



# COMPLIANCE PLAN

## APPLICABLE PRODUCT TYPE(S):

- Federal Health Exchange Marketplace
- Commercial
- ERISA
- Medicare

Robert Gilliland, Compliance Officer/Privacy Official  
Florida Health Care Plan, Inc.  
2450 Mason Avenue  
Daytona Beach, FL 32114  
[rgilliland@fhcp.com](mailto:rgilliland@fhcp.com)  
386-676-7105

FHCP Ethics & Concern Helpline 386-615-4080

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## INTRODUCTION AND OVERVIEW

### I. Purpose

This plan applies to all lines of business including Fully Insured, Self-Funded, Government Programs such as Medicare, all Commercial lines of business, and all Qualified Health Plans (including at least one QHP in the silver level of coverage, at least one QHP in the gold coverage level, and a child-only plan at the same level of coverage, as described in section 1302(d)(1) of the Affordable Care Act, as well as any QHP offered through the Exchange to individuals who, as of the beginning of the plan year, have not attained the age of 21, at least one small group market QHP at the silver level of coverage and one at the gold level of coverage). Beginning January 1, 2019, FHCP is no longer the direct holder of a Medicare Advantage/Prescription Plan (MAPD) contract with CMS, but, is the first tier entity under another GuideWell company holding the contract. As such, all MAPD requirements apply to services provided by FHCP under that agreement.

Specific plans/processes to comply with specific Marketplace requirements can be found in FHCP's administrative policies and procedures.

The purposes of this plan are to (i) stress FHCP's commitment to corporate compliance, and (ii) serve as a reference for FHCP Compliance Committee members, administrators, managers, employees, and contractors (including providers) in carrying out their functions in accordance with our Code of Conduct.

### II. What is a Compliance Program?

“A compliance program is a comprehensive strategy to ensure an organization consistently complies with applicable laws relating to its business activities.”

*Source: American Academy of Healthcare Lawyers*

“A compliance program is a process that assists an organization to improve its twin goals of servicing people who need quality medical care and operating a business efficiently under various laws and regulations.”

*Source: Model Compliance Plan for Hospitals, DHHS-OIG, June 1999*

A compliance program has two main objectives:

1. Prevent and detect violations of law that may result in a liability, and
2. When violations occur, ensure that corrective action is taken to prevent recurrence.

### **III. Why Have a Compliance Program?**

An effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, improving operational quality, improving the quality of health care and reducing the costs of health care. Attaining these goals provides positive results to business, Governments, individual citizens, and beneficiaries alike. In addition to fulfilling its legal duty to ensure that it is not submitting false or inaccurate information to the Government, an organization may gain numerous additional benefits by implementing an effective compliance program. These benefits may include:

- The formulation of effective internal controls to assure compliance with Federal and State laws and regulations;
- Improved collaboration, communication and cooperation between health care providers, contractors, and the organization, as well as within the organization itself;
- Improved communication with and satisfaction of enrollees;
- The ability to more quickly and accurately react to employees' operational concerns and the capability to effectively target resources to address those concerns;
- A concrete demonstration to employees and the community at large of the organization's strong commitment to honest and responsible corporate conduct;
- The ability to obtain an accurate behavioral assessment of employees, business partners, and vendors;
- Improved (clinical and non-clinical) quality of care and service;
- Improved assessment tools that could affect many or all of the organization's divisions or departments;
- Increased likelihood of identification and prevention of unlawful and unethical conduct;
- A centralized source for distributing information on health care statutes, regulations, and other program directives;
- An environment that encourages employees to report potential problems;
- Procedures that allow the prompt, thorough investigation of possible misconduct by employees and independent contractors;
- An improved relationship with entities that oversee the organizations operations;
- Early detection and reporting, minimizing the loss due to false claims, and thereby reducing the organization's exposure to civil damages and penalties, criminal sanctions, and administrative remedies such as program exclusion; and
- An enhancement of the structure of the organization's separate business units.

### **IV. Scope of the Compliance Plan**

- A. At a minimum, the Compliance Plan shall seek to oversee the following:
  - Compliance with all federal and state laws and regulations for all FHCP's lines of business
  - Laws, regulations, and instructions relating to Medicare Advantage and Part D Programs
  - Laws, regulations, and instructions relating to QHP Issuer participations standards
  - Compliance with internal policies, procedures, and regulatory standards

- Business ethics
- Conflicts of interest
- Marketing and advertising
- Anti-Dumping
- Relationships with contractors, including vendors, health care providers, and government agents
- Anti-kickback, reimbursement, and false claims issues
- Political contributions
- Restricted and confidential information
- Substance abuse
- Data submission to government health care programs and other third-party payors

B. The Compliance Plan shall not cover the following, except to the extent that these areas are regulated by law, rule, regulation, or internal policy:

- Bioethics
- Medical ethics

## **V. Compliance Plan Elements**

Listed below are the seven elements of Compliance Plans as defined in the Federal U.S. Sentencing Guidelines, discussed in the Office of Inspector General's Model Compliance Plan Guidance and expanded upon in Chapter 9 of the Medicare Prescription Drug Benefit Manual relating to part D Program to Control Fraud, Waste and Abuse ("Chapter 9"). These elements provide a blueprint for design and maintenance of an effective plan to prevent and detect violations of law.

### *Policies and Standards*

An organization must have established standards, policies and procedures, to be followed by its employees, contractors and other agents that are reasonably capable of reducing the prospect of criminal conduct.

### *Oversight Responsibility*

Specific individual(s) within high-level personnel of the organization must have responsibility to oversee compliance with such standards, policies, and procedures.

### *Training, Education & Communications*

The organization must take steps to communicate effectively its standards, policies and procedures to all employees, contractors and other agents, including, without limitation, mandating participation in training initiatives and disseminating publications that explain, in a practical manner, what is required.

### *Effective Lines of Communication*

The organization must maintain effective lines of communication between the Compliance Officer, the organization's employees, and the organization's contractors that include mechanisms for employees and contractors to ask questions, seek clarification, and report potential or actual noncompliance without fear of retaliation.

### *Enforcement & Discipline*

The standards must be consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific.

### *Monitoring, Auditing, and Reporting*

The organization must take reasonable steps to achieve compliance with its standards, including, without limitation, utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by employees, contractors and other agents, and by maintaining and publicizing a reporting system whereby employees, contractors and other agents can report potential and actual noncompliant and criminal conduct without fear of retribution.

### *Response and Corrective Action*

After an offense has been detected, the organization must take all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including undertaking any necessary modifications to its compliance plan to prevent and detect future noncompliance and violations of law. Responses and corrective action, if any, shall be timely so as to minimize any potential negative effects of the offense.

### *Fraud, Waste and Abuse Plan*

The organization shall maintain a comprehensive plan to prevent, detect, and correct fraud, waste, and abuse. The organization should develop as part of their work-plan a strategy to monitor its internal processes and downstream and related entities involved in the administration or delivery of services.

## **VI. Context of the Compliance Plan**

FHCP's Compliance Plan is a component of a broader program called "Our Values in Action." Our Values in Action is a program designed to define, promote, and maintain core values as an integral part of our corporate culture. The Plan has these main objectives:

- Affirm the personal dignity and ethical capabilities of all employees, respect the inherent good that forms the foundation of their character, and acknowledge their value to the organization and community;
- Communicate to all employees the critical importance of conducting business while adhering to the highest ethical standards;

- Help all employees increase their knowledge and understanding of compliance with laws and regulations; and
- Establish our commitment to ethical conduct by all employees and support for the program.

## **VII. Overview of the Regulatory Environment**

### **A. Fraud and Abuse**

The 1990s saw dramatic changes in the health care environment and health care fraud has become and remains a high priority for federal and state governments and law enforcement agencies.

#### **1. Effects of fraud and abuse in health care**

Everyone pays the price of these great and widespread financial losses. Beneficiaries pay more in premiums and out-of-pocket costs, businesses pay more to insure their employees, and taxpayers pay more to cover the expenses of government health care programs. Health care fraud and abuse also puts patients and health care employees at risk. Through the provision of medically unnecessary services, including prescription drugs, not in the patient's best interest, patients are put in harms way. Additionally, operating health care facilities below acceptable standards of quality, healthcare workers are exposed to physical harm.

#### **2. Government response**

In 1994, the Attorney General of the United States made health care fraud the number two priority of the Department of Justice, second only to violent crime. In addition, recent legislation provides additional funds to combat health care fraud. Federal investigations and conviction rates are rising dramatically. Those agencies examining suspected fraud and abuse have increased the number of auditors and investigators assigned to health care. Additionally, the U.S. District Attorneys and State Attorneys General have joined forces to pursue investigations on a regional basis.

For example, in 1996 the federal government passed the Health Insurance Portability and Accountability Act which included numerous provisions intended to address fraud and abuse. These include:

- Establishment of a Federal Fraud and Abuse Control Plan
- Provides additional funding for DHHS, DOJ and FBI to investigate fraud and abuse (several \$100 million)
- Enables HHS to contract with newly authorized Medicare Integrity Contractors to conduct activities such as reviewing provider activities, auditing of cost reports, educating providers, and pre-authorizing DME expenditures
- Encourages individuals to report omissions
- Provides for the establishment of OIG Advisory Opinions and Fraud Alerts
- Creates Civil Monetary Penalties of up to \$10,000 per fraudulent act (no proof of fraudulent intent required)

**B. False Claims Act**

Enacted soon after the American Civil War and since amended; the Act prohibits anyone from knowingly submitting a false claim to the government. The Act does not require proof of intent to defraud, only a reckless disregard of the truth or falsity of the information. The Act applies to FHCP's activities as a first tier entity providing services under the Medicare Advantage/Prescription Drug Plan Program.

The Act also provides additional guidance on implementing Compliance Plans including:

- The Compliance Plan must be in place before an offense is committed
- The Compliance Plan must address activities most likely to result in misconduct or mistakes
- The Compliance Plan must have a degree of formality that reflects the size and structure of the organization
- The Compliance Plan must be comparable to other plans within the industry

**C. Federal Fraud Civil Remedies Act**

The Federal Fraud Civil Remedies Act of 1986 allows the federal government to impose civil penalties against any person who makes, submits, or presents false, fictitious, or fraudulent claims or written statements to designated federal agencies, including the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services (“CMS”).

**D. Health Insurance Portability and Accountability Act (HIPAA)**

While the public focus of this Act was on its creation of a vehicle by which individuals who recently became unemployed could retain access to health insurance, the Act also included numerous unrelated provisions that changed the health care landscape in this country. The most dramatic of the changes are contained within the Administrative Simplification section of *Title II-Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform*.

The Department of Health and Human Services promulgated several rules to implement the Administration Simplification requirements, which deal with electronic data interchange, privacy and security of individuals' health information, and enforcement. (See FHCP's Privacy Policies RR007 – RR012 and RR015).

**E. Anti-Kickback Statute**

This statute prohibits the provision, or attempting to provide, offer, solicit, or accept any monetary or non-monetary remuneration for improperly obtaining or rewarding favorable treatment. It also covers a wide variety of payments and incentives to induce referrals or the purchase of services or supplies, such as payments made to a Medicare provider by a supplier to induce the purchase of Part B products from that supplier or payments or other incentives to a provider or contractor, such as a pharmacy, to induce Medicare beneficiaries to enroll in a particular Medicare Advantage or Part D Plan. The statute also:

- Creates 'Safe Harbors' where certain activities are exempted from the provisions of this statute
- Creates civil monetary penalties up to twice the amount of each kickback, but not more than \$10,000 per violation
- Creates criminal penalties that include fines and up to 10 years imprisonment

#### F. Medicare Modernization Act

On December 8, 2003, The President signed into law the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. This legislation provides seniors and people living with disabilities with a prescription drug benefit, additional plan choices and enhanced benefits under Medicare.

Title I of the MMA establishes Medicare's voluntary outpatient prescription drug benefit, known as Part D because of its placement as Part D of Title XVIII of the Social Security Act. The prescription drug benefit took effect in 2006, and FHCPI offers Part D benefits in connection with its participation as a first tier entity under the Medicare Advantage plans (so-called Medicare Advantage-Prescription Drug ("MA-PD") Plans). Regulations for Medicare Part D are set out in Part 423 of Title 42 of the Code of Federal Regulations, and CMS's guidance on compliance programs and combating fraud, waste and abuse in Part D is set out in Chapter 9.

Title II of the MMA renamed the Medicare+Choice (M+C) Program as the Medicare Advantage (MA) Program and modified the program to enhance private plan and Medicare beneficiary participation. Regulations for the Medicare Advantage Program are set out in Part 422 of Title 42 of the Code of Federal Regulations, and additional guidance is available through the Medicare Managed Care Manual issued by CMS.

#### G. The American Recovery and Reinvestment Act of 2009 abbreviated [ARRA \(Pub.L. 111-5\)](#) and commonly referred to as **the Stimulus**, is an economic stimulus package enacted by the 111th United States Congress in February 2009. The Act followed other economic recovery legislation passed in the final year of the Bush presidency including the Economic Stimulus Act of 2008 and the Emergency Economic Stabilization Act of 2008 which created the Troubled Assets Relief Program (TARP).

The purposes of ARRA include the following:

- (1) To preserve and create jobs and promote economic recovery.
- (2) To assist those most impacted by the recession.
- (3) To provide investments needed to increase economic efficiency by spurring technological advances in science and health.
- (4) To invest in transportation, environmental protection, and other infrastructure that will provide long-term economic benefits.
- (5) To stabilize State and local government budgets, in order to minimize and avoid reductions in essential services and counterproductive state and local tax increases.

The American Recovery and Reinvestment Act of 2009 includes the Health Information Technology for Economic and Clinical Health Act, or the “HITECH Act,” which established programs under Medicare and Medicaid to provide incentive payments for the “meaningful use” of certified electronic health records (EHR) technology.

- H. The Patient Protection and Affordable Care Act (ACA) was signed by President Obama on March 23, 2010. The Affordable Care Act puts in place strong consumer protections, provides new coverage options, and gives consumers the tools they need to make informed choices about their health.

The Patient Protection and Affordable Care Act will ensure that all Americans have access to quality, affordable health care and will create the transformation within the health care system necessary to contain costs. The Congressional Budget Office (CBO) has determined that the Patient Protection and Affordable Care Act is fully paid for, will provide coverage to more than 94% of Americans while staying under the \$900 billion limit that President Obama established, bending the health care cost curve, and reducing the deficit over the next ten years and beyond.

The Patient Protection and Affordable Care Act contains nine titles, each addressing an essential component of reform:

- Quality, affordable health care for all Americans
- The role of public programs
- Improving the quality and efficiency of health care
- Prevention of chronic disease and improving public health
- Health care workforce
- Transparency and program integrity
- Improving access to innovative medical therapies
- Community living assistance services and supports
- Revenue provisions

The Patient Protection and Affordable Care Act puts in place these comprehensive health insurance reforms that were rolled out beginning in 2010, over the next four years, and beyond.

I. Other Laws and Regulations Affecting Health Care Providers and Payors

Although government investigations have predominantly focused on the area of fraud and abuse, there are many other regulations that affect a health care plan’s operations. Although not the primary focus of recent government investigations, these other legal issues should be included in the corporate compliance program. Set forth below is a brief description of some of the other legal areas affecting health care organizations.

## VIII. Discrimination

FHCP will comply with all applicable Federal and State laws and regulations that prohibit improper discrimination. Such laws and regulations include, amongst others, Title VI of the Civil Rights Act, the Age Discrimination Act of 1975, Title II of the Americans With Disabilities Act (ADA) of 1990, Section 504 of the Rehabilitation Act of 1973, the Affordable Care Act (ACA), the Genetic Information Nondiscrimination Act of 2008 (GINA), and applicable non-discrimination regulations promulgated by the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services. FHCP will also comply with applicable Human Resource policies that prohibit unlawful discrimination. FHCP will not establish any policies, procedures, or processes that conflict with or prevent the application of regulations promulgated by HHS under Subtitle D of the ACA.

FHCP will not unlawfully discriminate against any individual on the basis of an individual's race, color, national origin, disability, age, sex, gender identity or sexual orientation in any aspect of our business. FHCP will also not unlawfully discriminate against individuals on the basis of an individual's genetic information, health factor, expected length of life, present or predicted disability, degree of medical dependency, quality of life, other health conditions, religion, political beliefs, marital status, familial or parental status, or if all or part of an individual's income is derived from any public assistance program.

FHCP has committed to upholding the language from Section 1557 of the Affordable Care Act which states that no person in the United States shall, on the ground of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity for which the Applicant receives Federal financial assistance from the Department. Examples of activities where FHCP will not discriminate include but are not limited to: benefit/product design, rates, marketing, eligibility, sales, provider contracting/network design, delivery of health care services/supplies, and delivery of pharmaceuticals.

FHCP will post its non-discrimination notice and tag lines in all clinical areas and pharmacies, and include copies with all significant publications and/or communications such as applications, documents/correspondences related to rights, benefits or services, and correspondences requiring a response. FHPC's notice of non-discrimination will include details about how to file a discrimination grievance. FHCP will also make free language services and aids available to ensure effective communication.

## 1. Regulations and Standards

Healthcare entities operate in a highly regulated field and must comply with the regulatory provisions of numerous agencies. While many of these regulations do not carry criminal penalties, they do affect licensure and certification of healthcare delivery organizations. Examples of such regulatory authorities include:

- Centers for Medicare and Medicaid Services (CMS)
- Department of Health and Human Services (HHS)
- Florida Agency for Health Care Administration (AHCA) licensure, Medicare certification and Certificate of Need for providers
- Florida Department of Business and Professional Regulation (health professional licensure)
- National Committee for Quality Assurance (NCQA Accreditation)
- Food & Drug Administration (FDA)
- Controlled Substance Registration
- Pharmacy Licensure and Registration
- Clinical Laboratory Licensure and Registration
- Occupational Safety and Health Regulations (OSHA)
- State of Florida Department of Financial Services/Office of Insurance Regulation (including oversight of health maintenance organizations) (DFS)

## IX. Enforcement Agencies

The following agencies are actively involved in efforts to curb health care fraud and abuse:

<u>Agency Name</u>	<u>Description</u>
Centers for Medicare & Medicaid Services (CMS)	Federal agency overseeing administration of the Medicare, Medicaid, State Child Health Insurance Programs, and Federally Facilitated Marketplace .
U.S. Department of Justice (DOJ)	The chief law enforcement agency at the Federal level, which includes U.S. Attorneys Offices
Federal Bureau of Investigation (FBI)	Investigative arm of federal government (domestic)
Medicaid Fraud Control Unit (MFCU):	State Medicaid agency's investigative arm
Medicaid Plans	State health insurance plans for the medically indigent.

Medicare Administrative Contractors (MACs)	Claims processors of the Medicare Part A hospitals, skilled nursing facilities, and home health agencies. Claims processes for Medicare Part B (e.g. physicians, clinical, laboratories, durable medical equipment, and nursing home supplies)
Medicare Drug Integrity Contractors (MEDICs)	Assistance to CMS in audit, oversight, and anti-fraud and abuse efforts for Medicare Part D
U.S. DHHS, Office of the Inspector General (OIG)	Investigative arm of the federal agency with oversight of federal government health care programs
State Attorney General's Office	Arm of state responsible for investigating and prosecuting violations of state laws
State Attorney's Office	Local authority responsible for investigating/prosecuting violations of state laws
Florida Agency for Health Care Administration (AHCA)	State agency overseeing healthcare delivery in Florida, and regulating healthcare professionals
Florida Department of Financial Services/Office of Insurance Regulation (DFS/OIR)	State agency responsible for overseeing HMO and Insurance products, rate and form approval, benefit requirements, and Agent licensing
U.S. DHHS, Office for Civil Rights (OCR)	Federal agency overseeing enforcement of the HIPAA Privacy Regulations

## X. Risk Areas

Identification of risk areas is a critical element in the maintenance of an effective Compliance Plan and in the development of policies and standards. The design of the program, and policies and standards are developed and/or updated based on the risk associated with noncompliance, e.g., the likelihood of harm to an enrollee. Risk areas are identified through numerous mechanisms, such as the following:

- Management interviews
- Reports by employees
- Results of employee surveys
- Observed and/or reported incidents or conditions
- Reports, instructions, and guidance issued by government agencies
- Correspondence from government agencies and third-party payors

- Model compliance plans, fraud alerts and advisories issued by enforcement agencies
- Work plans and audit reports of government oversight agencies
- Monitoring and external audits
- Industry compliance publications

Key categories of risk and examples of inappropriate activities for health plans include the following:

Risk Areas:

- Marketing Materials and Personnel, including selective marketing and enrollment
- Enrollment and Disenrollment
- Utilization and Quality of Care (including underutilization of medically-necessary services and over-utilization of health care services, such as prescription drugs and controlled substances)
- Data Collection and Submission Process
- Anti-Kickback Statute and Other Inducements
- Anti-Dumping
- Medical Necessity
- Provider Credentialing
- Provider Contracting
- Confidentiality and Privacy of Information
- Quality Assurance
- Provider Billings
- Claims Processing
- Improper Bid Submissions under the Medicare Advantage and Part D Programs
- Enrollee Grievances, Coverage Determinations, and Appeals
- Coordination of Benefits, including Medicare Secondary Payor
- Benefit Administration, including Premium Collection, Cost-Sharing, and tracking Medicare Part D True Out-of-Pocket (“TrOOP”) Costs
- Reporting of Pharmaceutical Manufacturer Rebates and Other Remuneration

Examples of illegal or inappropriate activities include:

- Misrepresenting a provider’s qualifications, credentialing, and/or licensing
- Employment of or contracting with an individual excluded from participation in federal health care programs
- Regularly denying a request for benefit(s) without sufficient documentation supporting the denial
- Paying kickbacks to primary care providers for referrals to fee-for-service specialists
- Excluding or dissuading enrollment of identifiable groups, e.g., those with HIV, mental illness, eligible subsidies, and individuals dually-eligible for Medicare and Medicaid
- Diverting an in-network patient to a non-network doctor in the same clinic and billing with the in-network doctors’ name
- Claiming procedures that are not discounted under the negotiated contract, e.g., billing for fingernail cutting as surgery

- Failing to notify beneficiaries of their rights to appeal a coverage denial, including coverage of a prescription drug under the applicable FHCP formulary
- Waiving copayments or deductibles to attract more patients
- Splitting fees for referrals with nonparticipating providers
- Claiming capitation payments for nonexistent patients, including payments under the Medicare Advantage and Part D Programs
- Falsifying identifiers so as to receive both a monthly cap and fee for service for the same patient
- Billing for unlicensed caregiver services under an in-network physician's name
- Assigning large numbers of enrollees to a particular provider, making the provision of quality service and care impossible to achieve
- Delayed payment of clean claims
- Providing insufficient documentation to support billing and utilization review
- Miscalculating and underreporting pharmaceutical manufacturer rebates and/or other remuneration under Medicare Part D to increase “allowable drug costs” incurred by the organization
- Improper formulary administration, including prescription drug switching and prescription drug splitting or shortening
- Prescription forging or altering or refill errors
- Submission of incorrect data to CMS in connection with Medicare Advantage and Part D Plans, including encounter data, enrollee risk adjustment data, and prescription drug event (“PDE”) data

## PERSONNEL AND ORGANIZATION

### I. Overview

FHCP's Compliance Officer and Compliance Committee shall provide direct oversight of this Plan. All Directors, Managers, and Supervisors shall support Plan oversight within their respective areas of responsibility. Periodic reports shall be presented to the Board of Directors to ensure that the organization is diligently adhering to the Plan, corrective actions are appropriate and timely, and, as needed, that regulatory bodies are informed of identified non-compliant activities. The effectiveness of FHCP's Compliance Program is audited annually by individuals outside of the Compliance Department and FHCP's Compliance Program is reviewed annually by the Board of Directors. Although it is common practice within the industry for organizations to enter into contracts with third parties to perform certain functions that would otherwise be the responsibility of the organization, FHCP is ultimately responsible for complying with all applicable laws and regulations and fulfilling the terms and conditions of FHCP's contracts for all FHCP's lines of business.

### II. Designation of a Compliance Officer, Privacy Officer, and Security Officer

FHCP shall designate a Compliance Officer, who shall also serve as the organization's Privacy Officer and who shall report directly to Legal. He shall be authorized to meet with the FHCP Board of Directors as necessary without the approval of Legal or the Chief Executive Officer. The Compliance Officer/Privacy Officer shall assume primary responsibility for formulating and implementing all compliance related activities. Additionally, the Compliance Officer/Privacy Officer will:

- Provide technical assistance to operational areas regarding regulatory and ethical issues.
- Conduct/oversee the compliance monitoring efforts of the organization, including in connection with FHCP's participation as a first tier entity under the Medicare Advantage and Part D Programs.
- As needed, coordinate investigations into activities that are not consistent with regulatory or organizational standards.
- Formulate and oversee the implementation of corrective action that will remedy non-compliant activities and prevent recurrence.

FHCP shall designate a Chief Information Officer (CIO) who shall also serve as the organization's Security Officer and shall report directly to the CEO. He shall assume primary responsibility for the following:

- Security management processes to prevent, detect, contain, and correct security violations to include risk analysis, risk management, sanction policies and information systems activity reviews.

- Workforce security oversight to ensure workforce members have appropriate access to electronic protected health information such as authorization and/or supervision of workforce through clearance and termination procedures.
- Information access management for authorizing access to electronic protected health information to include isolating health care clearinghouse functions if part of a larger organization, access authorization, and access establishment and modification.
- Security awareness and training for all workforce members such as security reminders, protection from malicious software, log-in monitoring, and password management.
- Security incident procedures to address security incidents to include response and reporting of suspected or known security incidents and to mitigate the harmful effects of security incidents known to the covered entity.
- Contingency planning for responding to an emergency or other occurrence (fire, vandalism, system failure, natural disasters) that damages systems that contain electronic protected health information to include a data backup plan, disaster recovery plan, emergency mode operation plan, testing and revision procedures and applications and data criticality analyses.
- Performing periodic technical and nontechnical evaluations in response to environmental or operational changes affecting the security of electronic protected health information.

### **III. Designation of the Compliance Committee**

The Compliance Committee shall meet at least quarterly and is charged with overseeing the administration of the Compliance Plan. This oversight shall encompass employee training, investigating suspected non-compliant activities, responding to activities that are not consistent with FHCP's Compliance Plan, coordinating internal compliance audits, overseeing compliance audits performed by outside professional firms, and overseeing any other functions necessary to ensure that the Compliance Plan meets its objectives. All conversations between Compliance Committee members and employees will be kept confidential to the maximum extent permitted by law.

In addition to the Compliance Officer, the Compliance Committee shall be comprised of:

- President/Chief Executive Officer
- Chief Medical Officer
- Chief Information Officer
- Legal/General Counsel
- Vice President/Chief Financial Officer, GuideWell Health

#### **IV. Duties of Compliance Officer and Compliance Committee**

The Compliance Officer and Compliance Committee shall participate in ongoing compliance activities such as:

- Facilitate FHCP-wide compliance oversight;
- Facilitate the exchange of compliance-related information and resources across FHCP facilities;
- Provide a mechanism by which the Board of Directors are apprised of compliance program activities;
- Facilitate the review, analysis and development of written policies and standards applicable to the Compliance Plan.

The Committee's primary focus will be on implementing and maintaining an effective compliance program modeled after the definitions contained in the U.S. Sentencing Guidelines and guidance published by the OIG and CMS. Activities will include:

- Discussion and analysis of compliance risks
- Policies and standards development
- Compliance oversight
- Delegation of authority
- Training, education, and communications
- Monitoring and investigating
- Enforcement and discipline
- Responses to problems and corrective action

Specific duties of the Compliance Officer and Compliance Committee shall include the following:

##### **A. Monitoring and Investigating**

The Compliance Officer shall be responsible for monitoring and, as needed, investigating the organization's processes to ensure adherence to regulatory standards and FHCP's administrative policies and procedures. Monitoring shall be ongoing and include both reviews conducted by Compliance as well as reports produced by operational areas of the organization or outside entities. In the event that an at-risk area is identified, either through monitoring or a report to the Compliance Officer/Committee, an investigation of the suspected practice shall promptly be initiated.

##### **B. Audits by Outside Professional Firms**

The Compliance Committee shall have the authority to retain outside professional firms as needed for guidance on issues arising under the Corporate Compliance Plan. The Compliance Officer shall oversee, organize, and implement all audits conducted by outside professional firms.

**C. Report to the Board**

The Compliance Committee shall provide periodic reports to the Board of Directors. Such reports shall include information such as status of the Compliance Plan and implementation of work plan(s), audit findings, investigation results, and corrective action plans.

**D. Employee Training**

The Compliance Officer shall be responsible for overseeing the development and implementation of employee education and training activities related to FHCP's Compliance Plan. All new employees shall attend the training during their 90-day introductory period. Additional training shall be provided as needed and as appropriate for the employee's job description.

**V. Role of Directors, Managers, and Supervisors**

While the Compliance Officer and Compliance Committee shall assume primary responsibility for the development and implementation of this Plan, all Directors, Managers, and Supervisors shall:

- Foster an ethical working environment that adheres to this Plan;
- Administer the elements of the compliance program within their department; and
- Act as liaison with the Compliance Officer and Compliance Committee.

Specific involvement in the Compliance Plan shall include:

**A. Policy and Procedure Development**

- Initiate, authorize and support process of policy review & revision;
- Maintain open lines of communication with Compliance Officer and Compliance Committee;
- Allocate reasonable and necessary resources to ensure Plan adherence;
- Give authority to the Compliance Officer to assist with Plan Implementation; and
- Take appropriate follow-up action regarding compliance activities.

**B. Compliance Oversight**

- Establish the proper "tone" at the top and support the Compliance Committee;
- Designate staff to help coordinate compliance program activity within FHCP;
- Be visible and accessible;
- Help remove barriers when issues are raised;
- Give the Compliance Officer "clout" and access to necessary resources; and
- Require compliance-related objectives in performance appraisals of all employees.

**C. Education and Training**

- Foster an environment of open and continuous education, training, and communication;
- Request appropriate resources to support training needs;
- Participate in training, education, and communications programs;
- Support efforts to train at department level

D. Reporting, Investigating, Monitoring, Auditing

- Communicate to subordinates the availability and importance of reporting systems (Help Line, e-mail, compliance alerts, compliance advisories and other compliance-related information);
- Encourage management to support reporting systems; and
- Support the Compliance Officer and Compliance Committee during all monitoring and investigating activities.

E. Enforcement and Discipline

- Support compliance and ethics as a component of performance appraisal at all levels;
- Require a timely response and aggressive follow-through when misconduct is detected;
- Support disciplinary actions taken by Human Resources and/or Compliance Committee;
- Support all applicable discipline policies and procedures; and
- Support FHCP's policy of non-retaliation.

F. Response to Violations

- Actively support corrective action plans implemented by the Compliance Officer and Compliance Committee;
- Support self-disclosure when appropriate;
- Help create an environment where we learn from our mistakes and where vulnerabilities are viewed as opportunities for improvement;
- Insist on periodic review of the Plan to ensure it is up-to-date and continuously improving; and
- Support root-cause analysis and corrective action planning at all levels of management.

## **VI. Role of First Tier, Downstream and Related Entities – (FDRs)**

CMS defines these individuals/organizations as follows:

**First Tier Entity:** any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.

**Downstream Entity:** any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

**Related Entity:** any entity that is related to the MA organization by common ownership or control and (1) performs some of the MA organization's management functions under contract or delegation; (2) furnishes services to Medicare enrollees under an oral or written agreement; or (3) leases real property or sells materials to the MA organization at a cost of more than \$2,500 during a contract period.

While the above definitions apply to the Medicare Advantage Program, FHCP is adopting this framework, as applicable, for all lines of business. Specific efforts and activities of FDRs include, but are not limited to, the following:

- Performance of all contracted services in compliance with all applicable laws, regulations, and other requirements;
- Establishment and maintenance of a compliance program that is appropriate to the size of the FDR and scope of the services being provided that includes the seven elements of a compliance plan, as described by the OIG;
- Certification as to the accuracy, completeness, and truthfulness of all data;
- Prior to engagement and monthly thereafter, ensure that the entity and all individuals performing activities for or on behalf of federally-funded health products are not included on the OIG/GSA/OFAC exclusions lists for participation in any government health care program; and
- Cooperation in all FHCP compliance activities, including monitoring activities, audits, investigations, and corrective actions.

## **EDUCATION AND TRAINING**

### **I. Purpose**

FHCP has developed a training plan for all of its employees so that all employees are familiar with the Corporate Compliance Plan and understand all FHCP policies and procedures, including the Code of Conduct.

### **II. New Employees**

As part of initial orientation, all new employees shall receive classroom style training that discusses the goals and objectives of the Corporate Compliance Plan and familiarizes new employees generally with the Corporate Compliance Plan. Within fifteen days of the orientation session, new employees will be asked to sign and return to the Compliance Department an acknowledgment that they are aware of, understand, and will abide by the Corporate Compliance Plan and Code of Conduct. All attendees shall receive a copy of this Compliance Plan that includes a detailed explanation of FHCP's Disciplinary Guidelines (see Section 8).

### **III. Incumbent Employees**

As part of the implementation plan, all existing employees will participate in a classroom style training session on this Corporate Compliance Plan and Code of Conduct. Within fifteen days of the training session, all incumbent employees will be asked to sign and return to the Compliance Department an acknowledgment that they are aware of, understand, and will abide by the Corporate Compliance Plan and Code of Conduct. All attendees shall receive a copy of this Compliance Plan that includes a detailed explanation of FHCP's Disciplinary Guidelines (see Section 8).

### **IV. Downstream and Related Entities of FHCP**

As a first tier entity, FHCP must comply with all applicable MAPD requirements. FHCP requires its Downstream Entities and Related Entities, including but not limited to those with responsibilities relating to the organization's activities under the Medicare Advantage and Part D Programs, to include in their respective compliance plans, a component that addresses education and training. All Downstream and Related Entities shall provide to FHCP upon request, certification that all employees providing services to, or on behalf of, FHCP have completed that entity's education and training within 90 days of hire or contracting. Downstream and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and education requirements for fraud, waste, and abuse.

In the event that it is unreasonable for such entity to conduct its own compliance education and training, FHCP shall make its training opportunities available to the employees of the entity performing activities to, or on behalf of, FHCP.

## **V. Recurring Annual Testing**

All employees will receive annual testing with respect to the *Our Values In Action* program binder as well as the HIPAA Privacy Rule. This testing will focus on key elements within the Corporate Compliance Plan, Code of Conduct, Anti-Fraud Plan and FHCP HIPAA Privacy policies. The testing will also focus upon changes in federal laws and regulations that affect FHCP, including CMS guidance and instructions relating to the Medicare Advantage and Part D Programs and recent government enforcement actions. This testing will be conducted as part of each employee's annual mandatory education located within FHCP's online training modules and through the GuideWell Learning system.

## **VI. Other Education and Training**

At the direction of the Compliance Officer and/or Compliance Committee, supplemental training may be conducted as needed to address changes and/or key developments in the Corporate Compliance Program, federal laws and regulations or any other area of interest. Additional training may be conducted for specific employees who have responsibilities in areas of high risk for fraud and abuse, such as billing and claims processing, as well as employees responsible for activities relating to FHCP's participation in government health care programs. In addition, if determined to be the most effective means of education, the Compliance Officer may direct specific employees to attend continuing education classes outside of FHCP. Additionally, the Compliance Department will publish informational articles in FHCP's employee, provider, and member newsletters. FHCP also offers department specific compliance training on a regular basis.

## **VII. Monitoring of Education**

Employee participation in training activities is mandatory. The Compliance Officer shall be responsible for developing, coordinating, and monitoring all training related to the Corporate Compliance Program and Code of Conduct. The Compliance Officer shall keep a written record of all such training sessions. The Compliance Officer will also be responsible for tracking employee participation in such training activities. Examples of tracking include attendance logs and examination results.

## **VIII. Training Content**

Employees shall be informed during the training session that strict compliance with the Corporate Compliance Program and the Code of Conduct is a condition of employment. Additionally, employees will be made aware that adherence to the Corporate Compliance Program and the Code of Conduct will be taken into consideration as part of the employee's annual evaluation. Employees also may be required to participate in other mandatory training sessions in addition to those conducted by the Compliance Officer or his/her designee pursuant to the Corporate Compliance Program, to the extent such employees have specific responsibilities for activities relating to FHCP's participation as a first tier entity under the Medicare Advantage and Part D Programs.

As applicable, training shall include, but not be limited to, laws related to fraud and abuse, accuracy and completeness of data, anti-dumping, conflicts of interest, business ethics, under/over utilization, and selective marketing and enrollment. For additional information, please refer to FHCP policy LD012 – Anti-Fraud Plan, which is available through the FHCP intranet and the PolicyTech software management program.

## **IX. Role of Managers and Supervisors in Training and Education**

Managers and supervisors are required to instruct subordinates in Corporate Compliance Program requirements and support their participation in such corporate training programs. Additionally, as noted elsewhere in this Corporate Compliance Plan, failure of managers and supervisors to detect non-compliance with applicable policies, including training and education initiatives, can result in disciplinary action.

## **X. Education Records**

The Compliance Officer shall be responsible for maintaining records as evidence that all employees have participated in compliance training activities. Examples of education records include attendance logs and test results. At a minimum, attendance logs shall include the session topic, date, instructor, and the name and department of all attendees. This data is also available in the GuideWell Learning system. Test results shall be maintained for each employee and shall include similar information. In the event that an employee fails to meet the minimum 80% standard set forth for the annual test, the Compliance Officer or his/her designee, shall maintain a record of follow-up actions taken to ensure the employee has adequate knowledge of the subject area.

## COMMUNICATIONS

### I. Purpose

Strict adherence to the Code of Conduct and Compliance Plan by the organization, its employees, and its Downstream and Related Entities is vital. Supervisors are responsible for ensuring that employees are aware of and adhere to the provisions of the Code of Conduct and Compliance Plan. For clarification or guidance on any point in the Code of Conduct or Compliance Plan, individuals may consult a member of the Compliance Committee or the Compliance Officer.

Employees are expected to report any suspected violations of the Code of Conduct or Compliance Plan. Individuals may report such suspected violations to his/her supervisor, the Compliance Officer, or a member of the Compliance Committee. If the employee wishes to protect their identity, the employee may submit his/her report through the Ethics and Concerns Help Line @ 386-615-4080, internal extension 4080. All FHCP Downstream and Related Entities should report suspected non-compliant behavior, either in accordance with their employer's compliance plan or directly to FHCP's Compliance Officer or Compliance Committee as described in this section.

FHCP understands its obligations to inform employees and Downstream and Related Entities of regulatory and policy changes in a timely manner in order to ensure effective implementation. Such information is shared with individuals in a variety of ways, including staff meetings, interoffice mail, and e-mail. The method of distribution is determined based on urgency and length of content.

### II. Reporting Suspected Violations or Irregularities

Reports of suspected violations or irregularities should contain sufficient information for the Compliance Officer to investigate the concerns raised. No adverse action or retribution of any kind will be taken by FHCP against an individual because he or she, in good faith, reports a suspected violation of this Compliance Plan or the Code of Conduct, as long as the individual was not a participant in the act(s). In an effort to encourage free and open reporting of activities or events that are suspected to be inconsistent with the Code of Conduct and/or Compliance Plan, FHCP has developed numerous mechanisms for reporting such issues. These include:

#### A. Direct Reporting

Employees should first attempt to address concerns through his or her supervisor. If an employee is uncomfortable going to their supervisor, the employee can go to the Compliance Officer. If uncomfortable going to the Compliance Officer, the employee can go to a member of the Compliance Committee. If the employee wishes, the report can be made anonymously through the Ethics and Concerns Help Line.

**B. Reporting through the Statement of Understanding**

Employees annually shall have an opportunity to raise concerns through completion of the Statement of Understanding. Upon initial adoption of the Compliance Program and annually thereafter, employees sign statements acknowledging their understanding of the Code of Conduct and Compliance Plan. This Statement of Understanding includes an opportunity to report violations in response to the following question: "At this time, I am not aware of any possible violation of the Code of Conduct or Compliance Plan, except as noted below." The Compliance Officer reviews responses to these statements.

**C. Reporting through Exit Interviews**

All employees leaving employment will complete an exit interview with the Human Resources department. Potential issues of non-compliance identified during the interview are referred to the Compliance Department for evaluation and action.

### **III. Other Types of Concerns**

In addition to the processes in place to address suspected violations of the Code of Conduct or Compliance Plan, FHCP maintains processes for responding to issues with Quality of Care and Employee Relations.

**A. Quality of Care Concerns**

If an employee encounters a situation where it is believed that the quality of care being rendered is inappropriate, the employee should immediately report it to the Administrator of Quality Management/Performance Improvement or the Chief Medical Officer. In these situations, the well-being of the patient takes precedence over all else.

**B. Employee Relations Concerns**

These concerns involve the relationship between an employee and their supervisor, another employee, or the Human Resources Department. Examples of concerns falling into this category include:

- A conflict with a supervisor regarding job performance or disciplinary action
- A conflict with a coworker
- Discrimination, harassment or abusive behavior, hostile workplace situations
- Improper denial of benefits or due process relating to a benefit.

FHCP's process by which concerns of this type are addressed can be initiated by making an appointment with the Human Resources Department or reporting to the Compliance Officer.

#### **IV. Maintaining Employee Confidentiality**

If requested, FHCP will attempt to protect the identity of the employee who has made a report to the maximum extent permitted by law. While in some circumstances it may be feasible to keep the identity of the complainant confidential while the complaint is being investigated, that is not always the case. If final resolution cannot occur without the employee coming forward to substantiate the allegation, the complainants will be informed of this fact prior to divulgence of their identity.

#### **V. Information Dissemination**

FHCP is committed to keeping its employees, Downstream and Related Entities apprised of new policies and procedures, key risk areas, and other compliance and anti-fraud, waste and abuse initiatives and information. In addition to the mandatory education and training programs, the following are some of the dissemination methods by which FHCP shall share such information:

**A. Manager and staff meetings**

Department meetings are generally held monthly. These meetings provide forums for communication of general compliance information that is not of an urgent nature.

**B. Interoffice Mail**

The interoffice mail system reaches all FHCP facilities and employees. In general, all interoffice mail is delivered to the recipient within 24 hours. It is typically used for formal compliance correspondences, reports, and items of a confidential nature.

**C. E-mail**

The electronic mail system is a fast and efficient communications method for alerts, advisories, meeting notices, and education announcements that are relatively short in length. It is an effective way to share information in a fast and accurate manner. E-mail distribution lists facilitate communications to specific groups such as managers, and performance improvement teams. Currently, e-mail systems reach all managers and supervisors and many employees, including 100% of the Compliance Committee.

**D. Fax**

All departments either have a fax machine or ready access to one for distribution of hard-copy material that does not exceed 10 pages in length. All such communications include a cover sheet that instructs the recipient to whom the correspondence should be sent and any action that is required.

**E. Voice Mail**

Voice messages can be broadcast using distribution lists. This system is generally used as a compliment to another method of information dissemination. For example, a voice mail may be left at all extensions informing the employees to be on the lookout for an upcoming urgent correspondence from the Compliance Department.

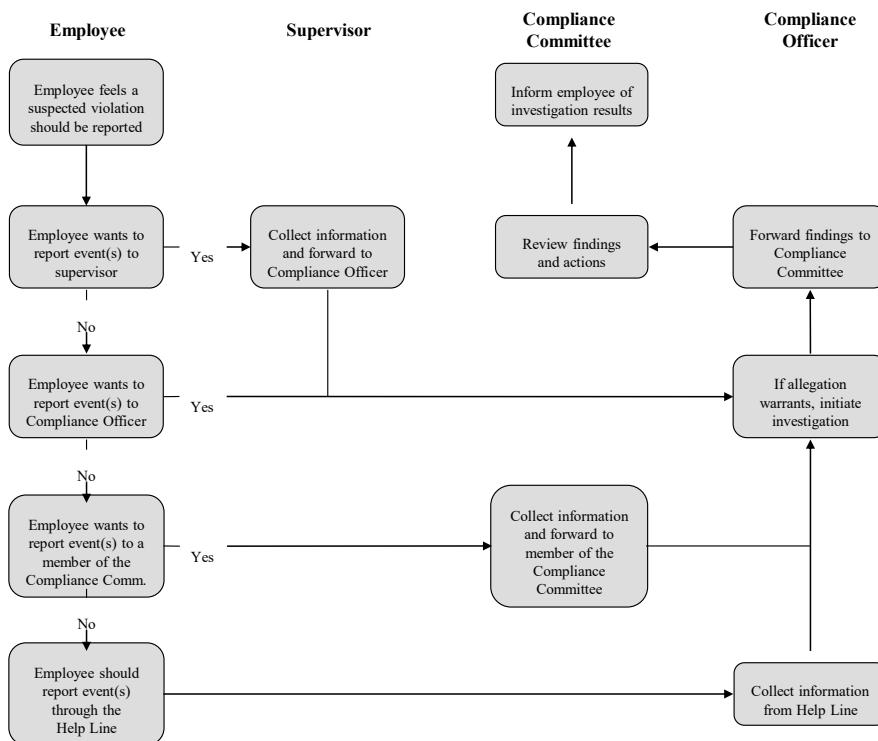
#### F. PolicyTech

The FHCP Corporate Compliance Plan, Code of Conduct, and administrative policies and procedures are available to all employees at all times through the FHCP intranet and the PolicyTech software management program.

#### G. Downstream and Related Entities of FHCP

As necessary, FHCP disseminates, via the US Postal Service and email, bulletins and notices to the affected FHCP Downstream and Related Entities apprising them of new regulatory requirements and other compliance concerns and initiatives. Informal communications also may be undertaken on a case-by-case basis as appropriate.

### Compliance Communication Flow Chart



## ALLEGATIONS

### I. Preliminary Evaluation

All reports made through the Ethics and Concerns Help Line or reports received in any other form will be referred to the Compliance Officer, regardless of whether such report originates from a FHCP employee, provider, or a contractor. Once a report of a suspected violation or irregularity has been received, the Compliance Officer shall immediately initiate a preliminary evaluation to determine if the report warrants an investigation. Such an evaluation shall seek to determine:

- Has the individual spoken to their supervisor about the issue? If not, why? If so, what was determined?
- Is there anyone else that may be aware of the situation, e.g., a coworker?
- What specific law, rule, regulation, policy, or procedure has been violated?
- What outcome does the individual expect or desire?
- Is an individual, member, or any other party vulnerable in any way, i.e., is immediate action necessary?
- Seek permission to discuss the case with those best able to handle it. If the individual wishes to remain anonymous, respect his/her wishes, but advise the individual that final resolution may require the individual to come forward at some point in the investigation.

Results of all preliminary evaluations shall be retained by the Compliance Officer including the determination of whether to proceed with an investigation or to close the case because the allegation could not be substantiated.

### II. Investigation

The investigation attempts to determine the cause, nature, and extent of any and all suspected violation or irregularity including identifying all those involved and those that were aware of the wrongdoing. Specifically, the investigation will attempt to:

- Determine how the incident or practice was identified, and the origin of the information that led to its discovery.
- Describe FHCP's efforts to investigate and document the incident or practice (e.g., use of internal or external legal, audit or consultative resources).
- Document the chronology of the investigative steps taken in connection with the organization's internal inquiry into the disclosed matter and may include:
  - Listing of all individuals interviewed, including each individual's business address, telephone number, and his/her position(s) and title(s) in the relevant entities during both the relevant period and at the time the disclosure is being made. For all individuals interviewed, FHCP will provide the dates of those interviews and the subject matter of each interview, as well as summaries of the interview. FHCP will be

- responsible for advising the individual to be interviewed that the information the individual provides may, in turn, be provided to regulatory entities;
- List those individuals who refused to be interviewed and provide the reasons cited;
  - Description of files, documents, and records reviewed with sufficient particularity to allow their retrieval, if necessary;
  - Copies of notices to any applicable Downstream and Related Entity regarding the cooperation FHCP expects in connection with such investigation; and
  - A summary of auditing activity undertaken and a summary of the documents relied upon in support of the estimation of losses. These documents and information will accompany the investigation report;
  - Description of the actions by FHCP and, if applicable any Downstream or Related Entity to stop the inappropriate conduct.
  - Description of any related health care businesses affected by the inappropriate conduct in which the health care provider is involved, all efforts by the health care provider to prevent a recurrence of the incident or practice in the affected division as well as in any related health care entities (e.g., new accounting or internal control procedures, increased internal audit efforts, increased supervision by higher management, or additional training).
  - Description of any disciplinary action recommended against corporate officials, employees and Downstream and Related Entities as a result of the matter.
  - Description of appropriate notices, if applicable, provided to other Government agencies, (e.g., Internal Revenue Service, AHCA, CMS or its designee(s) etc.) in connection with the disclosed matter, including, if applicable, a voluntary self-disclosure.

### **III. Final Report**

Upon conclusion of the investigation, the Compliance Officer shall deliver to the CEO a report containing the investigation findings, and, if applicable, recommendations for corrective and disciplinary actions.

In some instances, appropriate corrective action will be outside the control of any one manager. In these instances, the Compliance Officer will organize a meeting of the appropriate staff, including, if appropriate, the staff of applicable Downstream and Related Entities, to create a working group to address the issue. Depending on the issues presented, it may be appropriate for a Task Force to assume primary responsibility for coordinating this response.

Violations of the Code of Conduct and/or Compliance Plan may result in discipline ranging from warnings and reprimand to discharge or, where appropriate, informing the relevant government authorities. Employees will be informed of the violation(s) against them and will be given an opportunity to defend their actions before any disciplinary action is imposed. In addition, managers and supervisors may be sanctioned for failure to adequately instruct their subordinates or for failing to detect noncompliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of any problems or violations and given FHCP the opportunity to correct them earlier.

Once disciplinary or corrective action has occurred, the Compliance Officer will update the case file to include appropriate notations documenting the resolution of the case. Within 15 days of initiation of corrective action, the individual who initiated the report shall be notified of the outcome of the investigation.

## RISK ASSESSMENT, WORKPLAN, MONITORING AND AUDITING

### I. Risk Assessment

FHCP shall conduct a formal baseline assessment of all major compliance and FWA risk areas. FHCP shall take into account all Medicare business operational areas with each area being assessed for the types and levels of risk the area presents to FHCP and its Medicare program. Factors that FHCP may consider in determining the risks associated with each area include, but are not limited to:

- Size of department;
- Complexity of work;
- Amount of training that has taken place;
- Past compliance issues; and
- Budget.

Areas of particular concern for FHCP's Medicare Parts C and D activities include, but are not limited to, 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 vendor oversight and monitoring.

FHCP's approach to risk monitoring and allocation of resources will be based on the risk of noncompliance. Risk of noncompliance may be assessed through:

- Management interviews
- Reports by employees
- Results of employee surveys
- Observed and/or reported incidents or conditions
- Correspondence from government agencies and paying agents
- Model compliance plans, fraud alerts and advisories issued by enforcement agencies
- Work plans and audit reports of government agencies
- Results of internal or external audits
- Compliance industry publications

Risks identified through the risk assessment will be ranked to determine which risk areas will have the greatest impact on FHCP and/or Medicare program beneficiaries and to prioritize the monitoring and auditing strategy accordingly. FHCP is aware that risks change and evolve with changes in laws, regulations, CMS requirements and operational matters. Therefore, FHCP's review of potential risks of noncompliance and FWA shall be ongoing and include periodic re-evaluation of the accuracy of the baseline assessments. Risk areas identified through CMS audits and oversight, as well as through FHCP's own monitoring, audits, and investigations are considered priority risks. The results of FHCP's risk assessments will be considered during the development of the compliance monitoring and auditing work plan.

## **II. Compliance Work Plan**

Risk assessment results will be considered in the development of FHCP's monitoring and auditing work plan. The work plan may include:

- The audits to be performed;
- Audit schedules, including start and end dates
- Announced or unannounced audits;
- Audit methodology;
- Necessary resources;
- Types of Audit: desk or onsite;
- Person(s) responsible;
- Final audit report due date to Compliance Officer; and
- Follow up activities from findings.

FHCP has included in its Compliance Plan a process for responding to all monitoring and auditing results where non-compliance was found. Follow up reviews of areas found to be non-compliant will be performed to ensure that the implemented corrective actions have fully addressed the underlying problem. Corrective action and follow-up should be led or overseen by the Compliance Officer and assisted, if desired, by the Compliance Department staff, and will include actions such as reporting findings to CMS or to the NBI MEDICs, if necessary.

### **III. Monitoring and Auditing**

The Compliance Officer shall be responsible for monitoring and auditing the organization's processes to ensure adherence to regulatory standards and FHCP's administrative policies and procedures. Monitoring and auditing shall be ongoing and may focus on areas such as:

- Fraud and abuse issues, e.g., purchasing (including payment policies and discounts); relations with physicians and charitable donations, prescription drug billing and payment practices;
- Marketing and sales practices.
- Food and Drug Administration and prescription drug integrity issues;
- Third party billing practices, pricing practices (including transparency of prescription drug pricing), contractual relationships, and reporting and record keeping practices;
- Accuracy and completeness of data submitted to government health care programs;
- Regulatory compliance, e.g., claims processing, enrollee grievances, coverage determinations and appeals, accurate premium and cost-sharing charges;
- Department of Health and Human Services Office of the Inspector General list of excluded and debarred individuals and entities screening pre-employment or engagement and monthly thereafter
- Downstream, and Related Entities
- Enrollment and Disenrollment Issues
- Marketing Materials and Personnel
- Over/underutilization and Quality of Care review
- Anti-Kickback Statute and other Inducements
- Anti-Dumping
- Formulary Development, Updating, and Implementation

In the event that an area of potential risk is identified, either through a monitoring activity or a report to the Compliance Officer, an investigation of the suspected practice shall promptly be initiated. Investigation activities shall be undertaken under the supervision of the Compliance Officer. The investigation findings will be kept confidential to the maximum extent permitted by law. Investigations are described in Section 5-Allegations of this Plan.

#### **IV. External Audits**

External audits may be initiated at the request of Leadership, the Compliance Committee, government agencies, or non-government payers.

**A. Audits Initiated by Compliance Committee or Leadership:**

Examples of audits that may be initiated by the Compliance Committee or FHCP's Management include:

- HEDIS reporting
- State of Florida Quality Indicator reporting
- Financial audits
- Medical record chart master review
- One-time reviews in risk areas requiring specialized expertise, such as risk adjustment data submissions

**B. Selection of Third-Party Auditors/Consultants/Reviewers**

For external audits initiated by the Compliance Committee or management, the following guidelines should be followed:

1. Auditors should be independent of physicians, pharmacists and line management
2. Auditors should utilize generally recognized authoritative sources in conducting their reviews, such as:
  - All Federal and State regulatory guidelines
  - The National Center for Health Care Statistics
  - CMS Administration Guidelines
  - CMS Risk Adjustment Data Training for Medicare Advantage Organizations
  - Medicare Prescription Drug Benefit Manual and other instructions and guidance issued by CMS in connection with Medicare Part D
  - Medicare Managed Care Manual and other instructions and guidance issued by CMS in connection with the Medicare Advantage Program
  - American Association of Certified Public Accountants (AICPA) Guidelines
  - National Association of Insurance Commissioners (NAIC) Guidelines
  - National Committee for Quality Assurance (NCQA) HEDIS Guidelines
3. The audit firm should utilize appropriately credentialed and experienced individuals to conduct reviews. Issues to consider in evaluating credentials include:
  - Professional designations (RHIA, RHIT, CGS, CPA, MAA, and other professional licenses)
  - Expertise with the subject matter
  - Experience
  - Longevity with the company

C. Engagement of third-party auditors/consultants/reviewers

1. All compliance audits by third parties should be subject to a written agreement or engagement letter. The agreement or engagement letter should include:
  - Language requiring the work to be performed in a professional and workmanlike manner;
  - A representation that the firm's personnel assigned to the work are properly trained and have appropriate expertise, e.g., substantive knowledge of the applicable laws and regulations;
  - A representation that any advice given will be consistent with applicable state and federal laws and regulations, and that the reviewer will immediately notify management of information which suggests that the advice may be incorrect or has been challenged by governmental authorities;
  - A provision requiring the reviewer to assist the organization in defending allegations of improper conduct based on the review as advice, in whole or substantial part;
  - A representation (and proof) that the reviewer carries errors and omissions insurance covering negligent acts or intentional misconduct by its employees or agents;
  - A confidentiality statement whereby the auditors will not disclose the results of their audit except to designated FHCP personnel;
  - A requirement that they provide a written report of their findings that identifies problem areas and recommended corrective action and that such written report will be addressed to the CEO of Florida Health Care Plan, Inc.
  - Reference to generally accepted standards for conducting audits; Follow-up reviews to verify that corrective actions have been implemented successfully;
  - A contractor agreement to pay defense costs related to the organization's adherence to the contractors' advice.
2. The contract should not severely restrict the time within which claims under the contract can be made. Limitation of liability clauses and warranty disclaimers should be reviewed carefully.
3. If the review involves the identification of payment errors, the review should be designed to identify both underpayments and overpayments. The audit objectives must not include "optimizing" or "maximizing" revenue or reimbursement, but rather "correct" reimbursement.
4. The engagement must not provide for a contingent fee or fee based on revenue, or other incentives to withhold information regarding overpayments. The audit should include a review of internal policies and procedures.

D. Conduct of third-party audits/reviews

1. Audit scope should address known areas of risk identified internally, as well as areas that are the focus of attention by the fiscal intermediary or carrier, MEDICs, law enforcement agencies, and federal or state agencies, including CMS, OIG, AHCA, and DFS
2. The audit should be conducted using sampling protocols that are statistically valid, unbiased, and likely to identify variations from an established baseline.
3. Audit techniques to consider include:
  - On-site visits;
  - Desk-top audits;
  - Interviews with personnel, including First-Tier, Downstream and Related Entities, as applicable, involved in management, operations, coding, claim development and submission, patient care, and other relevant activities;
  - Interviews with personnel, including First-Tier, Downstream and Related Entities, as applicable, involved in enrollment, marketing, member services, member grievance, coverage determinations and appeals, and other related activities;
  - Questionnaires developed to solicit impressions of a broad cross-section of the organization's employees and contractors;
  - Reviews of medical and financial records and other source documents that support:
    - Payment of medical and prescription drug claims
    - Actuarial basis for bid submissions
    - Medical records and encounter data supporting member risk adjustment data submissions
    - Benefit tracking, including application of correct cost-sharing amounts
    - Member eligibility
  - Reviews of written materials and documentation prepared by the different divisions of the organization; and
  - Trend analyses, or longitudinal studies, that seek deviations, positive or negative, in specific areas over a given period.

**V. Government Audits, Investigations, Interviews, and Searches**

It is the policy of FHCP to comply fully with all of the complicated rules and regulations governing healthcare entities, including all Medicare Advantage and Part D laws, regulations, CMS instructions and guidance. Nevertheless, FHCP acknowledges that government health care regulations and their enforcement are very complex areas of the law. One purpose of the Compliance Plan is to provide a uniform method for FHCP to respond to any government employee (Federal or state) who contacts FHCP for information.

Additionally, the federal and state governments have made the investigation and prosecution of health care fraud one of their highest priorities and have proposed many new initiatives for identifying fraudulent practices. A number of these initiatives include conducting audits. Therefore, government investigations of health care entities have become and will continue to be commonplace. FHCP's policy has been and will continue to be to provide full cooperation to these government authorities, while at the same time protecting the rights of FHCP and all of its employees.

Such government agencies include but are not limited to:

<b>Agency Name</b>	<b>Description</b>
<i>Centers for Medicare &amp; Medicaid Services (CMS)</i>	Federal agency overseeing administration of the Medicare and Medicaid programs and FFM  This includes the MEDICs engaged by CMS to assist in audit, oversight and anti-fraud efforts.
<i>Federal Bureau of Investigation (FBI)</i>	Investigative arm of federal government programs
<i>Medicare Administrative Contractors</i>	Claims processors of the Medicare Part A hospitals, skilled nursing facilities, and home health agencies. Claims processors of the Medicare Part B program (e.g., physicians, clinical laboratories, durable medical equipment, and nursing home supplies).
<i>Office of the Inspector General (OIG)</i>	Investigative arm of federal government programs
<i>Florida Agency for Health Care Administration (AHCA)</i>	HMO licensure
<i>State of Florida Department of Financial Services (DFS)</i>	HMO benefits, rates, forms, and agent licensure.
<i>State Attorney General's Office</i>	Arm of the state responsible for investigating/prosecuting violations of state laws.
<i>State Attorney's Office</i>	Local authority responsible for investigating/prosecuting violations of state laws

**All employees should refer any governmental agency inquiries to the Compliance Officer or a member of the Compliance Committee.**

Additionally, FHCP recognizes that self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste, and abuse. If, after conducting a reasonable inquiry, FHCP determines that potential fraud or misconduct has occurred, the conduct will be referred to the MEDIC promptly, but no later than 60 days after the determination that a violation may have occurred. To the extent that potential fraud is discovered with respect to a Downstream or Related Entity, FHCP will refer the conduct to the MEDIC on an expedited basis so that the MEDIC can help identify and address any scams or schemes. If this timeframe cannot be met, FHCP shall contact the MEDIC for further guidance. FHCP also maintains, as part of this Compliance Plan, a protocol for voluntary self-disclosure to the OIG and such other law enforcement and/or government agencies. See the description regarding Voluntary Disclosure Submission, below.

## **VI. Medicare Advantage and Part D Fraud, Waste and Abuse Monitoring and Auditing**

FHCP recognizes the significant vulnerabilities that accompany FHCP's participation as a first tier entity under the Medicare Advantage and Part D Programs and has taken additional measures to ensure that Medicare beneficiaries receive timely access to covered drugs while also conducting its Part D operations in a manner that will minimize the risk of program funds being spent inappropriately. FHCP fills over 95% of all Part D prescriptions at its owned and operated retail pharmacies and FHCP-owned and operated mail-order pharmacy. This gives FHCP tremendous control over the delivery of prescription drugs to its members, and thus the ability to oversee, monitor and audit virtually all of the organization's Part D operations.

Examples of FHCP's efforts to combat fraud, waste and abuse in its Medicare Advantage and Part D operations include the following:

- On-going monitoring and review of member Part D coverage determination requests and appeals, including for exceptions to the formulary or cost-sharing obligation, to identify trends indicating inappropriate prescribing habits and potential need to modify a formulary provision or drug utilization mechanism
- On-going monitoring and review of Acumen reports for PDE, Patient Safety, etc.
- On-going monitoring and review of prescription drug utilization for various issues, including (i) use of pharmaceuticals identified on the National Specified List of Susceptible Products produced by the National Association of Boards of Pharmacy to ensure appropriate utilization; (ii) adverse drug events (ADR); (iii) allegations of drug-seeking/doctor shopping; theft of prescriber's DEA number or prescription pad; and prescription stockpiling
- On-going monitoring and review of use and dispensing of excluded drugs/off-label uses and utilization of contracted vs. FHCP-owned pharmacies.
- On-going monitoring and review of member TrOOP calculations to ensure accuracy of real-time tracking, proper application and collection of cost-sharing amounts, and potential for catastrophic coverage manipulation
- Audits of bid submissions, and internal Part D payment reconciliation and final payment determinations to minimize errors

**All identified risks will be investigated in accordance with FHCP Policy LD012 – Anti-Fraud Plan.**

## VOLUNTARY DISCLOSURES

In the event that FHCP identifies an event or act that violates a state or federal law, FHCP shall promptly report such activity to the appropriate regulatory entity. Additionally, any suspected act of insurance fraud related to FHCP commercial lines of business shall be reported by the Compliance Officer, or his designee, to the Florida Department of Financial Services, Division of Insurance Fraud via their website at [Division of Insurance Fraud](#).

FHCP will also follow the protocol published by the U.S. Department of Health and Human Services Office of the Inspector General related to federal health program lines of business as follows:

- A. Effective DISCLOSURE: The disclosure will be made in writing and will be submitted to the Assistant Inspector General for Investigative Operations, Office of Inspector General, Department of Health and Human Services, 330 Independence Avenue, SW, Cohen Building, Room 5409, Washington, DC 20201. Submissions by telecopier, facsimile or other electronic media will not be acceptable.

(Disclosures relating to the Medicare prescription drug benefit program may be made to the Medicare Drug Integrity Contractor (MEDIC) in addition to or in lieu of a disclosure to the OIG, as the Compliance Committee so determines based on Chapter 9 and such other guidance issued by CMS.)

- B. BASIC INFORMATION: The Submission will:
  1. Include FHCP's name, address, provider identification number(s) and tax identification number(s). Additionally, it will provide the name and address of FHCP's designated representative for purposes of the voluntary disclosure.
  2. Indicate whether FHCP has knowledge that the matter is under current inquiry by a Government agency or contractor. If FHCP has knowledge of a pending inquiry, identify any such Government entity or individual representatives involved. FHCP will also disclose whether it is under investigation or other inquiry for any other matters relating to a Federal Health Care Program and provide similar information relating to those other matters.
  3. A full description of the nature of the matter being disclosed, including the type of claim, transaction or other conduct giving rise to the matter, the names of entities and individuals believed to be implicated and an explanation of their roles in the matter, and the relevant periods involved.
  4. The type of health care provider implicated and any provider billing numbers or NPI/NCPDP numbers associated with the matter disclosed. Information will also include the federal health care programs affected (including Medicare Advantage and Part D Programs) affected government contractors (such as carriers and intermediaries) and other third-party payers.
  5. The reasons why FHCP believes that a violation of Federal criminal, civil or administrative law may have occurred.

- C. A certification by the authorized representative on behalf of FHCP stating that, to the best of the individual's knowledge, the submission contains truthful information and is based on a good faith effort to bring the matter to the Government's attention for the purpose of resolving any potential liabilities to the Government.
- D. SUBSTANTIVE INFORMATION: As part of its participation in the disclosure process, FHCP will conduct an internal investigation and a self-assessment, and then report its findings to CMS (and/or MEDIC) and OIG. The internal review will occur after the initial disclosure of the matter.

## DISCIPLINARY GUIDELINES

### I. Introduction

In order for FHCP's Compliance Plan to be effective, it is imperative that all employees understand the consequences of conduct inconsistent with FHCP's administrative and departmental Policies & Procedures or the laws, rules and regulations that govern FHCP's operations.

The Office of the Inspector General within the U.S. Department of Health and Human Services provides the following guidance on enforcement and discipline:

"It is vital to publish and disseminate the range of disciplinary standards for improper conduct and to educate officers and other staff regarding these standards. The consequences of noncompliance should be consistently applied and enforced, in order for the disciplinary policy to have the required deterrent effect. All levels of employees should be subject to the same disciplinary action for the commission of similar offenses. The commitment to compliance applies to all personnel levels within the organization. The OIG believes that corporate officers, managers, supervisors, medical staff and other health care professionals should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, laws, and procedures."

Accordingly, FHCP has developed the following Disciplinary Policy to communicate to employees the response that FHCP will take upon substantiating non-compliant behavior.

It should be noted that these guidelines are not intended to address behavior inconsistent with FHCP's Human Resources policies. Guidelines addressing behavior inconsistent with FHCP's Human Resources policies may be found in FHCP's Employee Handbook.

### II. Disciplinary Policy

It is the policy of FHCP to foster an environment wherein employees conduct themselves in accordance with the organizations administrative and departmental policies and procedures as well as the laws, rules, and regulations that govern the organization's operations. While FHCP can strive to minimize the occurrence of non-compliant behavior, FHCP recognizes that such occurrences are unavoidable. To ensure that allegations of non-compliant behavior are addressed in an appropriate, consistent, and timely manner, the following process will be followed:

#### A. Reporting

It is the responsibility of all employees to become familiar with the laws, rules, regulations, and the administrative and departmental policies & procedures that govern

FHCP's operations and to report conduct inconsistent with these standards. If inappropriate conduct by a full-time, part-time, or temporary FHCP employee or an agency employee is observed or detected, the individual witnessing or detecting the behavior shall immediately report the act(s) as described in Section 4 – Communications of this Plan.

**B. Allegation Report**

When an allegation of inappropriate conduct is brought forth, all relevant facts should be included. This should contain, at a minimum, the following:

- The date, time, and location of the conduct.
- The name of the individual alleged to have committed the violation.
- A description of the alleged act(s) that resulted in the violation.
- A description of the standard that was allegedly violated.
- The name of the individual that witnessed the act(s).
- Any evidence brought forward by the individual witnessing the alleged misconduct.

This information shall be forwarded to the Compliance Officer within 2 business days.

**C. Investigation**

Once the Compliance Officer has received the information, an investigation shall commence to substantiate/refute the claim. The Compliance Officer shall enlist the assistance of any necessary resources to promptly and thoroughly assess the validity of the allegation. The results of all investigations shall be documented and maintained by the Compliance Officer. In the event that it is determined that it would be inappropriate for the Compliance Officer to conduct the investigation; the Compliance Committee shall identify an alternate individual to manage the investigation.

**D. Offense Classification Guidelines**

All substantiated occurrences of conduct inconsistent with the standards that govern FHCP's operations shall be classified into one of four levels of offenses. The Administrator of the division where the employee is assigned and FHCP's Compliance Officer shall jointly determine the offense classification. Offenses shall be classified as follows:

### **III. Offense Classification Guidelines**

	<b>Description of Offense</b>	<b>Examples</b>	<b>Discipline</b>
<b>Level I</b>	Violation of a FHCP Policy/Procedure or a regulatory standard that does not compromise the safety of FHCP's members, patients or staff but may cause a minimal disruption to the workplace.	<ul style="list-style-type: none"> <li>• Distributing member communications to Medicare members without a CMS approval number.</li> <li>• Not logging off the computer system when leaving the workstation.</li> </ul>	Verbal Counseling and/or Supplementary Training
<b>Level II</b>	Violation of a FHCP Policy/Procedure or a regulatory standard that does not compromise the safety of FHCP's members, patients or staff but may cause a substantial disruption to the workplace.	<ul style="list-style-type: none"> <li>• Unauthorized access of the electronic protected health information of a relative who is a minor.</li> <li>• Leaving protected health information unattended in a non-secured area.</li> </ul>	Written Counseling and/or Supplementary Training
<b>Level III</b>	Violation of a FHCP Policy/Procedure or a regulatory standard that poses significant risk but does not result in harm to an individual, FHCP, or another entity.	<ul style="list-style-type: none"> <li>• Intentional unauthorized access of a member's protected health information.</li> <li>• Sharing passwords.</li> </ul>	Letter of Warning, Suspension Without Pay 1 day, Supplementary Training, and/or Demotion
<b>Level IV</b>	Violation of a FHCP Policy/Procedure or a regulatory standard that causes physical, financial, reputational, or other harm to an individual, FHCP, or another entity.	<ul style="list-style-type: none"> <li>• Intentional unallowable disclosure of member protected health information.</li> <li>• Refusing to cooperate with an internal or external investigation.</li> </ul>	Suspension Without Pay More Than 1 day or Termination

#### **E. Determination of Sanctions:**

FHCP's Compliance Officer and Human Resources Director shall jointly determine the level of discipline levied upon the offending individual. Prior instances of regulatory misconduct may result in increased disciplinary measures. In the event that the individual has been noncompliant with FHCP Human Resources policies, the employee's administrator shall be included to determine if a higher level of discipline is warranted.

#### F. Enforcement and Record Retention Responsibility

For all substantiated allegations of misconduct, the employee's Administrator shall be responsible for enforcing the prescribed discipline in accordance with this Policy. Additionally, the Compliance Officer shall ensure that all relevant documentation related to the substantiated allegation and the organization's response to such act(s) is retained. Such documentation shall include, at a minimum, all evidence supporting the allegation, the justification for the classification of the offense, and a description of the discipline taken. Such documentation shall be retained for the term of the violator's employment plus seven years.

#### G. Downstream and Related Entities of FHCP

FHCP shall take such corrective action with respect to any Downstream or Related Entity. Such corrective action shall take into consideration the recommendations of the Compliance Officer and the Compliance Committee, as well as the nature of any noncompliant activities and/or conduct, the severity of the action, the cooperation of the entity with respect to FHCP's investigation, the actions of the entity in correcting the issue of noncompliance, and such other factors that FHCP, the Compliance Officer and Compliance Committee consider relevant.

Such corrective action may include (i) imposition of a corrective action plan on the entity, which may include additional auditing and monitoring by FHCP; (ii) suspension or revocation of the entity's performance of a particular activity or service under the contract with FHCP; and/or termination of the entity's contract with FHCP. Reports to the MEDICs, CMS, OIG, OIR, and/or other federal or state agencies also may be made.