Title: COMPLIANCE PLAN	**Policy #: 0048 Dept: Compliance**
	Reviewed/Approved By: Quality & Compliance Committee
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BACKGROUND:
PrimaryHealth of Josephine County is a Coordinated Care Organization serving Medicaid and Medicare recipients in Oregon. The company's goal is to help assure that the people of Oregon, regardless of income or social circumstance, have access to high-quality health care from a stable network of providers.

DEFINITIONS:
PrimaryHealth and OHMS as delegated by PrimaryHealth collectively will be referred to as The CCO (Coordinated Care Organization).

Abuse includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary.

Delegated Entity is an entity to which the CCO has delegated functions required to be performed by Centers for Medicare and Medicaid (CMS), Oregon Health Authority (OHA) and other government regulations. These are divided into First Tier, Downstream and Related Entities (FDRs).

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS and OHA, with persons or entities involved with the benefits, below the level of the arrangement between the CCO and a first tier entity.

Example: All Pharmacies in PrimaryHealth Pharmacy Network are Downstream Entities because the Pharmacies contract with MedImpact and MedImpact is contracted with the CCO.

FDR means First Tier, Downstream or Related Entity

First Tier Entity is any party that enters into a written arrangement or contract, acceptable to CMS and OHA, with the CCO to provide administrative services or health care services for an eligible individual.

Example: Options is a First Tier Entity because they have a contract with the CCO to provide and coordinate the mental health benefit.

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program.

FWA means fraud, waste and abuse.

GSA means General Services Administration.

OIG is the Office of the Inspector General within the Department of Health and Human Services (DHHS). CMS is the agency within DHHS that administers the Medicare program.

Related Entity means any entity that is related to the CCO by common ownership or control and

1. Performs some of the CCO'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 PrimaryHealth at a cost of more than $2,500 during a contract period.

Example: OHMS is a Related Entities because of its ownership of the CCO.

Waste is defined as activities involving payment or the attempt to obtain reimbursement for items or services where there was not intent to deceive or misrepresent but the outcome of poor or inefficient billing or treatment methods causes unnecessary cost.

OVERVIEW:
PrimaryHealth of Josephine County (PHJC) and PHJC's Board of Directors are committed to supporting the Compliance Plan as a way of supporting the organization's mission. Each functional department within the CCO and all employees are responsible to ensure that the organization is in compliance with all CMS, Medicare and Medicaid requirements.

The purpose of the CCO's Compliance Plan is to ensure compliance with State and Federal requirements regarding Fraud, Waste and Abuse (FWA) in the Medicare and Medicaid programs, promote ethical behavior and compliance with laws, regulations, and company policy. As a participant in federal and state funded healthcare programs, the CCO is subject to heightened standards of compliance and must ensure that it delivers Medicare and Medicaid program services to members in compliance with applicable laws and in a manner that promotes honesty, integrity and accountability. The objectives of the compliance program are to ascertain that compliance requirements are met in a timely manner and that PrimaryHealth develops and adheres to appropriate compliance policies and procedures.

The CCO's Compliance Plan outlines the companies' strategy for preventing, detecting, and correcting non-compliance with Medicare and/or Medicaid program requirements as well as FWA. The objectives of the Compliance Plan are to:

- Promote and facilitate compliance with applicable laws, regulations, and Medicare and/or Medicaid program requirements, as well as with PrimaryHealth's policies and procedures;
- Prevent, detect, and correct compliance violations, including non-compliance with Medicare and/or Medicaid program requirements and FWA;
- Provide a framework for active compliance oversight; and
- Articulate clear legal and ethical standards that promote principles of integrity and serve as practical guidelines for employees, members of the Board of Directors, business associates, and First Tier, Downstream and Related Entities (FDRs) acting on behalf of PrimaryHealth.

The CCO's Compliance Plan is based upon the Centers for Medicare & Medicaid Services (CMS) Prescription Drug Benefit Manual Chapter 9 -Compliance Program Guidelines and Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines and criteria adopted by the Federal Government in the Federal sentencing guidelines. It is also based on 42 CFR 438.608.

The CCO's Compliance Plan includes the following core elements:

1. Written policies, procedures and a Code of Conduct articulating the organization's commitment to comply with all applicable Federal and State requirements;
2. Designation of a Compliance Officer and Compliance Committee accountable to senior management;
3. Effective training and education between the Compliance Officer and organization employees, business associates and FDRs;
4. Effective lines of communication between the Compliance Officer and the companies employees, members of the Internal Compliance Committee, business associates and FDRs;
5. Enforcement of standards through well-publicized disciplinary guidelines;
6. Procedures for effective internal monitoring and auditing of compliance risks; and
7. Procedures for ensuring prompt responses to detected offenses, with timely and reasonable inquiry upon discovery of evidence of misconduct.

All CCO employees, members of the Board of Directors, business associates and FDRs are required to adhere to the Code of Conduct, which outlines good business conduct and abidance with Federal and State laws and regulations. Specific procedures related to FWA prevention and detection is outlined in the CCO's Prevention, Detection, and Reporting of Fraud, Waste, and Abuse (FWA) Policy and Procedure.

As part of its Compliance Plan, the CCO is committed to cooperating with any CMS or other government related audit requests, as well as any auditor acting on behalf of the Federal Government or CMS to conduct audits. As such, the CCO agrees to provide full access to necessary records to these auditors.

Element I - Written Policies, Procedures and Standards of Conduct

PrimaryHealth has written policies, procedures and standards of conduct that:

- Articulate PrimaryHealth's commitment to comply with all applicable Federal and State standards;
- Describe compliance expectations as embodied in the Code of Conduct;
- Implement the operation of the compliance program;
- Provide guidance to employees and others on dealing with suspected, detected or reported compliance issues;
- Identify how to report compliance issues to appropriate compliance personnel;
- Describe how suspected, detected or reported compliance issues are investigated and resolved; and
- Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program.

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

Code of Conduct

The CCO's Code of Conduct states the principles and values by which we operate and define the underlying framework for the organization's policies and procedures (P&Ps). The Code of Conduct communicates to employees, members of the Board of Directors, business associates and FDRs that compliance is everyone's responsibility and each functional department and all personnel are responsible to ensure compliance with all CMS requirements. The Code of Conduct is reviewed and approved by the CCO's Board of Directors.

Policies and Procedures

The CCO has developed P&Ps to describe the operation of the compliance program. These P&Ps address:

- Compliance and FWA training requirements;
- Operation of other reporting mechanisms; and
- How suspected, detected or reported compliance and potential FWA issues are investigated, addressed, and resolved.
- Pre-delegation
- Compliance Program guidelines

P&Ps are updated as needed to incorporate any changes in applicable laws, regulations and other program requirements.

Distribution of Compliance Policies and Procedures and Standards of Conduct

Compliance P&Ps, including the Policy for Prevention, Detection, and Reporting of Fraud, Waste, and Abuse; and the False Claim Act and the Code of Conduct are distributed to employees within 90 days of hire. In-person training in general compliance and FWA topics is conducted within 90 days of hire for new employees and annually thereafter.

The CCO communicates our compliance expectations to FDRs by providing FWA training materials and our Code of Conduct at time of contracting. We also include appropriate contract requirements in contracts with FDRs requiring them to perform compliance and FWA training with their workforce on an annual basis. On an annual basis, a risk assessment is performed to determine a sample of FDRs who are requested to provide the Compliance Officer or delegate with an attestation that they have adequately trained their employees in general compliance and FWA.

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

The CCO has designated a Compliance Officer who reports directly to the Chief Executive Officer and the Board of Directors. The Compliance Officer and designee also reports at the Quality and Compliance Committee (QCC) who reports to the CCO's Board of Directors.

1. The CCO's Compliance Officer is an employee of Oregon Health Management Services.
2. The Compliance Officer and the Chairperson of the Quality and Compliance Committee periodically report directly to the Board of Directors on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.
3. The Board of Directors have been educated on and are knowledgeable about the content and operation of the compliance program and exercise reasonable oversight regarding the implementation and effectiveness of the compliance program.

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

Compliance Officer

The CCO's Compliance Officer is an employee who has the authority to provide unfiltered, in-person reports to the CCO's Chief Executive Officer and Board of Directors at their discretion. The Compliance Officer is free to raise compliance issues without fear of retaliation; as such, the Board of Directors must approve before the Compliance Officer can be terminated from employment.

Duties of the Compliance Officer may include, but are not limited to:

- Ensuring that compliance reports are provided regularly to the Board of Directors, CEO, and Internal Compliance Committee. Reports will include the status of the CCO's compliance program implementation, the identification and resolution of suspected, detected or reported instances of noncompliance, and the CCO's compliance oversight and audit activities;
- Being aware of daily business activity by interacting with the operational units of the CCO;

- Creating and coordinating educational training programs to ensure that the CCO's employees, Board of Directors, business associates, FDRs and other individuals working in the Medicare program are knowledgeable about the CCO's compliance program, its written Standards of Conduct, compliance P&Ps, and all applicable statutory and regulatory requirements;
- Developing and implementing methods and programs that encourage managers and employees to report Medicare program noncompliance and potential FWA without fear of retaliation;
- Maintaining compliance reporting mechanisms and closely coordinating with the internal audit department;
- Responding to reports of potential FWA, including the coordination of internal investigations with the Compliance Committee and the development of appropriate corrective or disciplinary actions, if necessary;
- Ensuring that the Office of Inspector General (OIG) Exclusion List has been checked at time of hire and then monthly for all employees, CEO, Board of Directors, and anyone else determined to fall into OIG guidelines;
- Maintaining documentation for each report of potential noncompliance or potential FWA received from any source, through any reporting method (e.g., hotline, mail, or in-person);
- Overseeing the development and monitoring of the implementation of corrective action plans;
- Coordinating potential fraud investigations or referrals with the Medicaid Fraud Control Unit (MFCU) of the Oregon Department of Justice and facilitating any documentation or procedural requests received from the MFCU; and
- Assessing the overall effectiveness of the Compliance Plan and taking steps to enhance the compliance program based on information learned in continual process improvement.

The CCO management recognizes that the Compliance Officer must have sufficient resources, authority, and respect to promote a culture of compliance and to achieve an effective and meaningful compliance program. As such, among other things, the Compliance Officer (or delegate) has authority to:

- Interview Company employees and other relevant individuals;
- Review Medicaid contracts and other documents pertinent to the Medicaid/Medicare program;
- Review and validate the submission of data to OHA to ensure that it is accurate and in compliance with OHA and CMS reporting requirements;
- Independently seek advice from legal counsel;
- Report potential FWA to CMS, its designee or law enforcement;
- Conduct and/or direct audits and investigations of any FDRs;
- Recommend policy, procedure, and process changes.

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

<u>Compliance Committee</u>

The CCO has established a multi-disciplinary Quality and Compliance Committee to address compliance considerations associated with the Medicaid/Medicare program. Working in conjunction with the Compliance Officer, some of the duties of the CCO's Quality and Compliance Committee include the following objectives:

- Meeting at least on a quarterly basis, or more frequently as necessary, to enable reasonable oversight of the compliance program;
- Developing strategies to promote compliance and the detection of any potential violations;
- Reviewing and approving compliance and FWA training, and ensuring that training and education are effective and appropriately completed;
- Assisting with the creation and implementation of the compliance risk assessment and of the compliance monitoring and auditing work plan;
- Assisting in the creation, implementation and monitoring of effective corrective actions;
- Developing innovative ways to implement corrective and preventative action;

- Reviewing effectiveness of the system of internal controls designed to ensure compliance with Medicare and/or Medicaid regulations in daily operations;
- Supporting the Compliance Officer's needs for sufficient staff and resources to carry out their duties;
- Ensuring that the CCO has appropriate, up-to-date compliance policies and procedures;
- Ensuring that the CCO has a system for employees and FDRs to ask compliance questions and report potential instances of Medicare and/or Medicaid program noncompliance and potential FWA confidentially or anonymously, without fear of retaliation;
- Reviewing and addressing reports of monitoring and auditing of areas in which the CCO is at risk for program noncompliance or potential FWA and ensuring that corrective action plans are implemented and monitored for effectiveness; and
- Providing regular and ad hoc reports on the status of compliance with recommendations to the CCO's Board of Directors.

The Compliance Officer reports on compliance activities no less than on a quarterly basis to ensure effective communication of Medicare and/or Medicaid compliance issues. The Internal Compliance Committee may elect to escalate items to the Board of Directors on an ad hoc basis.

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

Board of Directors – (Governing Body)

The CCO's Board of Directors exercise reasonable oversight of the implementation and effectiveness of the CCO's compliance program. The Board of Directors' remain accountable for reviewing the status of the compliance program.

The Board of Directors is to receive training and education as to the structure and operation of the compliance program. They should be knowledgeable about compliance risks and strategies, should understand the measurements of outcome, and should be able to gauge effectiveness of the compliance program.

Reasonable oversight by the Board of Directors (assisted by a committee, if desired) includes, but is not limited to:

- Approving the Standards of Conduct (to be performed by the Board of Directors and not a committee);
- Understanding the compliance program structure;
- Remaining informed about the compliance program outcomes, including results of internal and external audits;
- Remaining informed about governmental compliance enforcement activity such as Notices of Non-Compliance, Warning Letters and/or more formal sanctions;
- Receiving regularly scheduled, periodic updates from the compliance officer and compliance committee; and
- Reviewing the results of performance and effectiveness assessments of the compliance program.

The following are examples of activities in which the Board of Directors' may wish to have involvement. Alternatively, the Board of Directors' may delegate some or all of these activities to senior management or to designated Compliance Committee:

- Development, implementation and annual review of compliance policies and procedures;
- Approval of compliance policies and procedures;
- Review and approval of compliance and FWA training;
- Review and approval of the compliance risk assessment;
- Review of internal and external audit work plans and audit results;
- Review and approval of corrective action plans resulting from audits;
- Review and approval of appointment of the compliance officer;

- Review and approval of performance goals for the compliance officer;
- Evaluation of the senior management team's commitment to ethics and the compliance program; and
- Review of dashboards, scorecards, self-assessment tools, etc., that reveal compliance issues.

The Board of Directors' should collect and review measurable evidence that the compliance program is detecting and correcting Medicare/Medicaid program noncompliance on a timely basis. It is a best practice for the Board of Directors to be provided with data showing that the program has reduced the risks of program noncompliance and FWA. Some indicators of an effective compliance program are:

- Use of quantitative measurement tools (e.g., scorecards, dashboard reports, key performance indicators) to report, and track and compare over time, compliance operations such as appeals and grievances, prescription drug benefit administration;
- Use of monitoring to track and review open/closed corrective action plans, FDR compliance, Notices of Non-Compliance, warning letters, CMS sanctions, training completion/pass rates, etc.;
- Implementation of new or updated Medicare or Medicaid requirements 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
- Timely response to reported noncompliance and potential FWA, and effective resolution (i.e., non-recurring issues);
- Consistent, timely and appropriate disciplinary action; and
- Detection of noncompliance and FWA issues through monitoring and auditing;
- Whether root cause was determined and corrective action appropriately and timely implemented and tested for effectiveness;
- Detection of FWA trends and schemes via daily claims reviews, outlier reports, pharmacy audits, etc.; and
- Actions taken in response to compliance reports submitted by FDRs.

Senior Management Involvement in Compliance Program

The CCO's CEO and senior management fully support the compliance program. The Compliance Officer is integrated into the organization and is given the credibility, authority and resources necessary to operate a robust and effective compliance program. On a periodic basis, the Compliance Officer provides reports of risk areas facing the CCO, the strategies being implemented to address them and the results of such strategies. The CEO is informed of all governmental compliance enforcement activities, from Notices of Non-Compliance to formal enforcement actions.

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

Element III: Effective Training and Education

Compliance and FWA training is an important component of the Compliance Plan. A formal compliance training program, including FWA and Health Insurance Portability and Accountability Act (HIPAA), is provided to all employees, members of the Board of Directors and FDRs as part of new hire orientation (or contracting) and annually thereafter to ensure they understand the CCO's commitment to ethical behavior and compliance, including the proactive detection, investigation, and reporting of fraud, waste, and abuse. The CCO provides appropriate training to employees to ensure they are aware of the Medicare and Medicaid requirements related to their job functions.

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

General Compliance Training

All compliance training must be accomplished within ninety (90) days of initial hire and annually thereafter.

The CCO satisfies the general compliance training requirements by:

- Having new employees, members of the Board of Directors and FDR staff complete compliance training;
- Performing annual compliance training for all of the above ; and
- Requiring employees to acknowledge that they have received the CCO's Code of Conduct; Prevention, Detection, and Reporting of Fraud, Waste, and Abuse (FWA), and False Claims Act training.
- The CCO retains sign-in sheets and employee attestations (electronic certifications) as proof of the training.

Compliance expectations are communicated to FDRs at time of contracting and annually through distribution of our FWA and HIPPA Training Materials.

The CCO's Compliance Department reviews and updates, if necessary, general compliance training material whenever there are changes in regulations, policy or guidance, and at least annually.

Initial compliance training is conducted by the Compliance Officer or designee and covers the core compliance related topics listed below:

- A description of the compliance program, including FWA and articulation of the CCO's commitment to good business ethics and compliance with applicable state and federal laws and regulations;
- The process to ask questions or to report compliance issues, to directly or anonymously report potential compliance or FWA violations; complianceofficer@primaryhealthfamily.com
- The requirement to report to the CCO's Compliance Officer or designee actual or suspected Medicare or Medicaid program noncompliance or potential FWA;
- An overview of HIPAA/HITECH and the importance of maintaining the confidentiality of personal health information;
- Examples of reportable noncompliance and FWA that an employee might observe;
- A review of the disciplinary guidelines for non-compliant or fraudulent behavior. The guidelines communicate how such behavior can result in mandatory retraining and may result in disciplinary action, including possible termination when such behavior is serious or repeated or when knowledge of a possible violation is not reported;
- Attendance and participation in compliance and FWA training programs as a condition of continued employment;
- Review of issues related to contracting with the government, including pertinent laws addressing fraud and abuse, such as Anti-Kickback Statutes and the False Claims Act;
- An overview of the monitoring and auditing process; and
- A review of the laws that govern employee conduct in the Medicare program.

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

<u>Fraud, Waste, and Abuse Training</u>

The CCO employees, members of the Board of Directors, business associates, and FDR employees who have involvement in the administration or delivery of Medicaid/Medicare program benefits are to receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs) and annually thereafter. FWA training may be provided:

- upon appointment to a new job function;
- when requirements change;
- when employees are found to be noncompliant;
- as a corrective action to address a noncompliance issue; and
- when an employee works in an area implicated in past FWA.

The CCO will provide FWA and HIPPA education materials, but also allows delegated entities to provide their staff the FWA training directly. The CCO will use CMS provided standardized FWA training that meets CMS' FWA training requirements. The CCO would require all FRDs to also use this information. This material can be located at this link: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html

Topics that are addressed in FWA training include, but are not limited to the following:

- Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.);
- Obligations of FDRs to have appropriate policies and procedures to address FWA;
- Processes for the CCO employees to report suspected FWA to the CCO (or, as to FDR employees, either to the CCO directly or to their employers who then must report it to the CCO);
- Protections the CCO and FDR employees who report suspected FWA; and
- Types of FWA that can occur in the settings in the CCO employees work.

In addition, the CCO requires FDRs to annually certify that their employees participated in general compliance training and appropriate education and training to prevent, detect, and correct potential FWA and HIPPA within ninety (90) days of employment and completed all other required compliance training at least annually thereafter.

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

Element IV: Effective Lines of Communication

The CCO has established and implemented effective lines of communication that are intended to encourage and promote honest, effective, and efficient working relationships between the Compliance Officer, members of the Quality and Compliance Committee, employees, members of the Board of Directors and FDRs. These lines of communication are accessible to all and allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues.

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

The CCO has an effective way to communicate information from the Compliance Officer to others and includes the compliance officer's name and contact information (phone number and email address). This information is communicated in FWA training materials. Any compliance issue can be reported to:
Compliance officer@primaryhealthfamily.com

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

Communication and Reporting Mechanisms

The CCO's Code of Conduct and P&Ps require all employees, members of the Board of Directors, business associates, and FDRs to report compliance concerns and suspected or actual violations related to the Medicare/Medicaid program to the Compliance Officer.

The CCO uses a spreadsheet to record and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the Board of Directors, members, and business associates.

The CCO has adopted, widely publicized, and enforced a no-tolerance policy for retaliation or retribution against any employee or FDR who in good faith reports suspected FWA.

The methods available for reporting compliance are listed in the policy.

When a suspected compliance issue is reported, the Compliance Officer provides the complainant with information regarding expectations of a timely response, confidentiality, non-retaliation and progress reports.

If any employee, Board of Directors member, business associate knows or suspects that FWA or a compliance issue has occurred, they have an affirmative obligation to report the incident(s) to the CCO. A report can be made in the following methods:

1. Contact the Compliance Officer at PrimaryHealth.
   PrimaryHealth
   Attn: Compliance Officer
   1867 Williams Highway, Suite 108
   Grants Pass, OR 97527
   Complianceofficer@primaryhealthfamily.com

   541-471-4208.

Member Communication and Education
The CCO educates our members about identification and reporting of potential FWA.

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

Element V: Well-Publicized Disciplinary Standards
The CCO has disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program. These standards include policies that:
1. Articulate expectations for reporting compliance issues and assist in their resolution;
2. Identify noncompliance or unethical behavior; and
3. Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

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

Disciplinary Standards
All employees are held accountable for failing to comply with relevant laws, regulations, and Medicare or Medicaid program and contract requirements, as well as PrimaryHealth's policies and procedures.

Employees and business associates are informed that compliance violations may result in disciplinary action, up to and including termination of employment or contract. Disciplinary actions that can be imposed for non-compliance may include oral or written warnings or reprimands, suspensions, or terminations. Any employee who fails to report known or suspected violations by another employee may also be subject to disciplinary actions. Disciplinary actions may be imposed even if no violation has occurred, if otherwise deemed appropriate by the circumstances.

The disciplinary determination will be based upon the facts and circumstances of each violation or misconduct. If an employee has committed fraud, waste, abuse, violated federal or state laws, or failed to comply with the Compliance Program or Code of Conduct, that employee shall be the subject to appropriate disciplinary actions as determined by the employee's immediate manager and/or Human Resource Director, with input from the Compliance Officer, where appropriate.

The CCO strictly prohibits retaliation against an employee who, in good faith, reports known or suspected violations. Any person taking retaliatory action against an employee or subcontractor, who in good faith filed a report, will be subject to disciplinary action, including potential termination of employment or contract.

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

Methods to Publicize Disciplinary Standards

To encourage good faith participation in the compliance program, The CCO publicizes disciplinary standards for employees. The standards include the duty and expectation of all employees to report issues or concerns. The CCO uses the following types of publication mechanisms to encourage good faith participation in the compliance program:

- General compliance training; and
- Compliance and/or FWA flyers prominently displayed

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

Enforcing Disciplinary Standards

The CCO maintains records for a period of 10 years for all compliance violation disciplinary actions, capturing the date the violation was reported, a description of the violation, date of investigation, summary of findings, disciplinary action taken and the date it was taken. These records of discipline are periodically reviewed to ensure that disciplinary actions are appropriate for the seriousness of the violation, fairly and consistently administered and imposed within a reasonable timeframe.

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

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

The CCO has implemented an internal monitoring and auditing program to evaluate compliance with Medicare and/or Medicaid program requirements on an ongoing basis; to assess overall effectiveness of the compliance program; to protect the Medicare and/or Medicaid program and beneficiaries from FWA; and to mitigate the liability of company resulting from potentially fraudulent, abusive, or wasteful activities. Procedures are intended to test and confirm compliance with the regulations governing the Medicare and/or Medicaid program and other applicable legal requirements, guidance published by CMS, contractual requirements, and PrimaryHealth's policies and procedures.

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

Routine Monitoring and Auditing

The Compliance Officer or designee performs monitoring and auditing to test and confirm compliance with Medicare/Medicaid regulations, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare and/or Medicaid program noncompliance and potential FWA.

Departments within the CCO are responsible for monitoring activities as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are implemented and effective.

The monitoring and auditing work plan is coordinated, overseen and/or executed by the Compliance Officer, assisted by the Quality & Compliance Committee The Compliance Officer receives regular reports from those who are conducting the audits regarding the results of auditing and monitoring and the status and effectiveness of corrective actions taken.

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

Development of a System to Identify Compliance Risks

Each year, the Compliance Officer or delegate, in consultation with the Quality and Compliance Committee, develops an annual monitoring and auditing work plan that addresses any compliance risks associated with the Medicare or Medicaid programs. To determine the work plan's components, the Compliance Officer or delegate, conducts an annual risk assessment, which involves the evaluation of multiple data elements.

In developing the annual compliance risk assessment and work plan, the Compliance Officer or delegate and the Quality & Compliance Committee determine the appropriate priorities by evaluating a variety of factors, including:

- Internal and external audit results;
- Management and other monitoring reports and activities performed by FDR entities;

- Assessments and feedback from the senior management, employees, and FDRs;
- CMS regulatory and policy updates (including, without limitation, those implemented through new regulations,
- OIG guidance and other documents, including the OIG's work plan; and
- Feedback from CMS central or regional office representatives.

The Compliance Officer will document the results of the risk assessment as well as the work plan, which will include a list of all monitoring and auditing activities for the calendar year, and submit it to the Quality and Compliance Committee for review and approval.

Areas of particular concern in the program may include, but are not limited to:

- marketing and enrollment violations,
- enrollment/disenrollment noncompliance,
- credentialing,
- quality assessment,
- appeals and grievance procedures,
- benefit/formulary administration,
- utilization management,
- accuracy of claims processing,
- detection of potentially fraudulent claims, and
- FDR oversight and monitoring.

Development of the Monitoring and Auditing Work Plan

Once the risk assessment has been completed, a monitoring and auditing work plan is developed. The Compliance Officer may coordinate with each department to develop a monitoring and auditing work plan based upon the results of the risk assessment. The work plan may include:

- The audits to be performed;
- Audit schedules, including start and end dates
- Announced or unannounced audits;
- 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.

The Compliance Officer with approval from the QCC will include in our work plans a process for responding to all monitoring and auditing results and for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems.

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

Audit Schedule and Methodology

The CCO develops an audit schedule annually and provides the schedule to the Quality and Compliance Committee for review and approval.

The Compliance Team audits operational areas within the CCO and may work with management to perform audits of FDRs. In determining the types of audits to include in the work plan, the Compliance Officer and or designee

determines which risk areas will most likely affect the CCO, and prioritizes the monitoring and audit strategy accordingly;

- Utilizes appropriate methods in:
  - Selecting facilities, providers, claims, and other areas for audit;
  - Determining appropriate sample size;
  - Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe; and
  - Applying targeted or stratified sampling methods driven by data mining and complaint monitoring;
- Assesses compliance with internal processes and procedures;
- Examines the performance of the compliance program, which may include a review of training, reporting mechanisms, investigation files, OIG/GSA exclusion list screenings, evidence of employee receipt of Standards of Conduct and conflict of interest disclosures/attestations, and sampling for evidence in support of attestations, if attestations are used to monitor compliance; and
- Conducts follow up review by auditing, monitoring or otherwise of areas previously found non-compliant to determine if the implemented corrective actions have fully addressed the underlying problem.

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

Audit of the CCO's Operations and Compliance Program

Compliance staff and all employees will be responsible for monitoring and auditing the CCO's operational areas to ensure compliance with Medicare and/or Medicaid regulations. The CCO will allocate adequate resources to the audit function taking into consideration factors such as:

- Size and scope of PrimaryHealth's Medicaid/Medicare program;
- Current and past compliance history;
- Current compliance risks; and
- The amount of resources necessary to meet the goals of the annual audit plan.

Compliance staff is to be knowledgeable about OHA and CMS operational requirements for the areas under review. Staff may assist in audit activities provided the assistance is compatible with the independence of the audit function. For example, staff may gather data for samples requested by the Compliance Department and may provide other types of information. The CCO management ensures that Compliance staff has access to the relevant personnel, information, records and areas of operation under review, including the operational areas at the plan.

The CCO audits the effectiveness of the compliance program and the results are shared at least annually with the Quality & Compliance Committee and the Board of Directors.

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

Monitoring and Auditing FDRs

The CCO employees and business associates are responsible for lawful and compliant administration of the Compliance Plan, regardless of whether the CCO has delegated some of that responsibility to FDRs. The CCO has developed a strategy to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first tier entities are monitoring the compliance of the entities with which they contract (i.e. The CCO's "downstream" entities).

The Compliance Department includes in our work plan a number of first tier entities that will be audited each year and how the entities will be identified for auditing. On occasion, the CCO will conduct on-site audits of FDRs.

When FDRs perform their own audits, it is a best practice for the CCO to obtain a summary of the audit work plan and audit results that relate to the services the downstream entities perform. Examples of reports that the CCO should receive and review as part of their FDR monitoring and auditing efforts may include, but are not limited to:

- Drug Utilization Reports from MedImpact, our Pharmacy Benefit Manager (PBM) that identify the number of prescriptions filled by a particular member and in particular, numbers of prescriptions filled for suspect classes of drugs, such as narcotics, to identify possible therapeutic abuse or illegal activity by an enrollee. Members with an abnormal number of prescriptions or prescription patterns for certain drugs are be identified in reports;
- Provider Utilization Reports that identify the number and types of visits and services submitted for payment to identify possible spikes and/or irregularities such as a provider submitting claims for services that would not normally be performed by the provider's specialty; and
- Timely grievance/appeals
- Training completion/pass rates
- Increase or decrease in number and/or severity of complaints
- Compliance/non-compliance of potential FWA

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

Tracking and Documenting Compliance and Compliance Program Effectiveness

The CCO tracks and documents compliance by use of spreadsheets that show the extent to which operational areas and FDRs are meeting compliance goals. The CCO also considers compliance performance as a measure for FDR evaluations.

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

OIG/GSA Exclusion

Medicare and/or Medicaid payments may not be made for items or services furnished or prescribed by an excluded provider or entity. As such, the CCO will not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG).

The CCO's Credentialing Department reviews the DHHS OIG List of Excluded Individuals and Entities prior to the hiring or contracting of any new employee, temporary employee, or Board of Directors members. Reviewing the OIG exclusion list for those individuals with spending authority will be carried monthly to ensure that none of these persons are excluded or become excluded from participation in federal programs. The Credentialing Department reviews the DHHS OIG List of Excluded Individuals and Entities (LEIE list) prior to contracting with a provider and on a monthly basis to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs.

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

Use of Data Analysis for Fraud, Waste and Abuse Prevention and Detection

The CCO performs basic data analysis, including reviewing reports generated by our PBM to identify pharmacy over-utilization and doctor shopping to assist in the identification of potential FWA. Any issues identified are reviewed and investigated for possible FWA activity.

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

Special Investigative Units (SIUs)

The CCO does not utilize a separate SIU for investigations relating to potential FWA. Instead, investigations and research into potential FWA issues are conducted by the Compliance Officer (or designee).

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

Auditing by CMS, OHA or its Designee

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

Under the direction of the Compliance Officer, the CCO will fully cooperate with external audits performed by CMS, OHA, law enforcement agencies, or any auditor acting on behalf of the federal government or CMS. The Compliance Officer or designee will coordinate all internal activities relating to external CMS/OHA audits, including data collection and employee interviews. The OIG has independent authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare and/or reimbursement.

Upon request, the CCO and its FDRs must provide records to CMS/OHA or its designee. The CCO will cooperate in allowing access as requested. Contractors tasked to conduct audits by CMS, as well as contractors trained by CMS and engaged by sponsors to conduct CMS data validation audits, are acting on behalf of the federal government and are not required to sign the sponsor's confidentiality statement prior to the start of an on-site audit. The CCO and FDRs are required to cooperate with CMS and CMS' contractors.

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

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

The CCO has established and implemented procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

1. If the CCO discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
2. The CCO must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible individuals) in response to the potential violation referenced above.
3. The CCO has developed procedures to voluntarily self-report potential fraud or misconduct related to the Medicare and/or Medicaid program to CMS/OHA or its designee

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

Conducting a Timely and Reasonable Inquiry of Detected Offenses

The CCO conducts timely and well-documented reasonable inquiries into any compliance incident or issue involving potential Medicare and/or Medicaid program noncompliance or potential FWA.

Program noncompliance and FWA may occur at the CCO or its FDRs. It may be discovered through a phone call, a website, a member complaint, during routine monitoring or self-evaluation, an audit, or by regulatory authorities. Regardless of how the noncompliance or FWA is identified, the CCO will initiate a reasonable inquiry as quickly as possible, but not later than 2 weeks after the date the potential noncompliance or potential FWA incident was identified.

A reasonable inquiry includes a preliminary investigation of the matter by the compliance officer or a delegated member of their staff.

The Compliance Officer and individual departments within the CCO are responsible for monitoring for FWA and Medicare and/or Medicaid program noncompliance. When serious noncompliance or waste occurs, the Compliance officer will refer the matter to Medicaid Fraud Control Unit (MFCU).

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

Corrective Action
The CCO will undertake appropriate corrective actions in response to potential noncompliance or potential FWA.

The corrective actions will be designed to correct the underlying problem that results in program violations and to prevent future noncompliance. A root cause analysis to determine what caused or allowed the FWA, problem or deficiency to occur will be conducted. The corrective action will be tailored to address the particular FWA, problem or deficiency identified, and must include timeframes for specific achievements.

The CCO must ensure that FDRs have corrected any deficiencies. When developing corrective actions for FWA or program noncompliance by an FDR, the elements of the corrective action will be detailed in writing and include ramifications if the FDR fails to implement the corrective action satisfactorily.

In order to ensure that the FDR has implemented the corrective action, the CCO may conduct independent audits or review the FDR's monitoring or audit reports. The CCO Compliance Officer or designee will continue to monitor corrective actions after their implementation to ensure that they are effective.

The elements of the corrective action that address noncompliance or FWA committed by the CCO's employee(s) or FDRs must be documented, and include ramifications should the employee(s) or its FDRs fail to satisfactorily implement the corrective action. The CCO will enforce effective correction through disciplinary measures, including employment or contract termination, if warranted. Thorough documentation will be maintained of all deficiencies identified and corrective actions taken.

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

Procedures for Self-Reporting Potential FWA and Significant Non-Compliance
Self-reporting of FWA and Medicare and/or Medicaid program noncompliance is voluntary, however; PrimaryHealth does self-report program noncompliance as an important practice in maintaining an effective compliance program. The CCO self-reports potential FWA discovered at the plan level, and potential fraud and abuse by FDRs, as well as significant waste and significant incidents of Medicare and/or Medicaid program noncompliance.

The CCO actively investigates potential FWA activity to make a determination whether potential FWA has occurred and concludes investigations of potential FWA within a reasonable time period after the activity is discovered.

The CCO may also consider reporting potentially fraudulent conduct to government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol) or the Department of Justice. The Protocol offers a detailed step-by-step explanation of how a provider should proceed in reporting and assessing the extent of potential fraud and how the OIG will go about verifying irregularities.

Where the CCO discovers an incident of significant Medicare and/or Medicaid program noncompliance, the Compliance Officer will report the incident to CMS/OHA as soon as possible after its discovery. This will enable CMS/OHA to provide guidance to the Compliance Officer on mitigation of the harm caused by the incident of noncompliance. While no bright line definition exists as to what is a "significant" or "serious" incident that should be reported, the CCO should err on the side of over-reporting rather than under-reporting.

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

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

RELATED POLICIES AND PROCEDURES:
Prevention, Detection, and Reporting of Fraud, Waste, and Abuse Policy and Procedure
HIPAA Policy