Santa Clara Family Health Plan™

SANTA CLARA COUNTY HEALTH AUTHORITY d/b/a SANTA CLARA FAMILY HEALTH PLAN

Compliance Program 2018 - 2019

Governing Board Approval Date: September 27, 2018

Compliance Program Overview

Santa Clara County Health Authority d/b/a Santa Clara Family Health Plan ("SCFHP" or "Plan") has developed this Compliance Program to provide guidance and ensure its activities as a Medi-Cal and a Cal MediConnect Plan are conducted in an ethical and legal manner, in accordance with the 3-way Contract between the United States Department of Health Care Services, Center for Medicare and Medicaid Services ("CMS"), the California Department of Health Care Services ("DHCS"), and Plan, the with the Plan's Standards of Conduct and policies and procedures, and with applicable State and Federal law and regulations. The Compliance Program includes seven core elements with a particular focus in each of the following areas: oversight of first tier, downstream and related entities (FDRs), compliance program effectiveness measures, and fraud, waste and abuse (FWA) prevention, detection and correction principles. These elements serve as the directional basis and source of guidance for development of operational and oversight policies and procedures for all Plan lines of business. This Compliance Program also articulates the framework and guiding principles for how the Plan will effectively ensure its compliance with applicable program requirements. The Compliance Program reflects the Plan's commitment to compliance with all applicable program requirements, including all applicable Federal and State standards. It is updated annually, and as appropriate from time-to time, and such updates are reviewed, approved and adopted by the Plan's Compliance Committee and Governing Board ("Board").

The Compliance Program described herein governs the activities of the Plan's employees (including temporary staff), contractors and volunteers, as well as Board and Committee members, collectively referred to as "Personnel:"

The Compliance Program also applies to any subcontractors, vendors, agents or entities otherwise defined as FDRs under the Centers for Medicare & Medicaid Services (CMS) regulations and guidance, to whom Plan has delegated administrative or health care service functions relating to the Plan's 3-Way contract, and their employees (including temporary staff) and contractors who provide health and/or administrative services in connection with Plan's Cal Medi-Connect plan or that relate to Plan's Medicare functions.

The information contained in this Compliance Program is effective as of the date of approval by the Board.

Element I: Written Policies and Procedures and Standards of Conduct

SCFHP's Standards of Conduct is a policy and reference guide that describes the Plan's Standards of Conduct and Code of Ethics, including by way of practical application of the organization's core values and cultural attributes. This document sets forth the expectation of employees to report instances of potential non-compliance and Fraud Waste and Abuse ("FWA"). The Standards of Conduct, together with Plan's policies and procedures, are accessible to all employees within a shared location and demonstrate the Plan's commitment to comply with all applicable Federal and State laws and regulations. It is the Plan Leadership's expectation that all Personnel and FDRs shall adhere to the Plan's Standards of Conduct and policies and procedures, as well as applicable law, in the course of performing their duties on behalf of the Plan and its enrolled beneficiaries. This expectation is promoted through communications and training, and enforced through disciplinary, contractual and other standards.

The Standards of Conduct emphasize the need to maintain a high ethical standard for individual and organizational behavior and legal business practices. In addition, the Standards of Conduct and our policies and procedures provide practical guidance for Personnel and FDRs for effectuating compliance with law and promoting ethical and business practices in their daily roles. In doing so, the Standards of Conduct and our policies and procedures support the Plan's FWA prevention, detection and correction efforts, including but not limited to through emphasis on compliance with:

- Federal and state False Claims Acts;
- Federal and state Anti-Kickback Statutes;
- Health Insurance Portability and Accountability Act of 1996, as amended;
- Prohibition on inducements to beneficiaries; and
- Plan Conflict of Interest rules.

The Standards of Conduct, as well as SCFHP's policies and procedures, also describes the process that any and all Personnel and FDRs (and their employees) are expected to use to report possible compliance and FWA issues to management, or anonymously using the Plan's free hotline, and includes a statement of non-intimidation and non-retaliation for good faith participation in the Compliance Program. Disciplinary actions, such as suspension or termination of employment, termination of contractual relationship or removal from office or Board membership may be taken for failure to comply with the Standards of Conduct. Reported issues are investigated and resolved in accordance with Plan's established policies and procedures.

FDRs to whom Plan has delegated administrative or health care service functions relating to the Plan's Three-way contract may either adopt the Plan's policies and procedures (as relevant to delegated functions) and Standards of Conduct (as provided upon contracting and annually thereafter) or implement their own policies, procedures, and/or standards of conduct consistent with Plan's and in full compliance with DHCS, DMHC and CMS requirements. FDRs shall distribute such Standards of Conduct and/or policies and procedures to their employees upon hire, appointment or contracting, at any time material revisions are made, and annually thereafter. The FDR's compliance program, policies, procedures and standards of conduct are subject to review upon audit by the Plan.

The Standards of Conduct is presented to Personnel at the time of hire, appointment or contracting and any time material revisions are made. All Personnel must attest that they have read and agree to comply with the Standards of Conduct and guidelines. Such attestations are kept with the employee or other individual's record. Attestations of FDRs and their employees concerning receipt of the relevant materials are maintained by the FDRs and can be audited by the Plan at any time.

In addition to the Standards of Conduct, Plan has issued and implemented policies and procedures that are detailed and specific, and describe the operation of the Compliance Program. Compliance policies and procedures are reviewed and updated as necessary, but no less than annually, to incorporate any relevant changes in applicable laws, regulations and other program requirements. Proposed revisions are developed under the direction of the Chief Compliance Officer, referred to the Compliance Committee for review and approval, and reported to the Board.

Element II: Compliance Officer, Compliance Committee and High Level Oversight

The success of the Compliance Program is the responsibility of many individuals within the Plan. The Chief Compliance Officer, Senior Management, the Compliance Committee and the Board all play an important role in the implementation and success of the Compliance Program. As used in this Compliance Program, the phrase "Senior Management" refers to the Chief Executive Officer, the Chief Operating Officer, the Chief Financial Officer, the Chief Medical Officer, the Chief Information Officer, and such other executive level staff as may join the organization.

The sections below serve to describe the responsibilities of the Chief Compliance Officer, Compliance Committee, the Board and Senior Management.

A. The **Chief Compliance Officer** (CCO) serves as the Compliance Officer (as the term is used within Chapters 9 and 21 of the Prescription Drug Benefit Manual and Medicare Managed Care Manual, respectively) and is an employee of, and reports directly to, the Plan's CEO and Board. The CCO has detailed involvement in, and familiarity with, the Plan's operational and compliance activities (but shall be independent from, and not have direct responsibility over, program operations). The CCO directs the Plan's day-to-day operations and execution of the Compliance Program. The CCO is also a member of Senior Management and has direct access to the Plan's Chief Executive Officer (CEO) and the Board, and is provided with sufficient resources and authority to effectively carry out his or her duties.

The CCO shall have the authority to:

- Provide periodic written and/or in-person reports (as appropriate) directly to the Governing Board;
- Interview or delegate the responsibility to interview Plan employees and other relevant individuals;
- Review and retain company contracts and other documents pertinent to the Medi-Cal and Cal MediConnect programs;
- Review or delegate the responsibility to review the submission of data to CMS and DHCS to ensure that it is accurate and in compliance with their respective reporting requirements;
- Independently seek advice from legal counsel;
- Report misconduct and potential FWA to CMS, its designee and/or law enforcement;
- Conduct and direct audits and investigations of any first tier entities, downstream entities, or related entities;
- Conduct and/or direct audits of any area or function involved with Medi-Cal or Cal MediConnect plans (excluding those conducted under the purview of SCFHP's Executive/Finance Committee, such as external financial audits);
- Recommend policy, procedure and process changes;
- Enforce compliance program requirements at all levels of the Plan organization.

The duties for which the CCO is responsible include, but are not limited to:

- Communicating regularly with and reporting to the Board, Senior Management and the Compliance Committee on the status of the Compliance Program, including issues identified, investigated and resolved;

- Developing, implementing, managing, and monitoring the effectiveness of the Compliance Program and ensuring that the Board and Senior Management are aware of performance metrics and potential issues and their potential solutions;
- Identification and resolution of potential or actual instances of noncompliance or FWA;
- Creating, coordinating, and/or participating in educational training programs to ensure Personnel and FDRs are knowledgeable of Plan's Compliance Program, Standards of Conduct, operational and compliance policies and procedures, and applicable statutory, regulatory, and other program requirements;
- Monitoring Federal and State legal and regulatory developments (including but not limited to, Fraud Alerts and Advisory Opinions issued by the U.S. Department of Health and Human Services' Office of Inspector General (OIG) and Health Plan Management Systems (HPMS) memos and updating the Compliance Program as appropriate);
- Developing, maintaining and promoting use of retribution-free methods and programs for reporting in good faith suspected Medicare program non-compliance, misconduct or potential FWA by Personnel, FDRs or others;
- Working with Human Resources to ensure that the Plan conducts appropriate background checks, including routine screening, against all required exclusion lists;
- Developing risk analyses that are used to focus Compliance Program efforts in a manner designed to promote overall effectiveness;
- Developing and monitoring the implementation of, and adherence to, compliance policies and procedures through the creation and implementation of a compliance work plan (Work Plan) that defines internal monitoring, audit requirements, schedule and methodology;
- Maintaining documentation and tracking of each report of potential non-compliance and FWA received through any of the reporting methodologies or as self-identified through monitoring, auditing or other means;
- Conducting self-evaluations of the Compliance Program to assess overall effectiveness and identify areas for improvement;
- Conducting (or evaluating information obtained from) exit interviews; and,
- Responding to reports of potential instances of FWA, including through coordination of internal investigations and the development of appropriate corrective or disciplinary actions, or referral to law enforcement, as necessary.

B. The **Compliance Committee** assists the Plan's Board in the oversight of the Compliance Program and is accountable to provide support and guidance necessary to the CCO in overseeing the outcomes and performance of activities initiated under the Compliance Program. The Compliance Committee, through the CCO, shall periodically report directly to the Board on the activities and status of the Compliance Program, including issues identified, investigated, and resolved by the Compliance Program.

The Compliance Committee shall include individuals with a variety of backgrounds to ensure CCOss-functional representation. Such members shall have both decision-making authority and understanding of vulnerabilities within their areas of expertise. Members shall include representatives from areas including,

but may not be limited to, finance, health plan operations (including enrollment, appeals and grievances, and customer service), medical management, pharmacy services, quality improvement, marketing and sales, information technology and legal counsel. The Compliance Committee will be appointed by the Board and the CCO will act as the Compliance Committee chairperson.

The Committee may invite other individuals, such as members of management, auditors, or other technical experts to attend meetings and provide pertinent information, as necessary.

The Committee has been delegated by the Board to uphold certain responsibilities, including but not limited to:

- Meeting on a quarterly basis, or more frequently as necessary, to enable reasonable oversight of the Compliance Program;
- Development, implementation and annual review and approval of compliance policies and procedures;
- Reviewing and approving relevant compliance documents, including but not limited to:
    - CCO's performance goals;
    - Compliance and FWA training;
    - Compliance risk assessment;
    - Compliance and FWA monitoring and auditing Work Plan and audit results; and
    - Corrective action plans resulting from audits or other means of identification (and monitoring of their effectiveness);
- Developing strategies to promote compliance and the detection of any potential compliance violations, especially as they relate to core beneficiary protection issues such as, but not limited to, appeals and grievances, enrollment, transition, coverage determinations and exceptions;
- Reviewing effectiveness of the system of internal controls, such as dashboards, scorecards, self-assessment tools, etc. designed to reveal compliance issues or FWA issues, and metrics concerning operational compliance with key Medicare regulatory requirements, such as, but not limited to, those governing enrollment, appeals and grievances, and prescription drug benefit administration; and
- Ensuring that SCFHP has an easy to use system for employees and FDRs to ask compliance questions and report potential instances of noncompliance and potential FWA confidentially or anonymously (if desired) without fear of retaliation

The Compliance Committee will collect and review measurable evidence (using tools such as dashboards reports, scorecards and key performance indicators) concerning Compliance Program performance as a concrete means of measuring/demonstrating the extent to which the Compliance Program is detecting and correcting noncompliance and FWA on a timely basis, and providing insights into any potential needed process improvements. The CCO will provide the Compliance Committee with data showing the status of organizational compliance through:

- Use of monitoring tools to track and review open/closed corrective action plans, FDR compliance, Notices of Non-Compliance, Warning Letters, CMS sanctions, marketing material approval rates, training completion/pass rates, results of CMS readiness checklist review, past performance review

metrics, etc.;
- Implementation of new or updated Medicare program requirements (*e.g.*, tracking HPMS memo from receipt to implementation) including monitoring or auditing and quality control measures to confirm appropriate and timely implementation;
- Increase or decrease in number and/or severity of complaints from employees, FDRs, providers, or beneficiaries through customer service calls or the Complaint Tracking Module (CTM), including those relating to alleged marketing misrepresentations, etc.;
- Timely response to reported instances of potential noncompliance and FWA (including issues raised by CMS), and effective resolution (*i.e.,* non-recurring issues);
- Application of consistent, timely and appropriate disciplinary action; and
- Detection of noncompliance and FWA issues through monitoring and auditing:
    - Whether root cause was determined and corrective action appropriately and timely implemented and tested for effectiveness;
    - Detection of FWA trends and schemes via, for instance, daily claims reviews, outlier reports, pharmacy audits, etc.; and
    - Actions taken in response to non-compliance or FWA reports submitted by FDRs.

C. The governing body providing appropriate oversight of the Compliance Program is SCFHP's Board. The Board reviews and approves the Compliance Program and subsequent updates as revisions are made. As mentioned previously, the Board has delegated certain responsibilities to the Compliance Committee, but the Board as a whole remains accountable for Compliance Program oversight.

In addition to the above, the duties for which the Board is responsible include, but are not limited to, active oversight of the effectiveness of the Compliance Program and compliance results as follows:

- Understanding the Compliance Program structure, content and operation (including through appropriate training that educates Board Members regarding the Compliance Program operations, compliance risks and strategies and methods of gauging Compliance Program effectiveness);
- Evaluation of SCFHP's Senior Management team's commitment to ethics and the Compliance Program;
- Reviewing, understanding and questioning information provided within reports presented to them, including by the CCO, at least quarterly, on the activities of the Compliance Program. Such activities include, but are not limited to, actively considering:
    - Compliance Program outcomes (such as results of internal and external audits);
    - The effectiveness of corrective action plans implemented in response to identified issues;
    - Governmental compliance enforcement activity, such as Notices of Non-Compliance, Warning Letters, Corrective Action Plan requests, contract actions and/or other sanctions;
    - Reports of potential noncompliance and/or FWA issues identified, investigated, and resolved;

  - Identified risks and mitigation performed; and
  - The results of performance and effectiveness assessments (including self-assessments) of the Compliance Program;
- Conducting follow-up on issues and taking appropriate action when necessary; and
- Approval of Standards of Conduct and Compliance Program (and modifications thereto).

The Board shall document in meeting minutes and related records its active engagement in the oversight of the Compliance Program and include documentation of the Board's discussion, follow-up on issues and actions taken in response and to ensure an effective Compliance Program.

D. Senior Management

The CCO shall provide SCFHP's CEO with periodic reports of risk areas facing the organization, the strategies being implemented to address them, and the results of those strategies. The CCO shall notify the CEO and the Senior Management team, as appropriate, of all governmental compliance enforcement activity, including the issuance of Notices of Non-compliance, Warning Letters, Corrective Action Plan requests, and contract actions and/or other sanctions, and seek consultation and assistance regarding how best to respond to and address the same.

Element III: Effective Training and Education

A. General Compliance Training

SCFHP provides a comprehensive education and training program to ensure communication and understanding of the Compliance Program and SCFHP's Standards of Conduct and Compliance policies and procedures. The education, training and communication program is designed to ensure that all Personnel (including without limitation the CEO, Senior Management and Board members), and any other applicable individual acting on behalf of SCFHP in connection with its Medicare program(s), such as FDRs and their employees, are fully capable of carrying out their duties in compliance with the Compliance Program, Standards of Conduct and relevant policies and procedures. The education program includes general Compliance Program awareness training, and specific training and education tailored to individuals' roles and responsibilities. For example, employees whose job primarily focuses on enrollment or claims would receive additional training in these areas.

Compliance Program education and training occurs within ninety (90) days of hire (or appointment to Board), and, at a minimum, annually thereafter. The education and training may be provided through a variety of teaching methods, including classroom study, computer-based training, and distance learning. Additional tools may be used to communicate the Compliance Program process, such as use of posters, written Compliance Program updates, internet and intranet resources, and topical newsletters and other publications. SCFHP shall document and/or maintain records of Personnel who complete the required Compliance Program education and training in a format that is easily accessible. SCFHP shall implement controls to ensure that all Personnel are trained, as required. SCFHP shall review and update the general Compliance Program training, as necessary, whenever there are material changes in statute, regulation or Medicare Part C or Part D program guidance, and at least annually.

B. FWA Training

SCFHP provides Personnel with standard FWA training within ninety (90) days of initial hiring (or appointment to the Board), and annually thereafter. SCFHP may require that particular individuals participate in specialized or refresher training on issues posing FWA or other risks relevant to the individual's particular job function. Training may be required, as appropriate, when MMP program requirements change, when an individual is found to be non-compliant or needs additional training, or when training is appropriate to address an identified organizational deficiency or with respect to an area where FWA was identified in the past or presents heightened risk.

C. First Tier, Downstream and Related Entity Training

SCFHP requires FDRs, to whom SCFHP has delegated administrative or health care service functions relating to SCFHP's MMP contract(s), to conduct training that meets CMS training requirements and is consistent with SCFHP's training materials. SCFHP shall accept the certificate of completion of the CMS Standardized General Compliance Program Training and Education Module as satisfaction of the training requirement.

Any FDR that has met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier is deemed to have met, and fully satisfied, SCFHP's training and educational requirements related to FWA. In such context, no additional documentation beyond the documentation necessary for proper credentialing is required to establish that an employee or FDR or employee of an FDR has met SCFHP's FWA training requirements. In the case of chains, such as chain pharmacies, each individual location must be enrolled into Medicare Part A or B to be deemed. Such deemed individuals must, however, participate in the CMS general Medicare compliance training. FDRs that do not qualify for deeming status must take both the General Compliance and the FWA training programs offered by CMS.

Element IV: Effective Lines of Communication

SCFHP has established numerous mechanisms to ensure effective lines of communication exist between the CCO, members of the Compliance Committee, Personnel (including the Board) and SCFHP's FDRs (and their employees).

For instances, in order to facilitate communication among all Personnel, FDRs and the CCO, SCFHP offers a phone hotline, available 24 hours a day, 7 days a week, which can be used anonymously if preferred, through which an individual may seek guidance or disclose information about potential compliance or FWA issues. Through Compliance Program activities, Personnel and FDRs are encouraged to ask compliance and FWA related questions through various means, such as direct contact with the CCO, in order to assist such individuals in evaluating and dealing with suspected, detected or reported compliance or FWA issues. If requested and as appropriate, the CCO shall treat such communications confidentially. The CCO also communicates with Personnel, FDRs and enrollees concerning compliance and FWA issues through various educational mechanisms, as discussed more fully below.

A. Procedures for Reporting Noncompliant or Unethical Behavior

All Personnel and FDRs are required to report compliance concerns and suspected or actual violations related to SCFHP's MMP program to SCFHP. The reporting process set forth in this Compliance Program, as well as CCO name and contact information, is communicated to Personnel and FDRs and their employees through various means, including general Compliance Program training. An individual may confidentially report compliance and FWA concerns in multiple ways, at their option, including: 1) directly to his/her supervisor or manager (as applicable), 2) to SCFHP's CCO, or 3) anonymously using SCFHP's free phone hotline reporting tool (available 24/7). SCFHP's non-intimidation and non-retaliation policy provides the individual who makes a report, complaint, or inquiry in good faith with protection from retaliatory action, including with respect to reporting of False Claims Act complaints and/or reporting to appropriate officials. SCFHP has a no tolerance policy for intimidation of, or retaliation taken against, individuals making such good faith reports, complaints or inquiries and shall take disciplinary action against individuals who are determined to have intimidated or retaliated against such individuals.

SCFHP recognizes that enrollees, contracted providers and FDRs are important sources for identifying potential non-compliance and/or FWA. SCFHP widely publicizes the methods by which individuals and entities outside the SCFHP organization can report possible instances of fraud, waste, abuse or non-compliance to the organization and can ask questions, including through the hotline (which is accessible to all).

Hotline information is provided to enrollees through the quarterly enrollee newsletter and to FDRs and other means. As part of this communication process, FDRs receive quarterly informational bulletins containing, as a standing item, hotline availability and reasons for use (including for compliance questions). The CCO's contact information is also always contained within these materials. SCFHP customer service representatives, who intake calls from both enrollees and FDRs, including providers, have also been trained to recognize potential instances of non-compliance or FWA, and to properly

memorialize and direct issues within the Plans Sponsor organization for appropriate follow-up by the CCO or others.

B. Education

The CCO engages in active communication with Personnel, FDRs and enrollees concerning a wide range of compliance issues, including the standards for compliance with laws, regulation and guidance; changes in legal authorities and/or compliance policies and procedures; and guidance on how to identify and report FWA issues. Such communication is accomplished through various educational means, including through newsletters and posters, SCFHP Websites, formal training, and individual and group meetings.

C. Follow-Up and Tracking

Once received, issues of potential non-compliance or FWA will be documented and forwarded to the CCO and/or his or her designee for investigation/resolution and reporting to the Compliance Committee and the applicable State and/or Federal agency, or law enforcement, as required.

D. Integrated Communications

To enhance SCFHP's day-to-day communication, understanding and focus on its actual compliance, and to ensure that potential compliance and FWA issues are examined early and corrective actions are implemented timely, each department maintains a set of compliance "dashboard" metrics that are routinely shared with the CCO. These dashboard results are i) reported to department staff to increase their attention to compliance, and ii) reported to the CCO for monitoring and auditing activities (such as trend analysis and identification of anomalies), and to provide status of any corrective actions undertaken and implemented (including barriers to implementation). Reports on these and other compliance activities will be routinely reviewed by Senior Management and reported to the Compliance Committee and the Board at each meeting, as appropriate.

Element V: Well-Publicized Disciplinary Standards

Compliance training, in its various forms (*e.g.* mandatory formal training, newsletters, websites and posters), demonstrates practical application of the Standards of Conduct. These training programs provide instruction regarding various regulations and laws pertinent to our business, as well as "Questions and Answers" that describe the expectation that SCFHP has of Personnel when confronted with certain situations, including appropriate reporting and the duty to assist in issues resolution. These programs set forth the expectation by SCFHP of Personnel and FDRs and their employees to report illegal or unethical behavior and potential compliance and/or FWA issues, as well as to assist in their resolution. They also encourage Personnel to contact the CCO or others if they have questions concerning potential compliance or FWA issues.

In various communications, SCFHP explains the ramifications faced by SCFHP for non-compliance with regulations and laws affecting its business, as well as disciplinary action to be taken against individual(s) or entities who have either committed a crime and/or participated in or knew about potential non-compliance, unethical behavior and/or FWA, but failed to report it to SCFHP. *Disciplinary action will be assessed based on the infraction and could range from retraining of the individual/entity, up to termination of employment/Board membership/contract.*

Enforcement of the standards will be timely, consistent and effective when non-compliance or unethical behavior (such as fraud) is determined. As set forth in Element IV, Part A, employees have an affirmative obligation to identify non-compliance and unethical behaviors, and failure to meet this obligation will result in appropriate action according to the disciplinary standards. Records of enforcement of standards will be maintained for ten years for all disciplinary actions based on compliance violations or FWA (or the failure to report the same), and such records will capture the date the violation was reported, a description of the violation, the date(s) of investigation, a summary of findings, the disciplinary action taken and the date it was taken. SCFHP may, from time-to time, review such records to ensure that discipline is appropriate to the seriousness of the offense, fairly and consistently applied, and imposed within a reasonable time frame after the infraction and/or discovery of such.

Finally, compliance is a measurement on SCFHP's annual employee performance evaluation to reinforce the importance that compliance plays in each individual's role within the organization. Issues of non-compliance will be considered by SCFHP in connection with whether to renew or continue any particular arrangement with an FDR.

Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks and FWA

SCFHP will establish and implement an effective system for identification of non-compliance or unethical behavior (such as activities involving fraud and abuse) and evaluation of the Compliance Program through risk analysis, engagement in monitoring and auditing activities and review of reported issues (including any issues identified by CMS). The system will include, among other things, routine and targeted internal monitoring and auditing of operational areas and auditing and monitoring of FDRs. SCFHP may from time-to-time engage external auditors to assist with focused review of particular areas where it deems such appropriate (*e.g.,* because of expertise required or resource limitations).

Multiple methods will be employed to facilitate monitoring and auditing of operational areas in a focused and efficient manner, including without limitation conducting risk assessments, developing annual Work Plans, engaging in on-site audits or desk reviews, conducting monitoring, including through periodic reports, and analyzing and responding to such monitoring and auditing results.

A. Risk Assessment

SCFHP will regularly conduct a risk assessment of all business operational areas, and those of FDRs to whom SCFHP has delegated functions under its MMP contract(s). Each operational area (including those delegated to FDRs) will be assessed for the types and levels of risks the area presents to the MMP program, to SCFHP and to its Medicare beneficiaries, paying close attention to those areas CMS considers high risk, such as but not limited to:

- enrollment and disenrollment non-compliance;
- appeals and grievances;
- benefit and formulary administration;
- credentialing;
- quality assessment;
- organization determinations;
- coverage determinations;
- transition and protected class policy;
- utilization management;
- accuracy of claims processing;
- previously identified areas of vulnerability for potentially fraudulent claims;
- outbound enrollment verification calls;
- marketing and enrollment violations, agent/broker misrepresentation, and selective marketing; and
- FDR oversight and monitoring.

In addition, SCFHP's risk assessment(s) will take into account information received from the OIG's annual work plan and Medicare Managed Care Manual and Medicare Prescription Drug Benefit Manual chapter guidance updates, as well as other CMS program instructions, Fraud Alerts, CMS audits and other CMS indicators regarding plan performance (such as Warning Letter, Deficiency Notices, audit results, etc.). The risk assessment will expressly take into account CMS guidance provided concerning

its prior year audits findings and any recent interim sanction or civil monetary penalties assessed by the agency. The CCO will rank those risks identified during this process in order to identify those areas presenting the greatest potential risk to SCFHP. Risks identified through CMS audits and oversight, as well as SCFHP's own monitoring, auditing and investigations, will be considered priority items in the overall risk analysis. The CCO will develop the proposed annual Work Plan in consultation with the Compliance Committee and/or departmental staffs as appropriate, taking into account the results of the risk assessment.

B. Annual Monitoring and Auditing Work Plan

An annual Work Plan, based on the results of the risk assessment, will be developed and brought to the Compliance Committee for review, input and approval. The Work Plan will include the audits to be performed (both of SCFHP and FDRs), the audit schedule, methodology to be used, if it is to be performed desktop and/or onsite, and the responsible party for performing the audit, as well as specify routine monitoring to be conducted. Such monitoring and auditing activities are designed to test controls and prevent, detect and correct compliance issues and FWA through verification of compliance standards and adherence to State and Federal laws, contractual requirements, Medicare regulatory requirements, Part C and Part D program instruction, SCFHP Compliance Program policy and procedures, and Standards of Conduct. During the course of the year, the CCO may propose modifications to the Work Plan to the Compliance Committee, as developments warrant (such as changes in law or identified compliance or FWA issues).

C. Audits

The Compliance Department, which is independent from the Plan's daily operations, will perform, or will arrange for independent, external parties to perform, audits of SCFHP's internal operations and FDRs. The CCO shall coordinate with auditors regarding audit design and related considerations, and receive regular reports from the auditors regarding audit status and results. Auditors will be directed to use a standard audit report format addressing audit objectives, scope and methodology, findings (including regarding condition, cause and effect), and recommendations. They will use care in selecting sample and sample size, based on whether a targeted or statistically valid sample is intended. Auditors shall be knowledgeable about CMS operational requirements for the operational areas (whether internal or of FDRs) under review. Operations staff may assist auditors, as long as such assistance does not interfere with the auditors' independent review. Such assistance can take the form of gathering data for samples or providing other basic information to auditors. Auditors shall have access to relevant Personnel, records and areas of operation under review, including the operational departments at SCFHP, as well as FDR employees and operations. All Personnel and FDRs have a duty to cooperate with monitoring and auditing efforts directed by the CCO.

D. Monitoring

Routine operational metrics relative to regulatory standards and compliance measures will be maintained by the business units and the results reported to the CCO. Monitoring will also be conducted in each instance to determine whether corrective action plans are effective in addressing the compliance issue identified.

E. Analyzing and Responding to Monitoring and Auditing Results

Results of audits and monitoring, and any required root cause analyses and corrective action plans will be reported by the CCO (or his or her designee) to the Compliance Committee and, as appropriate, Senior Management (including the CEO) and/or the Board. Audit findings will also serve to identify Personnel, business units and/or FDRs requiring additional training (general or focused); the need for clarification or amendment of policies and/or procedures; the need for correction of system logic; and/or other necessary actions. The CCO shall be responsible for overseeing follow-up reviews of areas found to be non-compliant, as necessary, to determine if implemented corrective action has fully addressed the underlying problem identified. If applicable and appropriate, the CCO will consider whether to voluntarily self-report audit findings of non-compliance and/or potential fraud or misconduct related to the MMP program to CMS or its designee, such as the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC).

F. Excluded Parties

SCFHP, in an effort to prevent FWA, shall screen Personnel against United States Department of Health & Human Services' (DHHS) OIG List of Excluded Individuals and Entities and the General Services Administration's (GSA) Excluded Parties Lists System, prior to hiring or contracting and monthly thereafter, to ensure that such individual or entity does not appear on such list(s) (*i.e.,* is not an excluded individual or entity). SCFHP also requires its FDRs to have a similar policy and audits accordingly to ensure compliance with such requirements.

G. Compliance Program Effectiveness

SCFHP is committed to a process of continual process improvement with respect to its Compliance Program. As such, SCFHP will conduct an annual audit of the effectiveness of the Compliance Program. After completion of a baseline compliance program effectiveness audit, such audit will be conducted by external auditors (or Personnel not part of the Compliance department). To assist in determining effectiveness, the Compliance Committee will annually evaluate whether activities under the Work Plan were completed in a timely and appropriate manner, actual performance of the CCO against performance goals (if relevant), CMS compliance assessments *(e.g.,* Warning Letters, Notices of Non-compliance, CAP requests, audits, sanctions), results of CMS readiness checklist assessment, and past performance review measurements as they relate to compliance. Results of this audit will be shared with the Compliance Committee, Senior Management and the Board. Either the CCO, Compliance Committee and/or the Board may recommend modifications, such as enhancing or increasing internal monitoring frequency in areas that have previous low threshold results or areas that have become the subject of increased scrutiny (through regulation, audit or guidance), by state and/or federal regulatory agencies, including but not limited to CMS or the OIG.

Element VII: Procedures and System for Prompt Response to Compliance and FWA Issues

SCFHP has established and will maintain a process for assuring prompt response to reports or other identification of potential non-compliance and/or FWA, including timely investigation of potential problems, implementation of corrective actions to address past issues and mitigate future occurrences; appropriate self-reporting of fraud and misconduct, and processes to ensure appropriate action is taken with regard to identified overpayments.

A. Investigations of Compliance and FWA Issues

SCFHP will establish and implement procedures and a system for promptly responding to potential compliance and FWA issues as they are raised. Compliance or FWA problems identified in the course of self-evaluations, reports or complaints to the SCFHP, audits and/or other means and verified through investigation will be corrected promptly and thoroughly to address the issue, reduce the potential for recurrence, and promote ongoing compliance with CMS requirements. If a potentially serious violation is identified, SCFHP will consult with its designated FWA/SIU vendor for assistance to determine the type and extent of the potential violation and liability. SCFHP may invoke attorney-client privilege at any time during the investigation as determined by legal counsel. External legal, auditing, and other expert resources may be engaged to provide additional services. SCFHP will immediately cease, or instruct its FDR to immediately cease, questionable practices upon knowledge or clear indication of a violation. In addition:

- SCFHP will conduct a timely, reasonable inquiry into any evidence of misconduct related to a payment or delivery of items or services under the contract with CMS (with such inquiry initiated within 2 weeks after the date the potential non-compliance or FWA incident is identified);
- SCFHP will conduct appropriate corrective actions (for example, repayment of overpayments and/or disciplinary actions against responsible individuals) in response to the potential violations referenced above; and,
- SCFHP will have procedures to consider whether to voluntarily self-report fraud or misconduct related to the MMP program to CMS or its designee (such as NBI MEDIC) in appropriate situations, consistent with CMS guidelines and time frames.

SCFHP and its Pharmacy Benefit Manager (PBM) shall monitor Fraud Alerts and will review its contractual agreements (or direct the PBM to review contractual agreements) with the identified parties, as appropriate, to determine whether any additional action should be taken. SCFHP and/or its PBM will review past paid claims from the identified entities to determine if there are any claims that it may have paid that were not payable (*e.g.,* related to an Excluded Individual) and should be removed for prior sets of prescription drug event drug submissions.

Responses to detected offenses will vary according to the offense and circumstance; however the response will always be in accordance with requirements of regulation and law. The CCO shall maintain a record of reported issues, including documentation of the status, investigation, finding and resolution of each issue. This information shall be reported to the Compliance Committee regularly.

Any determination that potential FWA related to the MMP program has occurred will be referred to the appropriate regulatory agency, as appropriate, for further investigation after the determination that a violation may have occurred. SCFHP will, as appropriate, provide information timely in response to follow-up requests for information.

B. Corrective Action Plans (CAPs)

Corrective action plans will be implemented whenever it is determined by the CCO and the Compliance Committee that any Personnel, FDRs or their employees have engaged in an activity that violated SCFHP policies and procedures, federal or state laws or regulations or CMS contractual or other requirements. These corrective action plans will be in writing and developed based on a root cause analysis conducted in response to any wrongful activity discovered by way of investigation resulting from any report, complaint, and/or internal or external audit or monitoring efforts, or as identified by CMS. Through the root cause analysis, SCFHP will undertake to determine what caused or allowed the non-compliance or FWA to occur so that an appropriate and effective remedy can be developed.

The goal of any CAP implemented is to remedy underlying issues and prevent future recurrence. Each CAP will be tailored to the particular misconduct identified and include specific time frames for completion. SCFHP will immediately cease any non-compliant practice upon knowledge or clear indication of a violation. When developing a corrective action plan to address non-compliance by an FDR, the elements of the corrective action plan, and the ramifications for non-compliance, will be included in a written CAP provided to the FDR. Corrective actions may include, for instance, disciplinary action against any Personnel; prompt identification and refund of any overpayment to the government or any enrollee; and/or suspension or termination of any FDR contract (or delegated functions thereunder).

CAPs will be monitored to ensure the required remediation has been carried out, and is sustained over time. All corrective action plans recommended, in progress, and implemented, along with results of ongoing monitoring will be documented and reported at least quarterly to the Compliance Committee and to the Board.

C. Government Investigations

SCFHP's policy is to be forthright and cooperative when dealing with government investigations, inquiries, or requests for information. Any Personnel or FDR made aware of a government investigation, inquiry or request for information is required to notify the CCO and/or Compliance Department immediately to ensure prompt response to the request(s).

<u>Appendix A</u>
Fraud, Waste and Abuse (FWA)
(Measures for Prevention, Detection and Correction)

SCFHP employs multiple measures to prevent, detect and correct potential instances of FWA. Many of these measures are outlined in the Compliance Program, including, for instance:

- Communicating standards of individual and organizational ethical and legal business practices in the *Reference Guide*, including compliance with Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse;
- Educating Personnel and FDRs about FWA issues through appropriate training and the sharing of newsletters and other educational materials;
- Communicating to all (including FDRs and enrollees) the availability of an anonymous compliance hotline for potential FWA issue reporting and asking fraud related questions;
- Engaging in monitoring and auditing of Part C and Part D operations, based on risk analyses conducted that expressly consider FWA concerns;
- Engaging in timely and vigorous investigation of suspected FWA, in whatever manner reported to SCFHP;
- Responding to identified FWA, including as appropriate, by reporting to the MEDIC and/or returning identified overpayments and making adjustments to prescription drug event or other claims payment data.

SCFHP actively engages FDRs to assist in its FWA prevention, detection and correction efforts. Thus, for instance, FDRs perform compliance and FWA related activities on SCFHP's behalf, such as monitoring, auditing and training. SCFHP performs oversight of the FWA and compliance related activities of each FDR and has processes in place to revoke delegated functions in accordance with 42 C.F.R. § 42.422.504(i)(5) and42 C.F.R. § 423.505(i)(4) and its contractual rights if such functions are not being performed satisfactorily.

If identified instances of FWA are discovered, SCFHP, directly or through its FWA/SIU vendor, engages in vigorous investigation and will, as it determines appropriate, report to CMS, the MEDIC or other appropriate regulatory or law enforcement entities.

The purpose of this Appendix is to provide additional information concerning specific measures SCFHP will use to prevent, detect and correct FWA.

Targeted Efforts

A. Credentialing

SCFHP's credentialing program for contracted providers and pharmacies is comprehensive and includes elements that have both a direct and indirect effect on the quality, delivery, and outcome of health care provided to SCFHP's members. SCFHP's credentialing program is based on National Committee for Quality Assurance (NCQA) standards and in accordance with CMS requirements.

SCFHP has contracted with a PBM to provide pharmacy benefits to its members enrolled in the MMP. By contract, the PBM employs a similar, vigorous credentialing program for each pharmacy in SCFHP's network, with each pharmacy needing to partake in the credentialing and re-credentialing process, performed at a minimum every three years, for participation, or continued participation, within the SCFHP's network.

B. Claims Adjudication

MMP claims are processed on a system using adjudication rules which employ FWA edits. Thus, for instance, such adjudication rules are designed to eliminate duplicate payments for services and make

payment (or denial) of claims based on SCFHP eligibility rules, contracted provider pricing, referrals and authorizations and Correct Coding Initiative (CCI) edits. In addition, Local Coverage Determinations (LCDs) and national coverage determinations (NCDs) are also reviewed to ensure payment consistent with Medicare guidelines. Claims processes also ensure claims submitted, intentionally or unintentionally, by providers who have opted out of Medicare are not paid. Finally, certain check run controls are also in place to prevent inappropriate payments.

Similarly, Part D has point of sale system edits that ensure appropriate authorizations are in place before dispensing and that prevent SCFHP from paying for prescriptions written by excluded prescribers.

C. Auditing and Data Analytics

SCFHP engages in auditing -- directly or through contracted entities -- pursuant to the terms of the annual compliance Work Plan. As part of its standing audit practice, SCFHP, by engagement of an external consultant and use of internal coding staff, performs Part C retrospective coding reviews annually. The reviewers substantiate the documentation of the Hierarchical Condition Categories (HCCs) supporting the Risk Adjustment Factors (RAF) scores submitted to CMS for member premium payment. SCFHP submits "additions" *and* "deletions" as appropriate dependent upon its ability to substantiate the HCCs within the audited documentation. In addition to ensuring accurate payment is received by the SCFHP ("adds"), and paid by CMS ("deletes"), these reviews can reveal potential fraudulent provider documentation practices and allow SCFHP to take corrective actions, as appropriate. It also allows SCFHP to identify providers who may need additional training regarding the appropriate provision of encounter data.

Where claims administration is delegated to an FDR, SCFHP audits the FDR annually for proof of data integrity, timeliness of claims payment, proper payment consistent with contractual and other requirements, and proper payment amounts.

Similarly, SCFHP has engaged its PBM to engage in analysis of pharmacy, prescribing provider, and beneficiary data to detect potentially defective claims. Such data analysis is a tool for identifying coverage and payment errors, and other indicators of potential FWA and non-compliance. To gather and analyze data to protect against FWA, on behalf of the SCFHP, the PBM, among other audits, performs retrospective (post-pay) audits. Standardized algorithms are applied to root out overpayments or erroneous payments to pharmacies. Through use of sophisticated modeling techniques, auditors can identify patterns in the data that may indicate potential FWA that may not be readily apparent. Such data mining activities will focus on areas of concern identified by CMS in guidance and entities identified by the MEDIC, as well as known areas of potentially aberrant behavior or high incidence of fraud based on industry experience. SCFHP's PBM employs staff pharmacists, physicians and others (as appropriate) to engage in follow-up research and investigation of suspect claims.

Pharmacies within the SCFHP's network are also subject to desk top and/or onsite audit. Pharmacies can be chosen for a variety of reasons, such as aberrant claims patterns revealed through the modeling techniques noted above. Claim sample selection will focus on identifying claims and/or claims patterns that potentially deviate from the norm. SCFHP can designate particular pharmacies for in-depth audits, upon request.

If FWA is found through any of the auditing methodologies applied by the PBM, the SCFHP will receive a FWA alert and take appropriate follow-up action in a prompt manner.

In addition to PBM audits, SCFHP receives various reports daily, weekly and monthly from the PBM. The reports are reviewed promptly and on a routine basis by the SCFHP's Pharmacy Department. Review of these reports can reveal potential fraudulent activity requiring investigation and action. Examples of reports received and reviewed regularly include (but are not limited to): summaries of controlled substances claims per member; top 3% prescribers; prescriber dispensing patterns; and FWA reports, which include results of all claims adjusted or reversed during the quarter due to audit results.