-regulatory guidance produced by CMS and HHS such as manuals, training materials, HPMS memos, and guides

Addendum "A"

Commercial and/or Marketplace Addendum:

1. In addition to complying with all applicable laws, regulations, and guidance, The Plan is committed to complying with all applicable Marketplace requirements.

2. Compliance with Marketplace requirements will be monitored by the Compliance Officer and the compliance committee to ensure compliance with rules and regulations promulgated for the Marketplace. Marketplace requirements will be shared with first tier, downstream, and related entities and their compliance will also be monitored with the assistance of The Plan auditors.

HISTORY
