



# COMPLIANCE & FRAUD, WASTE AND ABUSE PROGRAM

## OPENING STATEMENT

To our Employees, Board Members and Contractors:

At PacificSource, its subsidiaries and affiliates (collectively, “PacificSource”), we are committed to our corporate mission of providing better health, better care, and better cost to the people and communities we serve. We strive towards this mission under the guidance of our vision and corporate values.

To that end, we have implemented an integrated Compliance Program and Fraud Waste and Abuse (FWA) Plan. The Compliance Program is the framework and foundation by which we articulate our commitment to comply with State and Federal laws, regulations, and our internal policies and procedures. The Compliance Program has the full support of our Board of Directors, our CEO, and our entire Executive Management Group (EMG).

No matter the line of business we work with, compliance is everyone’s responsibility. We want you to familiarize yourself with this document, and use all the tools at your disposal to maintain our high standard of compliance and ethical behavior. We thank you for your continued support in our ongoing commitment to serve our members in the best and most ethical manner.

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## WHO DOES THIS APPLY TO?

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This Compliance and FWA Program applies to all PacificSource employees, officers, Board and Committee members who handle or participate in any of our lines of business, such as Commercial, Medicare and Medicaid. In addition, this Compliance and FWA Program applies to all first tier, downstream or related (FDR) entities and/or subcontractors, that contract with PacificSource to perform a core service. The above mentioned individuals and entities are collectively referred to as “covered persons”.

## WHAT ARE MY EXPECTATIONS?

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You are required to read and be familiar with this Compliance and FWA Program at the time of your hire, appointment or contracting, and annually thereafter. You should learn to recognize potential noncompliant and FWA issues that may arise during your work, report them to the appropriate channel, and assist in remediating them. You should strive to improve your department’s process to minimize compliance risks to PacificSource, our members, and our State and Federal regulatory agencies. Ultimately, you are a champion and an advocate for compliance, and you are a part of our culture of compliance.

## DISSEMINATION

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This Compliance and FWA Program is disseminated in accordance with the following schedule:

*At time of hire:* Human Resources shall disseminate the Compliance and FWA Program, including the Standards of Conduct, to employees within **90 days** of hire.

*Annually:* The Corporate Compliance Department shall disseminate the Compliance and FWA Program, and the Standards of Conduct, to employees **annually** thereafter, and when there are substantial updates.

*Delegates:* The contract administrator shall disseminate the Compliance and FWA Program and Standards of Conduct to applicable delegates within **90 days** of contracting. The Corporate Compliance Department disseminates the document to Delegates **annually** thereafter.

PacificSource may use various dissemination methods, including:

- Hard copies
- Electronic copies
- Posting on company intranet
- Posting on public website

The respective disseminating party shall document that this has been done, including any record of acknowledgment of receipt, and provide evidence to the Corporate Compliance Department for retention.

## OUR COMPLIANCE PROGRAM AT A GLANCE

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The Compliance Program and the content contained herein are a series of incorporated policies, procedures, and guidance by which our State and Federal programs are governed. These policies implement the Compliance and FWA Program. The FWA Plan is also incorporated within the Compliance Program. If an applicable policy exists outside of the Compliance Program, it will be referenced accordingly.

The Compliance and FWA Program is made up of 7 core elements. Each core element has its own policy and procedure that is associated with and implements that particular element. For your convenience, here is a summary of each element:

**Element 1 (Compliance with State and Federal Laws):** We must comply with applicable laws and regulations that pertain to government programs, such as HIPAA, Federal False Claims Act, and the Social Security Act.

**Element 2 (Corporate Compliance Officer and Compliance Committee):** We must maintain a Corporate Compliance Officer and a Compliance Committee to oversee the enforcement and effectiveness of the Compliance and FWA Program.

**Element 3 (Compliance and FWA Training):** We must administer effective training and education for all employees, Board and Committee members, and applicable delegates at the time of hire, appointment or contracting, and annually thereafter.

**Element 4 (Effective Lines of Communication):** We maintain effective lines of communication to ensure that you can report compliance and FWA issues to the appropriate channel, including anonymous and confidential reporting.

**Element 5 (Disciplinary Standards):** In order to be effective, we must maintain disciplinary standards to ensure that people who commit a compliance or FWA violation are subject to appropriate corrective actions, up to and including termination of employment or contract.

**Element 6 (Monitoring and Auditing):** We adopt the doctrine of “trust but verify”. We conduct routine monitoring reviews and audits of our internal operations and external business partners to ensure that they are performing in accordance with State and Federal guidelines.

**Element 7 (Compliance Investigation & Corrective Action Plan):** Lastly, upon discovery of a potential noncompliant or FWA issue, we will initiate a thorough investigation of the incident. We then track deficiencies and instances of noncompliance by formal Corrective Action Plans (CAPs) to ensure that they are remedied and are not likely to reoccur.

**COMPLIANCE POLICIES**

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## POLICY NUMBER C-1: COMPLIANCE WITH FEDERAL & STATE LAWS

### POLICY

PacificSource, PacificSource Community Health Plans, PacificSource Health Plans and PacificSource Community Solutions (collectively, "PacificSource") will comply with applicable Federal and State laws and statutes, Code of Federal Regulations, and sub-regulatory guidance.

### PROCEDURE

PacificSource administers its government programs in accordance with the following statutes, laws, regulations, and agency requirements that are promulgated by the Federal and State government. Applicable covered persons are required to maintain current knowledge of these requirements, and implement and integrate the requirements within the operational, administrative and compliance areas.

**Anti-Kickback Statute:** This statute prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal health care program business, including Medicare and Medicaid. This can take many forms, such as cash payments, entertainment, credits, gifts, free goods or services, the forgiveness of debt, or the sale or purchase of items at a price that is not consistent with fair market value. It also may include the routine waiver of co-payments and/or co-insurance.

The offense is classified as a felony and is punishable by fines of up to \$25,000, imprisonment for up to five years, civil money penalties up to \$50,000, and exclusion from participation in federal health care programs.

**Anti-Money Laundering:** Money laundering involves hiding the origin of unlawfully gained money, for example through drug transactions, bribery, terrorism or fraud. PacificSource is committed to complying fully with all anti-money laundering laws and regulations. We will conduct business only with reputable customers involved in legitimate business activities, with funds derived from legitimate sources.

**Antitrust Laws:** These laws are designed to protect competition by prohibiting monopolies, price fixing, predatory pricing and other practices that restrain trade. We never discuss pricing, suppliers or territories with competitors, nor make agreements with them on these or other competitive issues. We gain information about competitors only in legal and ethical ways. Improperly obtained competitor proprietary information cannot be used to the advantage of PacificSource.

**Beneficiaries Inducement Statute:** Medicare marketing guidelines prohibit PacificSource from offering rebates or other cash inducements of any sort to beneficiaries. The guidelines prohibit us from offering or giving remuneration to induce the referral of a Medicare beneficiary, or to induce a person to purchase, or arrange for, or recommend the purchase or ordering of an item or service paid in whole or in part by the Medicare program.

**Civil Monetary Penalties (CMPs):** In addition to criminal penalties, the United States Government may also impose civil monetary penalties and exclude a person or entity from participation in Medicare, Medicaid and all other Federal health care programs.

**Code of Federal Regulations (CFRs):** PacificSource must comply with Federal regulations that implement and oversee the Medicare and Medicaid programs. These regulations include:

42 CFR §400: Overview

42 CFR §403: Special programs

42 CFR §411: Benefit and payment exclusions

42 CFR §417: Health maintenance organizations, competitive medical plans, and health care prepayment plans

42 CFR §422: Medicare Advantage program. This is the authoritative regulation that implements the Medicare Advantage Program under the Social Security Act.

42 CFR §423: Prescription drug program. This is the authoritative regulation that implements the Prescription Drug Program under the Social Security Act.

42 CFR §433, §438, §455, §1002: Medicaid program. This is the authoritative regulation that implements the Medicaid Program under the Social Security Act.

42 CFR §1001: OIG program exclusions

42 CFR §1003: OIG civil money penalties, assessments and exclusions

**Contractual Commitments:** PacificSource contracts with government agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Oregon Health Authority (OHA) to administer the Medicare and Medicaid programs, respectively. We are bound by the terms and conditions of those contracts. Non-compliance with contractual obligations may result in the suspension or termination of our contracts with CMS and OHA.

**Employee Retirement Income Security Act (ERISA):** ERISA establishes minimum standards for pension plans, including health insurance plans, and provides for extensive rules on the federal income tax effects of transactions associated with employee benefit plans. It was enacted to protect employee benefit plan participants and their dependents by requiring the disclosure of financial and other information concerning the plan to participants, establishing standards of conduct for plan fiduciaries, and providing for appropriate remedies and access to the federal courts.

**Federal Criminal False Claims Statutes:** Federal laws make it a criminal offense for anyone who makes a claim to the United States government knowing that it is false, fictitious, or fraudulent. This offense carries a criminal penalty of 5 years in prison and a monetary fine.

**False Claims Act (FCA):** This act prohibits any person from engaging in any of the following activities:

1. Knowingly submit a false or fraudulent claim for payment to the United States Government;
2. Knowingly make a false record or statement to get a false or fraudulent claim paid or approved by the Government;



3. Conspire to defraud the Government by getting a false or fraudulent claim paid or approved by the Government; or
4. Knowingly make a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

Violations may result in a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustained due to the violation.

The FCA defines “knowingly” broadly to mean a person who: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, even without a specific intent to defraud.

The FCA also allows an individual to file a *qui tam* action that entitles the individual to receive between 15-30 % of a settlement or action stemming from the suit. Under the FCA, individuals are protected from being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in their employment as a result of filing a *qui tam* action. Remedies include reinstatement with the same seniority, two times the amount of any back pay, interest on any back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys’ fees.

**Federal Food, Drug and Cosmetic Act (FDA):** This Act authorizes the FDA to oversee drugs and medical devices.

**Fraud Enforcement and Recovery Act of 2009 (FERA):** This law reinforces criminal violations of certain federal fraud laws, federal false claim laws, including financial institution fraud, mortgage fraud, and securities and commodities fraud.

**Health Insurance Portability and Accountability Act (HIPAA) & HITECH Act:** These acts protect the confidentiality and integrity of protected health information. The HIPAA Privacy Rule provides federal protections for personal health information held by PacificSource and its business partners and gives patients an array of rights with respect to that information.

The Security Rule specifies a series of administrative, physical, and technical safeguards for PacificSource and its business partners to use to assure the confidentiality, integrity, and availability of electronic protected health information.

**OIG List of Excluded Individuals and Entities (LEIE) & GSA System for Award Management (SAM):** Federal law prohibits the payment by Medicare, Medicaid or any other federal health care program for any item or service furnished by a person or entity excluded from participation in these federal programs. No Part C or D Sponsor or FDR/Subcontractor may submit for payment any item or service provided by an excluded person or entity, or at the medical direction or on the prescription of a physician or other authorized person who is excluded. The Office of Inspector General (OIG) maintains the LEIE and the General Services Administration (GSA) maintains the SAM.

**Oregon Administrative Rules (OARs):** PacificSource must comply with applicable OARs that govern the Medicaid program, such as 410-120 and 410-141, *et. al.*

**Patient Protection and Affordable Care Act (ACA):** This law requires health insurers to sell insurance to individuals regardless of their health status or any pre-existing medical conditions, requires individuals who don't have health insurance to purchase health insurance or face a penalty, and created a health insurance exchange system that allows individuals to purchase standardized, state-regulated health care plans that are eligible for federal subsidies.

**Physician Self-Referral ("Stark") Statute:** This statute, which is also articulated in §1877 of the Social Security Act, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies. The statute prohibits the submission of claims to Medicare for those referred services.

**Social Security Act: Title XVIII** of the Social Security Act implements the Medicare Advantage Program (§1851-1859) and the Prescription Drug Program (§1860D-1860D-31), and serves as the statutory foundation by which these two Medicare programs are governed. In addition, and when applicable, PacificSource complies with Original Medicare requirements under §1811-1848. **Title XIX** of the Social Security Act implements the Medicaid program (§1900-1946).

**State Laws:** As a health care service contractor, PacificSource is licensed under the relevant statutes in Oregon, Idaho and Montana and is required to comply with all laws applicable to health care service contractors contained in the Insurance Code. We are also subject to oversight by the relevant Insurance Divisions. We are subject to annual filings, audits, and other oversight measures. Many types of transactions require prior approval by the agency. PacificSource's Finance Department, Legal Affairs, and Corporate Compliance Department are responsible for these filings.

**Sub-Regulatory Guidance:** CMS and OHA periodically issue sub-regulatory guidance via HPMS memos, manuals, instructions, and the CMS website. PacificSource shall comply with such guidance.

## References

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.1)
- Chapter 21: Medicare Managed Care Manual-Compliance Program Guidelines (§50.1)

## POLICY NUMBER C-2: CORPORATE COMPLIANCE OFFICER, COMPLIANCE COMMITTEE & GOVERNING BODY

### POLICY

PacificSource, PacificSource Community Health Plans, PacificSource Health Plans, and PacificSource Community Solutions (collectively, “PacificSource”) maintain a Corporate Compliance Officer and a Corporate Compliance Committee. The Corporate Compliance Officer and Compliance Committee are accountable to members of the Executive Management Group (EMG), and report to the Audit and Compliance Committee of the Board of Directors on the activities and status of the Compliance Program at least quarterly.

The Corporate Compliance Officer is vested with the day-to-day operations of the compliance program, is an employee of the organization, a member of the EMG and reports to the CEO. In no event shall the Corporate Compliance Officer be an employee of a PacificSource FDR/Subcontractor, or serve dual roles in operational areas.

The Corporate Compliance Committee advises the Corporate Compliance Officer, and assists in the implementation of the Compliance Program. The Audit and Compliance Committee is accountable for and exercises reasonable oversight over the effectiveness and implementation of the Compliance Program, and maintains current knowledge about the content and operation of the Compliance Program.

### PROCEDURE

#### Corporate Compliance Officer

**Reporting & Accountability:** The Corporate Compliance Officer reports to and is directly accountable to the President and Chief Executive Officer (CEO) of PacificSource.

The Corporate Compliance Officer reports *at least quarterly* to the Board of Directors, Corporate Compliance Committee and Audit and Compliance Committee on the activities and status of the Compliance Program, including issues identified, investigated, and resolved by the Compliance Program. This is done to ensure board directors, committee members and senior leadership are knowledgeable about the content and operation of the Compliance Program, and to allow them to exercise reasonable oversight with respect to the implementation and effectiveness of the Compliance Program. The Corporate Compliance Officer has the authority to provide unfiltered, in-person reports to both the Compliance Committee and Audit Committee. The Corporate Compliance Officer also provides bi-weekly compliance reports to the PacificSource CEO.

**Roles & Responsibilities:** The Corporate Compliance Officer maintains the following, but not limited, roles and responsibilities:

1. Implement the Compliance Program, including defining the program structure, educational requirements, reporting and complaint mechanisms, response and correction procedures, and compliance expectations of all personnel and FDR/Subcontractors.
2. Provide compliance reports *at least quarterly* to the CEO, Compliance and Audit and Compliance Committee on the status of the Compliance Program, the identification and resolution of potential or actual instances of noncompliance, and the compliance oversight and audit activities.
3. Interact with business owners and operational units and be involved in and aware of the daily business activities. The Corporate Compliance Officer or his/her designee implements this by engaging in operational meetings, such as the Government and Commercial Operations Committee, Stars Steering Committee, Medicare Leadership Team, and Medicaid Leadership Team.
4. Create and coordinate (or delegate) educational training programs to ensure that officers, directors, managers, employees, FDR/Subcontractors, and other individuals working in government programs are knowledgeable about the Compliance Program, written Code of Conduct, compliance policies and procedures, and all applicable statutory and regulatory requirements.
5. Develop and implement methods and programs that encourage managers and employees to report program noncompliance and suspected FWA and other misconduct without fear of retaliation.
6. Maintain the compliance reporting mechanism and closely coordinate with the internal audit department, where applicable.
7. Respond to reports of potential instances of FWA, coordinate internal investigations and develop appropriate corrective or disciplinary actions, if necessary.
8. Coordinate personnel issues with Human Resources to ensure that covered persons are checked against the OIG exclusion lists and GSA debarment lists monthly. PacificSource may require the FDR/Subcontractors to provide signed attestation/certification of their compliance with this requirement, subject to validation.
9. Maintain documentation for each report of potential noncompliance or FWA received from any source, which describes the initial report of noncompliance, the investigation, the results of the investigation, and all corrective and/or disciplinary action(s) taken as a result of the investigation.
10. Oversee the development and monitoring of corrective action plans.

11. Coordinate potential fraud investigations/referrals with the appropriate National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC), collaborate with other sponsors, State Medicaid programs, Medicaid Fraud Control Units (MFCUs), commercial payers, and other organizations, where appropriate, when an FWA issue is discovered that involves multiple parties.

12. Has the authority to:

- Interview employees regarding compliance issues.
- Review and retain company contracts and other documents.
- Review the submission of data to CMS and State agencies to ensure accuracy and compliance with CMS, OHA, and state insurance division reporting requirements.
- Seek independent advice from legal counsel.
- Report misconduct to CMS and OHA or law enforcement.
- Conduct and direct internal audits and investigations of any FDR/Subcontractors.
- Recommend policy, procedure and process changes.

**Training & Maintaining Current Knowledge:** The Corporate Compliance Officer maintains current and comprehensive knowledge of Federal and State regulations and program requirements through various methods, including reading the CMS website, HPMS memos, manuals, attending industry-sponsored conferences, and interacting with other plans' Corporate Compliance Officers.

In addition, the Corporate Compliance Officer, or his or her designee, participates in important government-sponsored conferences and workgroups such as, but not limited to:

- Spring/Fall CMS Medicare Advantage and Prescription Drug Plan Conference
- CMS-sponsored Center for Program Integrity (CPI) NBI MEDIC Fraud Work Group Quarterly Meetings
- United States Attorney's Office Health Care Fraud Working Group
- Monthly Issues Management with CMS Regional Officer
- OHA sponsored compliance and CCO contract meetings

### Corporate Compliance Committee

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**Purpose:** The Corporate Compliance Committee is responsible for advising the Corporate Compliance Officer and assisting in the implementation and administration of the Compliance Program. The Committee oversees compliance for all lines of business including, Commercial, Medicare and Medicaid programs.

**Reporting & Accountability:** The Corporate Compliance Committee is accountable to the CEO. Through the Corporate Compliance Officer, the Corporate Compliance Committee reports at least quarterly to the Audit and Compliance Committee on the status and effectiveness of the Compliance Program.

**Membership<sup>1</sup>:** The Corporate Compliance Committee maintains memberships from a variety of backgrounds, including Pharmacy Services, Health Services, Legal, Human Resources, Operations, Internal Audit, and representatives from the Executive Management Group (EMG). Committee members have decision-making authority in their respective business area of expertise.

<b>EXECUTIVE SPONSOR</b>	
Ken Provencher	President and Chief Executive Officer (EMG)
<b>COMMITTEE CHAIR</b>	
Wendy Carver	Corporate Compliance Officer (EMG)
<b>COMMITTEE MEMBERS</b>	
Andy Duffield	Internal Audit Manager
Dan Roth	EVP, Chief Medical Officer (EMG)
Dan Stevens	EVP, Product Line Management (EMG)
Erick Doolen	EVP, Chief Operating Officer (EMG)
Jennifer Moss Lewis	VP, Medicare Programs (EMG)
Kristi Kernutt	VP, Legal Affairs and General Counsel (EMG)
Laurie Lemieux	VP, Administration/HR (EMG)
Lindsey Hopper	VP, Medicaid Programs (EMG)
Peter Davidson	EVP, Chief Financial Officer (EMG)
Sharon Thomson	EVP, Community Strategy & Marketing (EMG)
Tony Kopki	VP, Commercial Programs (EMG)

Membership considerations, including the addition and removal of committee members, can be made by any committee member at any time. An assessment of the adequacy of the current membership representation shall be conducted on an annual basis.

**Meeting Protocol:** The committee shall meet at least quarterly. Meetings shall be documented by minutes. Relevant documentations submitted to the committee shall be retained in accordance with CMS record retention requirements. 2/3 membership will constitute a quorum for the committee.

**Roles & Responsibilities:** The Committee maintains the following, but not limited, roles and responsibilities:

1. Meet at least quarterly.
2. Develop strategies to promote compliance and the detection of potential violations.

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<sup>1</sup> Membership listing may be modified from time to time without requiring Compliance Committee approval of updates to this policy.

3. Review and approve compliance and FWA training, and ensure that training and education are effective and appropriately completed.
4. Assist with the creation and implementation of risk assessment and monitoring and auditing work plan.
5. Assist in the creation, implementation and monitoring of effective corrective actions.
6. Develop innovative ways to implement appropriate corrective and preventative action.
7. Review the effectiveness of the system of internal controls designed to ensure compliance with regulations in daily operations.
8. Support the Corporate Compliance Officer's need for sufficient staff and resources to carry out his/her duties.
9. Ensure up-to-date compliance policies and procedures.
10. Ensure that there is a system for employees and FDR/Subcontractors to ask compliance questions and report potential instances of noncompliance and FWA, confidentially or anonymously without fear of retaliation.
11. Review and address reports of monitoring and auditing of areas at risk for noncompliance or FWA and ensure that corrective action plans are implemented and monitored for effectiveness.
12. Provide regular and ad hoc reports on the status of compliance with recommendations to the governing body.

### **Audit and Compliance Committee**

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The Board of Directors (BOD) has delegated compliance oversight to the Audit and Compliance Committee. Please see the committee's charter for a detailed description of the scope of delegation of activities. To that end, the committee exercises reasonable oversight in the development and implementation of the Compliance Program, and is ultimately accountable for compliance. On an annual basis, the committee shall adopt a resolution stating the organization's commitment to lawful and ethical conduct.

The committee maintains the following, but not limited, roles and responsibilities:

1. Understand the compliance program structure.
2. Be informed about compliance enforcement activities such as notices of non-compliance, warning letters, and other formal sanctions.

3. Be informed of compliance program outcomes, including results from internal and external audits.
4. Receive regularly scheduled updates, measurable evidence, and data from the Corporate Compliance Officer and Corporate Compliance Committee showing that the compliance program is detecting and correcting noncompliant issues on a timely basis.
5. Review results from the assessment of the Compliance Program's performance and effectiveness.
6. Be knowledgeable about the content and operation of the Compliance Program through updates, training and education.
7. Hold Management accountable for compliance and take appropriate action, as necessary, to promote and support compliance and/or address significant issues of non-compliance.

In addition, Committee members stay engaged in the oversight of the Compliance Program by continually asking critical questions, such as:

- What does the committee need to do to stay educated on new regulations?
- Where are the compliance risk areas?
- What operational areas are performing well and not performing well, and what is the root of success and lack of success?
- What areas are strong and weak within the Compliance Program, and what is the root to the strength and weakness?
- What are the primary root causes for compliance issues?
- Do the reports given to the committee provide the appropriate level of detail that the committee needs to oversee the program?
- Is the compliance program effective and how does the Corporate Compliance Department measure compliance effectiveness?
- How does the Corporate Compliance Department ensure that the work it is doing appropriately addresses the risks associated?
- What is the Corporate Compliance Officer's escalation process when dealing with difficult issues, such as repeat findings and issues that management may not be responsive to resolve?
- Does the Corporate Compliance Officer have the freedom and authority to provide unfiltered reports to the committee without fear of retaliation?
- Does management support the compliance program?
- What is management doing to ensure Corrective Action Plans (CAPs) are resolved timely, and repeat findings do not occur again?



- What is management doing to hold people accountable for non-performance?
- What types of internal controls are in place (as instituted by management) to ensure processes are running in a compliant manner?
- Are departments adequately staffed and trained to achieve success?
- What is the company doing to prevent issues from occurring?
- What is the company doing to ensure compliance improvement from year-to-year?
- How is the company performing relative to State and Federal expectations, the competitors, and the industry as a whole?

### **CEO & Executive Management Group (EMG) Engagement**

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The President and CEO of PacificSource, who is also the CEO/President of PacificSource Community Health Plans, PacificSource Community Solutions., and PacificSource Health Plans, and applicable EMG members shall ensure that the Corporate Compliance Officer is integrated into the organization and is given the credibility, authority and resources necessary to operate a robust and effective compliance program.

The President and CEO receives periodic reports from the Corporate Compliance Officer of risk areas facing the organization, the strategies implemented to address those risks, and the results of those strategies. The President and CEO is advised of all compliance enforcement activity, including Notices of Non-Compliance and formal enforcement actions.

### **Governing Body**

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The Board of Directors has delegated compliance oversight to the Audit and Compliance Committee. The Board exercises reasonable oversight over the compliance program by reviewing minutes from the Audit and Compliance Committee; the Board may request additional information and/or discuss any matter brought to the Audit and Compliance Committee. The minutes document the compliance reporting that the Corporate Compliance Officer provides to the Audit and Compliance Committee on a *quarterly* basis. The Board approves the Standards of Conduct. This function may not be delegated.

The Board acts as a policy-making body that exercises oversight and control over policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees. The policy-making body also controls the appointment and removal of the executive manager, who is the President and Chief Executive Officer, a member of the organization's EMG.

### **Reporting**

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On an annual basis, PacificSource shall submit its compliance program and FWA policies and procedures to the OHA Contract Administrator, CMS and other appropriate bodies charged with the responsibility of operating and monitoring the Fraud and Abuse program. For OHA, the policy must be submitted no later than January 31<sup>st</sup> each year. If the policy has not been changed since the last submission, PacificSource shall submit an Attestation of Revision and

Submission of Contractually Required Reporting by the annual deadline. Upon any significant changes to the policy, OHA must be notified prior to any formal adoption of the policy.

### **Program Revision**

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Changes to this Policy Number C-2, and the other policies that comprise the Compliance and FWA Program, shall be sent to the Corporate Compliance Committee for review and approval before incorporation into the Compliance and FWA Program.

### **Reference**

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- 42 CFR §422.503(b)(4)
- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.2)
- Chapter 21: Medicare Managed Care Manual-Compliance Program Guidelines (§50.2)
- Oregon Health Plan, Health Plan Services Contract #143119-11 (Central Oregon), and #143903-11 (Columbia Gorge), Exhibit B, Part 8, Section 14

## POLICY NUMBER C-3: COMPLIANCE TRAINING AND EDUCATION

### POLICY

PacificSource, PacificSource Community Health Plans, and PacificSource Community Solutions (collectively, "PacificSource") administer effective training and education for all covered persons who are responsible for the administration or delivery of a government program at the time of hire or contracting, and annually thereafter. Training and education cover general compliance training, specialized compliance training, and fraud, waste and abuse (FWA) training.

### PROCEDURE

**Corporate Compliance:** Creates general and FWA training content for covered persons; administers training to the Board of Directors, and committee members (including the Quality Assurance/Utilization Management Committee (QAUM), Pharmacy and Therapeutics (P & T) Committee, Corporate Compliance Committee, and Audit and Compliance Committee); posts compliance posters in high-visibility common areas, annually distributes CMS' General Compliance and FWA Training to FDRs/subcontractors and periodically disseminates compliance tips to raise compliance awareness.

**Human Resources:** Administers general and FWA training to plan employees at time of hire and annually thereafter; maintains records of time, attendance and results of training.

**Operations:** Creates and administers specialized training for their employees; maintains records of time, attendance and results of training. Although not an exhaustive list:

**Sales:** Creates (or delegates) agent/broker training content and administers (or delegates) training for contract agents and brokers; administers maintains records of time, attendance and results of training.

**FDRs/Subcontractors:** Create and administer the training for their employees; maintain records of time, attendance and results of training; submit attestation/certification of their compliance with this requirement, subject to validation of compliance.

#### General Compliance & FWA Training

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PacificSource administers effective general compliance and FWA training and education to covered persons in accordance with the following schedule:

*Employees:* Within **ninety (90) days** of hire, and annually thereafter as a condition of employment.

*Board and Committee Members:* Within **ninety (90) days** of appointment, and annually thereafter as a condition of appointment.

*FDRs/Subcontractors:* The training content for all FDRs must include the material developed by CMS through its Medicare Learning Network (MLN) website at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html>

- *Vendors:* Within **ninety (90) days** of contracting, and annually thereafter. Accepted methods of delivery include a certification of completion from the MLN training, an attestation from the FDR that training content included the material from the MLN training, or a contract/agreement between PacificSource and the FDR that includes the full content of the MLN training.

The FDR/Subcontractor may develop its own modules to provide employees with specific, on- the-job training. It may also develop additional training to supplement the General Compliance and FWA Training content, but it cannot replace them. PacificSource may require the FDR/Subcontractors to provide signed attestation/certification of their compliance with this requirement, subject to validation of compliance. PacificSource may also validate the FDR/Subcontractor's compliance with this requirement through auditing a sample of the highest risk FDR/Subcontractors.

- *Agents/Brokers:* During the initial and annual sales appointment process. In no event may an agent or broker be appointed or market to a beneficiary without completing training.
- *Providers:* Within **ninety (90) days** of contracting, and annually thereafter. Providers who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse. However, these providers still must receive general compliance training.
- *Pharmacies:* For network pharmacies, we require the pharmacy benefits manager (PBM) to administer the training to its network pharmacies.

All records of time, attendance and results of employee training will be documented in the LMS system. FDR/Subcontractors are responsible for tracking and maintaining training records. All training records must be retained for a minimum period of **10 years**. Compliance training materials are updated annually, and contain topics such as:

- Description of the Compliance Program, including a review of compliance policies and procedures, the Standards of Conduct, and the organization's commitment to business ethics

and compliance with all government program requirements.

How to ask compliance questions, request compliance clarification or report potential noncompliance, emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of potential noncompliance or FWA.

- Requirement to report potential compliance and FWA issues.
- Examples of reportable compliance and FWA issues.
- Disciplinary guidelines for non-compliant or fraudulent behavior, 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 formal training programs as a condition of continued employment and a criterion to be included in employee evaluations.
- Policies related to contracting with the government, such as the laws addressing fraud and abuse or gifts and gratuities for government employees.
- Potential conflicts of interest and the disclosure requirement.
- HIPAA, the CMS Data Use Agreement, and the importance of maintaining the confidentiality of personal health information.
- Monitoring and auditing process and work plan.
- Laws that govern employees and the compliance program.
- Laws and regulations related to FWA (i.e. False Claims Act, Anti-Kickback statute, HIPAA).
- Obligations of FDRs/Subcontractors to have appropriate policies and procedures to address FWA.
- A process for reporting suspected FWA.
- Protections for those who report suspected FWA.
- Types of FWA that can occur in the settings in which employees work.

## Measure of Effectiveness

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Training effectiveness is measured by a number of methods, including:

- Number of CAPs
- Results from compliance audits
- Requests for compliance interpretations
- CMS self-disclosures
- Training follow-up assessments
- Decrease in compliance issues or findings in a business area
- Increase in compliance awareness
- Increase in compliance inquiry and reporting

## References

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.3)
- Chapter 21: Medicare Managed Care Manual-Compliance Program Guidelines (§50.3)
- 2/10/2016 HPMS Memo: Additional Guidance – Compliance Program Training Requirements and Audit Process Update

## POLICY NUMBER C-4: EFFECTIVE LINES OF COMPLIANCE COMMUNICATION, REPORTING & NON-RETALIATION

### POLICY

#### Effective Lines of Communication

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PacificSource, PacificSource Community Health Plans, PacificSource Health Plans, and PacificSource Community Solutions (collectively, “PacificSource”) maintain effective lines of communication to ensure confidentiality between the Corporate Compliance Officer, Compliance Committee, employees, managers, Board of Directors, first tier, downstream and related entities (FDRs) and subcontractors. The lines of communication are accessible to all, allow compliance issues to be reported when they arise and provide a means for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

#### Reporting

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To ensure ethical conduct, all covered persons have an obligation to raise concerns they might have about conduct that falls short of compliance standards, and report issues to the appropriate channel. They are also expected to assist in the investigation and resolution of compliance and fraud, waste or abuse (FWA) issues. Failure to do so may result in disciplinary actions, up to and including termination of employment or contract.

#### Non-Retaliation

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To create a work environment where employees and individuals feel comfortable addressing and reporting any instances of non-compliance or FWA, unfair or unethical acts, PacificSource maintains a non-intimidation and non-retaliation environment that allows individuals to make good faith reports against any person or action by PacificSource or its FDRs/Subcontractors, without repercussion or fear of retaliation. Those who retaliate against an individual who makes a good faith effort to report a compliance or FWA issue will be subject to corrective action.

### PROCEDURE

#### Compliance Communication

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The Corporate Compliance Officer routinely communicates compliance and FWA requirements throughout applicable areas of the organization using various channels, such as email, internet website, and other methods.

The Corporate Compliance Department disseminates updated regulatory guidance and instructions, including HPMS memorandums, manuals, and Part C/D User Group Calls to applicable business departments. We track and document this process to ensure that new regulations and instructions are properly implemented. Business owners are responsible for taking follow-up actions to ensure compliance with the new requirements. Areas of deficiency must be communicated to the Corporate Compliance Department immediately. The regulatory dissemination process is as follows:

## **Regulatory Notices:**

1. Upon receipt of an HPMS memo or other State and Federal guidance, the Corporate Compliance Department logs the document in the Regulatory Dissemination Tracking Module and assigns them to business owners within **5 business** days of receipt. If the memo is urgent or time sensitive, we will forward the memo via email to the business owner for immediate action.
  2. Each business owner receives an immediate email notification from SharePoint indicating that a memo has been assigned to them.
  3. For important memos and guidance that have significant operational impact, significant changes to current processes, or cross-functional impact, the Corporate Compliance Department will analyze them for content and applicability, meet with individual business owners to discuss their action plan (as needed), and answer any interpretation questions. Important memos may also be discussed during the bi-monthly Government Operations meeting. Notes taken during these meetings are incorporated into the Regulatory notice as part of the Regulatory Dissemination Tracking Module.
  4. The business owners will have **7 business days** to review the guidance and document the action plan in the Tracking Module. The actual action or implementation plan may take longer to develop, but the initial analysis and response must occur within **7 business days** (or longer at the Corporate Compliance Officer's discretion).
  5. Once all necessary actions have been taken, the business owner reassigns the notice to Compliance. Prior to closing out the case, Compliance reviews each response to ensure appropriate and complete actions have been/will be taken.
  6. If the business owner's comments are incomplete, Compliance will work with the business owner to ensure all appropriate actions are taken and documented properly in SharePoint.
  7. If all necessary actions have been taken and are properly documented, Compliance will change the status to "closed".
  8. Non-responses will follow the escalation procedure:
    - a. SharePoint will send a reminder 1 day before the upcoming deadline [this will be a manual process until we deploy the automated SharePoint solution]
    - b. SharePoint will send a reminder 1 day past the deadline [this will be a manual process until we deploy the automated SharePoint solution]
    - c. If the deadline exceeds 5 days, SharePoint will escalate the issue to the business owner's EMG [this will be a manual process until we deploy the automated SharePoint solution]
- Departments showing a pattern of non-responsiveness or untimeliness will receive further compliance remedial action, up to and including implementing a corrective action plan.
9. The Corporate Compliance Department will incorporate high-risk requirements from the guidance into existing auditing and monitoring protocols to verify the accurate and timely implementation of the requirements.



10. On a bi-weekly basis, Compliance will review all outstanding notices to ensure appropriate and complete actions have been taken.
11. The Corporate Compliance Department will participate in operational meetings to provide oversight of complex or high-risk issues. Business owners are also encouraged to request the Corporate Compliance Department participate in other operational meetings during implementation.

The business owners (who receive direct notices from regulatory agencies) should not wait for the Corporate Compliance Department to disseminate the information. Rather, they should start the process of reviewing and analyzing the notices right away and take the appropriate actions necessary to meet the notice's content.

**Part C/D User Group Calls:** The Corporate Compliance Department also tracks and documents regulatory guidance through the CMS user group calls, and communicates this to business owners when applicable. Compliance sends out notices to business owners impacted by the content of the call. We retain documentation of the calls, including recorded audit, in SharePoint.

**Regulatory Educational Notices:** The Corporate Compliance Department routinely disseminates new compliance information to business owners and applicable FDRs/Subcontractors. The notices summarize changes in CMS, OHA and other regulations, CMS sanctions and enforcement actions against other health plans, CMS and OHA conferences, and industry/association training and conferences.

**Employee Newsletter:** We provide compliance newsletters as an additional line of communication between our employees and the Corporate Compliance Officer and Corporate Compliance Department, with tips and instructions on how to detect and report FWA. The newsletters also provide information on disciplinary standards and non-retaliation and non-intimidation policy.

**Compliance Posters:** We routinely disseminate compliance posters, tips, and FAQs and post them in high-visible common areas to raise awareness of compliance requirements, FWA implications, non-retaliation, and reporting protocols.

**Regulatory Interpretations:** You can request clarification on a regulatory or compliance question, or request an interpretation of the rule by sending your request to [ComplianceQ&A@PacificSource.com](mailto:ComplianceQ&A@PacificSource.com).

### **Member & FDR/Subcontractor Communication**

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Corporate Compliance, Sales, Regulatory Communications, and MarComm communicate compliance and FWA requirements to beneficiaries and existing members through various methods, including the plan website, marketing materials, and member newsletters.

In addition, PacificSource maintains a [Compliance Website](#) accessible to FDRs/Subcontractors and members to provide information on FWA training and reporting.

### **Reporting Requirement**

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All covered persons must report a compliance or FWA issue promptly upon discovery of the potential

violation. Though this should not be construed to be an exhaustive list, below are some examples of issues that must be reported:

- CDAG and ODAG
  - Untimely effectuation
  - Inappropriate denials
  - Access to care issues
  - Member notice issues
  - Misclassification of cases
- Untimely or inaccurate EOB
- Call center
  - Not meeting performance standards
  - Inaccurate information provided
  - Downtime
- Enrollment & disenrollment
  - Untimely member notice
  - Inappropriate enrollment & disenrollment
- Premium billing
  - Untimely or inaccurate billing
  - Invoice errors
- Formulary administration
  - Access to care issues
  - Inappropriate denials
  - Untimely transition claims
  - Protected class drug issues
- Issues caused by an FDR/Subcontractor
- Sales and marketing
  - Untimely or inaccurate ANOC/EOC
  - Inappropriate agent/broker behavior
- Claims
  - Access to care issues
  - Untimely or inaccurate claim adjudication
  - Inappropriate denial of benefits
- Provider network
  - Network adequacy deficiencies
  - Access issues
  - Credentialing issues
- HR
  - Excluded persons
- IT issues that trigger deficiency in any of the above-referenced areas

## Method of Reporting

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PacificSource maintains various lines of communication to ensure confidentiality in reporting. The communication channels are accessible to all. Any covered person may report a compliance or FWA issue, concern, or violation through the following methods:

1. Report to your immediate supervisor.
2. Report directly to the Corporate Compliance Officer:  
[Wendy Carver](#)  
971-222-1003
3. Report anonymously to EthicsPoint 24 hours a day/7 days a week:  
Phone: 1-888-265-4068  
[EthicsPoint Online Reporting](#)
4. Report to any member of the [Executive Management Group](#).
5. Report to any member of the Human Resources Department.
6. Report to:  
[Kristi Kernutt](#), General Counsel  
541-225-1967
7. Internal Audit Manager  
[Andy Duffield](#)  
541-225-2826

If you are a PacificSource vendor, in addition to any of the methods outlined above, you may report to your PacificSource contract administrator.

Please also refer to our Whistleblower Policy: Reporting of Ethical or Legal Concerns.

## Reporting Protocols

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When reporting, please be sure to provide enough information about the situation to allow us to investigate it, such as:

- Your name and contact information (optional)
- Description of the incident
- Business area(s) involved
- Names of individuals involved
- Date when event or incident occurred
- Whether this is a one-time incident or reoccurring event

The Corporate Compliance Department, Human Resources, or the appropriate department investigating the incident will document all reports of a compliance or FWA issue, concern, or violation, and shall initiate an investigation within **2 weeks** of receiving the report. When appropriate and possible, the reporting party will be provided a response on the outcome of the investigation. Please refer to the *Policy Number C-7: Compliance Investigations* for a detailed description of the investigative process.

## Non-Retaliation

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No employees will be discriminated or retaliated against in any way for bringing forward a question or good faith complaint. All employees are required to support both the letter and spirit of this commitment. Those who retaliate against an individual who makes a good faith effort to report a compliance or FWA issue will be subject to PacificSource's corrective action policy.

Furthermore, if you are filing a *qui tam* action under the Federal False Claims Act, you are protected by law from being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in your employment as a result of filing a *qui tam* action.

If you suspect that you are being retaliated against for making a good faith report of a compliance or FWA issue, you may contact any person(s) outlined in this policy, including the Corporate Compliance Officer or a member of Human Resources.

Your allegation of retaliation will be investigated by the appropriate personnel, and those who are found to have violated PacificSource's non-retaliation Policy will be subject to the disciplinary policy.

## Disclosure to Regulatory Agency

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In the spirit of transparency, the Corporate Compliance Department will disclose to the appropriate regulatory agency incidents of noncompliance and FWA that impact member safety and access to care, and which impact 100 or more members.

## Coordination with Human Resources

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For issues that have an impact on personnel matters, Human Resources will be engaged appropriately to handle compliance or FWA issues that impact such personnel matters.

## Exit Interview

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Employees who depart from PacificSource's employ are given an Exit Interview Questionnaire, which asks the departing employee to evaluate the effectiveness and availability of the organization's line of communications to report compliance and FWA concerns. Human Resources will review each Exit Interview Questionnaire for compliance reporting, and inform the Corporate Compliance Department appropriately.

## Documentation & Investigation

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The Corporate Compliance Department will document and retain all reports of noncompliance and FWA in their original content. Please see the *Policy Number C-7: Compliance Investigations* for a detailed description of the investigative process.

## References

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.1.5, 50.1.7)
- Chapter 21: Medicare Managed Care Manual-Compliance Program Guidelines (§50.1.5, 50.1.7)
- Policy Number C-7: Compliance Investigations
- Whistleblower Policy: Reporting of Ethical or Legal Concerns
- [Compliance Website](#)

## POLICY NUMBER C-5: PERSONNEL CORRECTIVE ACTIONS

### POLICY

PacificSource is an at-will employer and reserves the right to terminate any employee for any reason at any time. PacificSource's policy with respect to administering corrective actions is designed to ensure that employees whose performance or conduct does not meet the Company's standards are treated fairly and in a consistent manner. Employees whose performance or conduct does not meet the Company's standards will be subject to corrective actions up to and including dismissal and risk potential reporting to law enforcement/regulatory agencies.

### PROCEDURE

#### Definition

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"Performance or conduct issue" means any activity or inactivity that is inconsistent with the PacificSource values, mission, or culture, including but not limited to:

- Violation of a PacificSource policy or procedure, including the Code of Conduct and Employee Handbook
- Violation of a compliance, fraud, waste and abuse (FWA), State or Federal requirement, including failure to report
- Work performance and/or attendance issues
- Workplace violence, harassment, discrimination, or retaliation
- Disclosure of confidential information

"Covered Person" means an employee, officer, director, contractor, or first tier, downstream and related (FDR) entity or subcontractor.

#### Approach to Corrective Actions

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In building a high performance and compliant work culture, and one free of harassment and discrimination, PacificSource will take a proactive approach to addressing performance and conduct issues in the work place. The company's intent is to address issues quickly, and in a manner which minimizes risk to the organization, increases the likelihood of the covered person's success or remediation, and has a deterrent effect on future behavior.

The types of corrective actions taken will depend on the individual situation. The principle of "reason, record and circumstance" will be applied to each situation giving rise to the corrective action.

#### Types of Corrective Actions

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Whenever any form of corrective action is taken with an employee, the supervisor must first consult with HR. The supervisor and HR will then decide on the type of corrective action to be taken.

PacificSource maintains the following, but not limited types of corrective actions, arranged in order of severity. PacificSource reserves the right to initiate any corrective action deemed appropriate, and does not have to follow a particular sequence of order. In addition, we may require that the person retake compliance training.

The immediate supervisor is responsible for monitoring their employees' performance. If a performance or conduct issue arises, the immediate supervisor will contact Human Resources to review the circumstances of the performance or conduct issue to mutually determine the appropriate level of corrective action to be taken based on the seriousness of the situation. Performance or conduct issues are resolved as expeditiously as possible depending on the complexity and issue at hand. Complexity is based on factors such as the risks involved, amount of data and facts to be researched and confirmed in order to form a conclusion, clarity of issue and root cause, actions needed to resolve the issue, and the available resources. Every single performance or conduct issue varies by fact, circumstance, complexity, and resource availability. Thus, it is sometimes not possible to come to a resolution to a performance issue within a strict and defined timeframe because doing so will compromise the integrity, quality and thoroughness of the issue, specifically if an investigation into the conduct is required. To that end, performance or conduct issues are generally resolved within **30 days** of occurrence. PacificSource reserves the right to extend this timeframe for more complex performance or conduct issues.

All disciplinary records must be retained for **10 years**, and capture the dates of the violation, the investigation, the findings, the disciplinary action taken, and the date it was taken.

#### **I. Verbal Warning**

- a. The supervisor meets with the covered person to outline the problem(s) and state the supervisor and the Company's expectations. HR may attend as appropriate.
- b. The supervisor writes a written summary of the issue using the Company's corrective action form that outlines the agreement and documents the meeting. Both the covered person and the supervisor must acknowledge receipt and date of the document. If the covered person refuses to acknowledge the document, the supervisor should reference that on the document.
- c. The supervisor sends the original corrective action document to HR to be filed in the covered person's personnel file.

#### **II. Written Warning**

- a. The supervisor meets with the covered person to outline the problem(s) and state the supervisor and The Company's expectations. HR may attend as appropriate.
- b. The supervisor writes a written summary of the issue using the Company's corrective action form that outlines the agreement and documents the meeting. The verbal warning should be referenced in the written warning, if applicable. A timeframe for meeting those expectations should be specifically outlined. Both the covered person and the supervisor must acknowledge receipt and date of the document. If the

covered person refuses to acknowledge the document, the supervisor should reference that on the document.

- c. The supervisor sends the original corrective action document to HR to be filed in the covered person personnel file.

### **III. Final Written Warning**

- a. A meeting will take place with the covered person and the supervisor. A written detail of the problem will be presented with a history of the previous attempts to rectify the problem, e.g. verbal and/or written warnings. Notice will be given to the covered person at this time that this is a final warning and immediate corrective action is required. All present must acknowledge and date the document.
- b. The supervisor sends the original corrective action document to HR to be filed in the covered person's personnel file.

### **IV. Termination**

- a. No terminations will occur without the prior consent of the VP of Administration, or a person delegated by the VP of Administration with such authority. A meeting will take place with the covered person and his/her supervisor. A written detail of the problem will be presented with a history of the previous attempts to rectify the problem, e.g. verbal and/or written warnings. A member of HR will conduct the exit interview, or send the exit interview questionnaire, and provide the covered person's final paycheck and any documents regarding continuing benefits.

## **Policy Consistency**

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PacificSource ensures that corrective action policies and actions are applied consistently by:

- Addressing and responding to all inappropriate behavior and poor performance promptly.
- Following the organization's Personnel Corrective Actions Policy when determining that corrective action is appropriate.
- Treating all similar offenses in the same manner while taking into consideration the seriousness of the offense, the consistency with previous corrective actions for similar offenses, any mitigating circumstances, and the offender's prior conduct, past performance record, length of service, and willingness and ability to correct the problem.

## **Obligation to Report**

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PacificSource requires all covered persons to report and disclose issues that may be deemed an actionable activity, such as a compliance or FWA issue. Covered persons are also expected to assist in the investigation and resolution of these issues. Failure to report a compliance issue may result in corrective actions, up to and including termination of employment or contract.



Please refer to our policy on Effective Lines of Compliance Communication, Reporting & Non-Retaliation Policy and our Whistleblower Policy: Reporting of Ethical or Legal Concerns for detail on reporting requirements.

### Coordination with Compliance

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When an individual is subject to corrective action, Human Resources will review the case for compliance violations to ensure that issues impacting compliance are resolved appropriately in addition to the personnel issue. The Corporate Compliance Department will be notified of a compliance issue for further compliance action, if any.

### Publicizing Corrective Action Standards

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PacificSource publicizes corrective action guidelines through various mediums, including during initial employee orientation, and at annual compliance training. In addition, employees and supervisors are encouraged to discuss corrective action guidelines during regular staff meetings.

### Examples of Non-Compliant Activities

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The following are some examples of noncompliant behavior:

- Bid: Overstating or understating bid data to obtain higher premiums from members or higher reimbursement from the government.
- Call center: Intentionally providing beneficiaries with inaccurate information.
- Claims: Submitting claims to the government for services that were never rendered, failure to pay providers at the correct rate, paying providers who are on the Medicare opt-out or OIG exclusion list.
- Enrollment and disenrollment: Improperly enrolling members to obtain higher reimbursement from the government, improperly disenrolling members due to high medical expenses or other medically-related reasons.
- Exceptions and appeals: Not approving members for medically necessary services.
- Health services: Failing to approve members for medically necessary services.
- Premium billing: Billing members at the incorrect premium amount, not providing members with the required grace period to pay their bills.
- Pharmacy: Denying members their transition supply, applying utilization management rules that have not been approved, inappropriately denying drugs that should be covered.

- Provider network: Not credentialing providers in accordance with credentialing laws and regulations, contracting with providers who are on the Medicare opt-out or OIG exclusion list.
- Sales and marketing: Misleading beneficiaries, violating a CMS marketing rule, allowing agents and brokers to conduct illegal marketing activities.

## References

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.5)
- Chapter 21: Medicare Managed Care Manual – Compliance Program Guidelines (§50.5)
- C-4. Effective Lines of Compliance Communication, Reporting & Non-Retaliation Policy
- Whistleblower Policy: Reporting of Ethical or Legal Concerns
- [PacificSource Employee Handbook](#)

## POLICY NUMBER C-6: COMPLIANCE MONITORING & AUDITING

### POLICY

PacificSource, PacificSource Community Health Plans, and PacificSource Community Solutions (collectively, “PacificSource”) maintain an effective system for routine monitoring and auditing of operational areas to evaluate the organization’s compliance with regulatory requirements and the overall effectiveness of the Compliance Program.

### PROCEDURE

#### Compliance Work plan

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Annually, the Corporate Compliance Department conducts a risk assessment of operational areas and develops a work plan. The work plan contains, among other things, monitoring and auditing activities to be conducted for that year. The Corporate Compliance Department oversees and executes ongoing monitoring and auditing activities in high risk areas, and oversees corrective actions and implementation plans pursuant to a compliance finding.

#### Risk Assessment

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As a precursor to creating the annual compliance work plan, the Corporate Compliance Department conducts two formal risk assessments; one for internal compliance and operational issues, and a second for functions delegated to FDRs. Relative to monitoring of FDR/Subcontractors, the risk assessment will identify the highest risk FDR/ Subcontractors and select a reasonable number of FDR/ Subcontractors for review. We will also assess the need to conduct an onsite review versus desktop. High-risk FDR/ Subcontractors may undergo an onsite review.

Substantial information is considered when completing the risk assessments. This information includes but is not limited to:

- CMS audit scope
- CMS areas of concern (i.e., marketing, enrollment, agent/broker oversight, credentialing, quality assessment, appeals and grievance, benefit/formulary administration, transition, protected classes, utilization management, claims processing accuracy, network adequacy, provider directory accuracy, and FDR/Subcontractor oversight)
- CMS Common Conditions, Improvement Strategies, and Best Practices
- Oregon Health Authority (OHA), areas of concern, such as claims, prior authorization, service verification, utilization management, encounter data, and quality review
- CMS and other industry conferences
- CMS audit protocols
- CMS Compliance Actions and Enforcement Letters
- CMS Regional Office feedback
- HPMS memos

- Impact to beneficiary access to care, safety and protection
- New/updated guidance and regulation
- OIG Work plan
- Results from prior monitoring & auditing activities
- Risk Assessment of operational areas
- Business owner feedback
- Past compliance issues
- Internal CAPs
- Complaint Tracking Module (CTM)
- Extent of FDR/Subcontractor delegated activities
- Company/department size, resources, structure, business model
- Complexity of work

We request feedback from business owners and EMG members to assess their areas of concern, and incorporate those areas into the risk assessment when appropriate. Areas are assigned a risk score for 6 different risk factors. Each risk score is ranked from 1 to 5 with 1 being lowest and 5 being highest. Descriptions of the risk factors and levels are provided below:

RISK RATING	VALUE	EXPLANATION
5	Extreme/ Certain	The issue has an extreme compliance impact and is virtually certain to occur. This area is typically a regular government focus. The issue has a direct and significant member or financial impact and affects beneficiary protection and access to care. Plans have been fined, sanctioned or terminated due to deficiencies in these areas. It is a mandate to review all issues ranked in this category.
4	High/Likely	The issue has high likelihood of occurrence or significant compliance impact, and may also be a regular government focus. The issue has a direct member or financial impact and affects beneficiary protection and access to care. Plans have been fined, sanctioned or terminated due to deficiencies in these areas. It is a mandate to review the majority of high-risk issues. It is a strong recommendation to review all of the high-risk issues. Inactivity may lead to significant risk.
3	Moderate/ Possible	The issue has medium or moderate compliance impact. The issue has moderate financial or member impact. It is recommended that it be reviewed. Inactivity may lead to moderate risk.
2	Low/ Unlikely	The issue has low compliance impact and is not likely to occur. It has either been reviewed previously, or is not a focus of government agencies. Deficiencies found in these areas are not likely to have any negative member or financial impact. Inactivity does not pose a significant or moderate risk.
1	Low/Rare	The issue has very low compliance impact and would rarely occur. It is considered stable. In the event of an issue, there would be minimal to no financial impact nor negative impact to beneficiaries

<b>RISK FACTOR</b>	<b>DESCRIPTION</b>
Complexity of Operations	Are the operations of the function of low or high complexity? This should also take into account automation vs. manual processes. (1 = low complexity/very automated, 5 = high complexity/very manual)
Government Agency Oversight	To what extent is a regulatory agency concerned about and/or overseeing this activity? (1 = low degree of government oversight/attention, 5 = high degree of government oversight/attention)
Degree of Change from Prior Year	To what degree did the activity change from the prior year? This could include changes in systems, leadership, staffing, process flow, regulation, etc. (1 = minor to no change, 5 = extreme change)
Financial Impact	Does the function have a low or high degree of financial impact for PacificSource? (1 = low degree of financial impact, 5 = high degree of financial impact)
Beneficiary/Member Risk	To what degree would a beneficiary or member be put at risk if non-compliance occurred? For example, if coverage determinations are not processed timely, this could significantly impact a member's ability to obtain needed medications which could result in a high level of risk to the member. (1 = low beneficiary/member risk, 5 = high beneficiary/member risk)
Prior Compliance Issues Detected	To what extent in the past 2 years has there been compliance issues detected, corrective actions implemented, or repeat findings in the area in question? (1= low/no prior compliance issues detected, 5= high number of compliance concerns and/or more than 2 repeat findings)

Areas and/or processes are ranked by their total risk score. Those with the highest scores are incorporated into the work plan. The compliance work plan is then submitted to the Corporate Compliance Committee for approval, and reported to the Board's Audit and Compliance Committee. While the work plan reflects our best effort to assess risks to the organization and mitigate those risks, we recognize that operational and compliance risks and the regulatory landscape are constantly changing. To that end, the work plan is routinely reviewed and revised from time to time to meet those changing needs.

### **Routine Compliance Monitoring and Oversight**

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The Corporate Compliance Department conducts routine compliance monitoring and oversight on an ongoing basis. During this routine monitoring, operational performance is measured in key, high risk areas. Routine monitoring consists of regular independent reviews performed by the compliance department during normal operations to confirm ongoing compliance. Routine monitoring may also be used to ensure that corrective actions have been implemented and are effective. In general, Routine Compliance Monitoring measures current, "real-time" performance. The following protocols apply:

1. Compliance staff will have a monitoring schedule that outlines the specific areas/processes that will be measured. The schedule is based on the annual work plan, and will detail the timing and scope of each measure. The monitoring schedule is evaluated and updated routinely as needed to account for changes in process and risk that occur throughout the year.

2. In accordance with the monitoring schedule, the Compliance staff extracts metrics and data from internal systems and/or works with business owners to obtain needed data.
3. The data is analyzed and measured based on applicable regulatory requirements. Results are populated in the Compliance Oversight & Routine Monitoring Report.
4. Deficiencies and any downward trends (from the previous reporting months) are shared with business owners for correction. If there is a continued pattern of deficiencies, Compliance will require corrective action in accordance with *Policy Number C-7: Compliance Investigation & Corrective Action Plan*.

### **Business Unit Status Reports**

There are many operational units that conduct their own quality and compliance checks on processes that occur within their respective areas. These business units will provide the results of these quality checks to the Compliance Department on a periodic, routine basis. The Compliance Department will review the results and compare them with routine compliance monitoring results. Inconsistencies will be investigated to ensure that the methods of measurement are sound and results are accurate. The quality check results will also be shared with the Compliance Committee.

### **Compliance Audits**

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The Corporate Compliance Department also conducts Compliance Audits that require an analysis of policies and procedures, interviews with key stakeholders, universe requests, sample extractions, detailed data analysis, and testing based on internal and CMS or OHA methodologies. Compliance Audits are formal reviews of policies and procedures and operational performance against laws and regulations. Generally, Compliance Audits evaluate recent past performance.

All compliance audits are conducted in accordance with regulations and requirements. When deficiencies are detected pursuant to an audit, follow-up reviews may be conducted to measure the effectiveness of any corrective action. Services of independent external auditors may be retained to assist in the auditing of high-risk areas, including FDR/Subcontractors performing a high-risk function. Compliance Audits abide by the following protocols:

#### **Phase I: Work Assignment & Engagement Notice**

1. The Compliance Manager assigns a Review Team with a Lead Auditor to conduct the review. The Compliance Manager or Lead Auditor will develop and/or update the audit workbook that will be used by the Review Team. The Review Team is made up of personnel from the Corporate Compliance Department. Independent contracted auditors may be used to assist the Review Team when necessary.
2. The Lead Compliance Auditor will provide business owners, and FDR/Subcontractors as

applicable, with an Engagement Notification at least 2-4 weeks in advance of starting an audit, with a cc to the FDR/Subcontractor if applicable. For a review that impacts an FDR/Subcontractor, the FDR/Subcontractor will be provided at least 30 days advance notice of the review, or within a timeframe stipulated in the FDR/Subcontractor contract.

3. The role of the Lead Auditor is to:
  - a. Manage and coordinate the end-to-end phases of the audit.
  - b. Develop strategies, in conjunction with the Review Team, to execute the project in an accurate and efficient manner.
  - c. Assign work to members of the Review Team in a fair and efficient manner.
  - d. Be aware and knowledgeable of all work performed by other members of the Review Team.
  - e. Ensure that all work is completed timely and accurately by the Review Team.
  - f. Scrutinize the work of the Review Team to meet a satisfactory level of acceptance.
  - g. Be the point of contact for the Compliance Manager and Corporate Compliance Officer to receive status updates.

#### **Phase II: Research & Strategy**

4. The Review Team:
  - a. Reviews the workbook in detail in order to command an expert knowledge of the workbook and all the pertinent regulations contained therein.
  - b. Develops and formulates review strategies, including methods of critique and scrutiny.
  - c. Identifies all relevant business owners as accurately and completely as possible.
  - d. Develops document requests and an audit timeline.
  - e. Develops all other project documents prior to meeting with business owners.

#### **Phase III: Entrance Meeting**

5. The Review Team schedules an Entrance Meeting with the manager/director of the business unit to go over the following:
  - a. Scope of the review
  - b. Point(s) of Contact
  - c. Document and data requests
  - d. Project deadlines
  - e. Strategy for contact with FDR/Subcontractors:
    - i. Review Team works directly with the FDR/Subcontractor and keeps the business owner in the loop, or
    - ii. Review Team works through the business owner
  - f. Business owner's preferred method to provide requested documents, policies and procedures, universes, and samples:
    - i. Business owner provides the data/document to the Review Team, or
    - ii. Review Team gets access to the system and pulls the data/document itself
  - g. Scoring Criteria

- h. CAP process, including:
  - i. Types of findings that would require a CAP
  - ii. CAP timeframe
  - iii. CAP tracking and closure process

#### **Phase IV: Review Protocol**

6. The Review Team conducts the review.
7. Depending on the scope, universes will be pulled and sample cases will be selected. The individual audit workbook will stipulate the exact number of samples to be pulled, depending on the risk, scope and resource.
8. To avoid scope creep, the review should not deviate from the workbook. If out-of-scope issues are discovered that pose significant risk to members or the organization, they should be addressed outside the audit process and through the investigations process.
9. The Review Team should resolve any delays or disagreements with the business owners. Unresolved delays and disagreements should be escalated to the Compliance Manager when necessary. The Compliance Manager will further escalate any high-risk unresolved issues to the Corporate Compliance Officer as needed. Anticipated delays that will jeopardize the review deadline must be communicated to the Compliance Manager and Corporate Compliance Officer as soon as possible.
10. The Review Team provides status updates on an ongoing basis within the workplan task on the Compliance SharePoint site.
11. Audit work papers must document all positive and negative findings, including root cause. Working papers such as policies and procedures reviewed, universes and cases sampled, tools used to document testing results, issue logs, and any other supporting documentation should be stored in a centralized location in the Corporate Compliance Department's shared drive (L drive). Final audit reports will be stored on the SharePoint site.

#### **Phase V: Findings**

12. The Review Team conducts the review and keeps business owners informed of tentative findings throughout the review using an Issues Log. The Issues Log will track each potential finding, any business owner responses/comments, and the final determination for each issue.
13. If a finding is fully corrected prior to the issuance of the final report, it will be noted in the final report and no additional corrective action plan will be required. This is contingent on the Review Team's ability to confirm the correction prior to finalizing the report. If the Review Team is unable to confirm (i.e. through validation) that the finding has been corrected, the final report



will indicate the need for a corrective action plan. Any actions taken to correct the finding will be documented through the corrective action plan process. Note: It is acceptable to add a comment from Management within the final report that explains actions that have already been taken prior to the issuance of the final report.

14. The following scoring methodology will be applied during an audit:

- a. **Met/Not Met:** A requirement/element will receive a success rate based on compliance with the requirements being tested.

**Met:** Received when the requirement/element meets requirements. When the total sample cases yield either at or above any specifically identified regulatory compliance threshold. In the absence of a specifically identified regulatory compliance threshold, 90% or greater in compliance, and no significant risk factors are present.

**Not Met:** When the requirement/element does not meet requirements. When the success rate is either below the regulatory compliance threshold or less than 90% in compliance, regardless of reason.

**Significant Risk Factors:** A Not Met may be assessed when any number of sample cases fail due to a systemic deficiency, or when the finding is determined to have either potentially or actually caused harm to a member. Examples of member harm include but are not limited to the following:

- i. Inappropriate denial or limitation on access to medications
- ii. Inappropriate denial or limitation on access to services
- iii. Inappropriate or inaccurate financial burden (i.e. excess premium billing, incorrect cost share or MOOP calculations, etc.)

The determination of Met or Not Met will take into account both mitigating and aggravating factors. Each situation will be evaluated against the above criteria and the compliance team's professional judgement. The final determination of Met or Not Met will be at the sole discretion of the Compliance Department. Generally, an assessment of Not Met will require some form of curative action.

- b. **Observations:** These are noted for immaterial instances of non-compliance due to isolated human error, universe inaccuracy, and other non-systemic issues. Observations may suggest process improvements; however curative action is not mandatory.

15. For audit elements that are covered by a CMS Audit Protocol, the CMS scoring methodology will be used whenever possible. See the most current CMS Audit Protocols for the most up to date CMS scoring methodology.

## Phase VI: Status Update

16. Close to the anticipated completion of the review, the Compliance Manager meets with the Review Team to go over tentative findings. During the meeting, the Review Team must be prepared to:
  - a. Discuss all positive and negative findings in detail
  - b. Provide rationale, justification and logic to support findings
  - c. Provide recommendation and conclusion of findings
  - d. Articulate all findings in a clear, concise, and complete manner

#### **Phase VII: Publication**

17. The Review Team drafts a Compliance Audit Report to send to the Compliance Manager and Corporate Compliance Officer for review. By the time the Compliance Manager and Corporate Compliance Officer receives the first draft, the Review Team has already ensured that business owners are aware of the findings, and whenever possible, agree with the findings and recommendations.
18. Upon review of the draft report by the Compliance Manager and Corporate Compliance Officer, the Review Team sends the draft report to business owners for review. Dissemination of the draft report should include the Manager and EMG member of the business unit(s) involved in the audit. For those audits involving Operations, also include the SLT member.
19. The Review Team provides up to 7 days for the business owner to review and respond to the draft report. This is the business unit's opportunity to review the report for any errors or misunderstandings that may have been made by the Review Team. The business owner may ask clarifying questions and request changes where errors were made by the Review Team. The Compliance Team has the final decision regarding the content of the report.
20. The Review Team disseminates the final report to:
  - a. Management of the business unit
  - b. The EMG member over the business unit
  - c. For audits involving Operations, include the SLT member
  - d. Corporate Compliance Officer and Compliance Project Coordinator
  - e. All Final Reports will be disseminated to Compliance Committee at the next regularly scheduled meeting.

#### **Phase VIII: Corrective Action Plan**

21. All deficiencies and findings pursuant to a compliance audit will require a corrective action plan in accordance with *POLICY NUMBER C-7: COMPLIANCE INVESTIGATION & CORRECTIVE ACTION PLAN*.
22. All deficiencies and findings, especially those that have a negative member impact, will be assessed to determine whether they need to be disclosed to Federal and/or State regulatory agencies in accordance with the agency's reporting and disclosure protocols.

23. Compliance may conduct follow-up reviews to validate that deficiencies and findings have been remediated satisfactorily and are not likely to reoccur.

## Reporting

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All monitoring and auditing activities are reported to the Compliance Committee, Audit Committee, and applicable members of EMG. Results are also reported via compliance scorecards and other forms of compliance reporting measures. The Board of Directors will receive a summary of the monitoring and auditing activities.

## Measuring Compliance Effectiveness

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The overall effectiveness of the Corporate Compliance Program is measured by the use of performance dashboards, scorecards, metrics reporting, and other similar measures. We measure program effectiveness by parameters such as:

- Results and trends from comprehensive audits
- Results and trends from routine compliance monitoring and quantitative measurement tools in high-risk areas such as FDR/Subcontractor oversight, compliance program effectiveness, enrollment and disenrollment, Part C ODAG, Part D CDAG, Call Center, and Provider Network
- Annual Compliance Program Effectiveness Assessment
- Number of CAPs opened
- CAP Validation Process
- Number of reoccurring CAPs impacting the same issue
- FDR/Subcontractor compliance
- CMS notices of non-compliance, warning letters and sanctions
- Marketing material approval rates
- Number of detected or self-reported issues
- Number of issues disclosed to Federal and/or State regulatory agencies
- Number of disciplinary actions
- Trend analysis over a monthly, quarterly, semi-annual, or annual period
- Compliance training completion and test score results
- Trend in CTM cases
- Self-assessments and surveys

The effectiveness of the Corporate Compliance Program is evaluated frequently, at least annually. The results are reported to Corporate Compliance Committee, Audit & Compliance Committee, and applicable members of EMG. The Board of Directors will also receive a summary of the results.

## FWA Data Analysis

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Corporate Compliance, Pharmacy Services, Provider Network, Claims, and the PBM conduct data analysis through the use of data mining tools to prevent, detect, and correct noncompliance and FWA. We utilize payment integrity tools to detect FWA schemes, algorithms and aberrant patterns and

behaviors at the member and provider level, such as:

- Fraud alerts
- Retrospective DUR claim audits
- Concurrent DUR claim audits
- Member drug abuse audits
- Pharmacy audits

On a quarterly basis, the PBM reviews member, physician, and pharmacy prescriptions and claims for potential FWA issues, such as high quantities of controlled substances, high cost utilization, multiple prescriber utilization, and multiple pharmacy dispensing. Potential FWA found is shared with the Pharmacy Services department. Audited reports reviewed include:

- Medicare Retail Pharmacy Audit Summary Report
- Medicare Audited Claim Detail
- Medicare Part D Top Member Report
- Medicare Part D Top Physician Report
- Medicare Part D Top Member & Physician Report
- Member Multi Pharmacy/Multi Physician Report

Please refer to *Caremark Standard Audit Practice Guidelines, CIG-0222. Caremark Medicare Part D Fraud, Waste, and Abuse Investigations*, and *CIG-0360. Caremark Medicare Part D Compliance OIG and GSA Exclusion Review of FDR/Subcontractors* for additional reference. In addition, we utilize the payment integrity services of Truven Health Analytics to perform data mining on claims, which includes the following:

- Payment analysis
- Drug utilization analysis
- Provider utilization analysis
- Prescribing and referral pattern analysis
- Geographic zip analysis

### Provider Fraud Alert Investigation

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The following procedures are established to review, investigate and analyze provider fraud alerts.

1. On a monthly basis, the Corporate Compliance Department checks the following websites for national fraud issues:
  - a. <http://www.justice.gov/> (Justice News)
  - b. <https://www.fbi.gov/investigate/white-collar-crime/health-care-fraud/health-care-fraud-news>.
  - c. <https://oig.hhs.gov/fraud/enforcement/state/index.asp>
  - d. <https://oig.hhs.gov/fraud/strike-force/>
2. If fraud alerts are issued directly to plans (i.e., through HPMS or CMS), initiate investigation within 1 week of the issuance.

3. When necessary, verify the suspect provider's information, including NPI, through:
  - a. <https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do>
  - b. <http://www.medicare.gov/find-a-doctor/provider-search.aspx>
  - c. <http://www.oig.hhs.gov/exclusions/index.asp>
  - d. Secretary of state website
  - e. State licensing/medical board website
4. Verify the provider's contract status with Provider Network.
  - a. If no match, retain screen print or document "no match" finding and follow Step 8.
  - b. If positive match, document in Step 7
5. Run claim analysis against the following systems:
  - a. Facets (medical), or coordinate investigation with a member of the Claims Department.
  - b. Compass (pharmacy)
6. If no match, retain screen print of "no match" finding and follow Step 8.
7. If positive match:
  - a. Create impact analysis to claim dollar, member, and provider.
  - b. Report all positive match findings to FWA Committee if investigation warrants with recommendation to recover/recoup, suspend/terminate provider, and other appropriate actions.
  - c. The FWA Committee then follows its procedure.
8. Provide monthly summary report to the Corporate Compliance Officer.

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### SIU/Fraud Committee

**Purpose:** The Fraud Committee serves dually as the company's Special Investigation Unit (SIU) and fraud workgroup, and oversees the implementation and enforcement of detected FWA issues stemming from sources such as data mining and claim monitoring and audits. See the FWA Committee Charter for details regarding membership, roles, and responsibilities of the Committee.

**Reporting:** Anyone can report compliance or FWA concerns to any member of the FWA Committee. Anonymous reporting can also be done 24 hours a day/7 days a week to:

EthicsPoint

1-888-265-4068

<https://secure.ethicspoint.com/domain/media/en/gui/16499/index.html>

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### Recovery Unit

See the FWA Process.

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### Coordination with Internal Audit Plan

As part of developing the annual work plans, the Corporate Compliance Department and Internal Audit will coordinate their activities and work plans to ensure that high-risk areas are adequately covered, and that the work plans are administered in a timely and efficient manner throughout the year.

As part of this coordination, the Corporate Compliance Department and Internal Audit will share routine compliance monitoring results, audit findings, and other areas of concern as needed in order to adequately address those issues. Internal Audit will review, audit and verify activities such as process improvements, business efficiency analysis, root cause analysis, internal controls, and any other parameters that may impact the business area's overall performance.

Please refer to the Internal Audit Plan for a detailed description of the Internal Audit Department's auditing principles and protocols.

### **Annual Compliance Program Assessment**

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On an annual basis, PacificSource shall audit the effectiveness of the compliance program through the use of third-party independent auditors or Internal Audit personnel who are not a part of the Corporate Compliance Department. The results shall be reported to the Corporate Compliance Committee and the Audit Committee.

### **References**

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.6)
- Chapter 21: Medicare Managed Care Manual – Compliance Program Guidelines (§50.6)
- 2017 CMS Audit Protocols
- Caremark Standard Audit Practice Guidelines
- CIG-0222. Caremark Medicare Part D Fraud, Waste, and Abuse Investigations
- CIG-0360. Caremark Medicare Part D Compliance OIG and GSA Exclusion Review of FDRs

## POLICY NUMBER C-6A: EXCLUSION & BACKGROUND CHECK

### POLICY

PacificSource shall not hire, contract with, or allow any individual who has been sanctioned or excluded from participating in Medicare or Medicaid programs to work in such programs.

All new and existing employees, board members and officers, and contractors are to immediately disclose to PacificSource any debarment, exclusion or any other event that makes them ineligible to perform work related directly or indirectly to Federal health care programs.

In addition, PacificSource will conduct other background checks prior to an offer of employment, such as criminal records, driving records, and education and professional credentials.

PacificSource will not contract with or pay claims to providers who have been sanctioned or excluded from participating in Medicare or Medicaid programs, or who have opted-out of the Medicare program.

All contracted providers are to immediately disclose to PacificSource any debarment, exclusion or any other event that makes them ineligible to perform work or receive payment for work related directly or indirectly to Federal health care programs.

### PROCEDURE

#### Exclusion List

The OIG's List of Excluded Individuals/Entities (LEIE) and GSA's System for Award Management (SAM) search utilizes the government's database for individuals and businesses excluded or sanctioned from participating in Medicare, Medicaid or other federally funded programs. Bases for exclusions include convictions for program-related fraud and patient abuse, licensing board actions, and default on Health Education Assistance loans. Any applicant, board member or officer appearing on this list will not be considered for employment or appointment.

#### At Time of Hire/Appointment:

**Step 1:** Prior to any offer of employment or appointment, a member of HR will check the OIG LEIE and GSA SAM for all candidates, board members and officers.

**Step 2:** The LEIE search is performed via an internet database, <http://exclusions.oig.hhs.gov/>. The SAM search is performed via <https://www.sam.gov/portal/public/SAM/>. The search is conducted using the first and last name of the applicant. The results are then printed and retained in the individual's confidential personnel file.

- *Match:* If a search of the database results in a match with a name in the database, verify the identity of the individual by entering the social security number.

- Before taking adverse action, HR will provide the applicant a pre-adverse action disclosure that includes a copy of the LEIE match, and a copy of "A Summary of Your rights Under the Fair Credit Reporting Act."
  - Once the decision is made not to hire the applicant, HR will provide the applicant notice that the action has been taken in an adverse action notice.
- *No Match*: If a search of the database results in no name matches, the message will state no record found and the individual's confidential reference file will reflect this.

#### Monthly Review:

Each month, HR will check the LEIE and SAM for all employees, board members and officers to ensure that no existing individuals are on the list.

- *Match*: If any individual is on such list, PacificSource shall require the immediate removal of such individual from any work related directly or indirectly to all Federal health care programs, and may take appropriate corrective actions, up to and including termination of employment or contract.
- *No Match*: The individual's confidential reference file will reflect this.

#### **Other Background Checks**

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HR also conducts other background checks, including criminal records, driving records, and education and professional credentials. For applicants who have adverse background records, HR in collaboration with the hiring supervisor will determine whether the applicant is eligible for employment with PacificSource, based on the specific role and job function, and the nature of the adverse event or record.

#### **Fair Credit Reporting Act (FCRA)**

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The FCRA requires PacificSource to provide specific notice, authorization and adverse action procedures for all background checks. The FCRA is designed primarily to protect the privacy of consumer report information and to guarantee that the information supplied by consumer reporting agencies is as accurate as possible. It ensures that individuals are aware that consumer reports may be used for employment purposes, the individuals agree to such use, and individuals are notified promptly if information obtained may result in a negative employment decision.

#### **Notification**

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All applicants, board members and officers must complete the Background Authorization form that authorizes HR to conduct background checks. If a decision is made not to hire an applicant due to the applicant being listed on the LEIE or SAM, or due to an adverse background record, HR will provide the applicant with a pre-adverse action disclosure that includes a copy of the adverse background record and a copy of "A Summary of Your rights Under the Fair Credit Reporting Act." Once the decision is made not to hire the applicant, HR will provide the applicant notice that the action has been taken in an adverse action notice.



## Provider & FDR/Subcontractor Verification

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Medical Providers: Provider Network checks medical providers against the following data sources at the time of credentialing, monthly, and prior to claim payment to ensure that PacificSource does not contract with or reimburse providers who are ineligible to perform work or receive payment for work related directly or indirectly to Federal health care programs:

1. Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE)
2. General Services Administration (GSA) System for Award Management (SAM)
3. Medicare Exclusion Database (MED)
4. Medicare Opt-Out

Please refer to Provider Network's credentialing and re-credentialing policy for detail.

Any Medicare claims received from providers, including non-contracted providers, will be checked weekly against the 4 data sources. Provider Network will also verify the providers' Medicare eligibility and enrollment status, and Medicare assignment status. Provider Network will rely on sources such as the National Plan and Provider Enumeration System (NPPES) and [www.Medicare.gov](http://www.Medicare.gov) to obtain the NPI, taxonomy and PTAN numbers. If a provider is found to not be eligible for Medicare payment, the claim will not be paid.

Pharmacy Providers: Pharmacy Services, through its PBM, also screens pharmacies and pharmacists against the exclusion list. Please refer to *CIG-0360. Caremark Medicare Part D Compliance OIG and GSA Exclusion Review of FDRs* for a detailed description of this process.

Agents/Brokers: As part of the appointment process, the Sales Department screens agents and brokers against the OIG and GSA list before the agents are allowed to market and sell on behalf of PacificSource. This screening is also conducted monthly for all contracted agents and brokers.

Attestation: On an annual basis, the Corporate Compliance Department will require FDR/Subcontractors performing a core government programs function to attest and certify their compliance with this requirement. The attestation and certification are subject to validation by the Corporate Compliance Department.

## Self-Disclosure

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All covered persons are required to immediately disclose to HR any exclusion or other events that make them ineligible to perform work related directly or indirectly to a government health care program. FDR/Subcontractors are to disclose such information to their PacificSource contract administrator. Failure to disclose may result in appropriate corrective actions, up to and including termination of employment or contract.

## References

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- 42 CFR §422. 204(b)(4), 752(a)(8)
- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.6.8)
- Chapter 21: Medicare Managed Care Manual – Compliance Program Guidelines (§50.6.8)
- CIG-0360. Caremark Medicare Part D Compliance OIG and GSA Exclusion Review of FDRs
- [OIG](#)
- [GSA](#)
- [Medicare Opt-Out](#)
- [NPPES](#)
- CMS Memo: Excluded Providers (June 29, 2011)
- CMS Medicare Exclusion Database (MED) User Manual (Version 1.0)(May 20, 2011)

## POLICY NUMBER C-6B: FDR/SUBCONTRACTOR COMPLIANCE OVERSIGHT

### POLICY

PacificSource, PacificSource Community Health Plans, and PacificSource Community Solutions (collectively, “PacificSource”) are ultimately responsible for actions delegated to first tier, downstream and related (FDR) entities and subcontractors. To that end, PacificSource maintains adequate and effective oversight over the FDR/Subcontractors to ensure that they comply with applicable regulatory requirements. In addition, this policy outlines certain expectations PacificSource requires of its FDR/Subcontractors.

### PROCEDURE

#### Definition

Contract Administrator: The business owner responsible for the implementation, operations, oversight and monitoring, and day-to-day relationship with the FDR/Subcontractor.

Delegated Vendor Oversight Committee (DVOC): Committee whose purpose is to ensure and document that delegated entities are compliant with all applicable laws and regulations and that PacificSource is compliant with regulatory guidelines as it relates to the delegation of core administrative and management functions.

#### FDR/Subcontractor Assessment & Core Services

In determining whether an entity is an FDR/Subcontractor (and thus the function is delegated) for the purpose of exercising compliance and operational oversight over the entity, the Contract Administrator, in conjunction with the Corporate Compliance Department, shall consider the following attributes:

- Whether the entity performs a core service
- Whether the function is a service PacificSource is required to do or provide under its contract with Medicare and Medicaid, applicable federal regulations or guidance
- Whether the function directly impacts enrollees
- Whether the entity has interaction with enrollees
- Whether the entity has access to beneficiary information or personal health information
- Whether the entity has decision-making authority
- Whether the function places the entity in a position to commit health care fraud, waste or abuse
- The risk that the entity could harm enrollees or violate Medicare and/or Medicaid program requirements

Once identified as an FDR/Subcontractor, PacificSource shall exercise oversight over the FDR/Subcontractor who performs a delegated, core service on behalf of PacificSource. A core service is an administrative or health care function related to PacificSource’s Medicare and/or Medicaid contract, and includes such activities as:

- Sales and marketing
- Health care services
- Utilization management
  - Quality improvement
- Enrollment, disenrollment, membership functions
  - Outbound enrollment verification
  - Applications processing
- Claims administration, processing and coverage adjudication
- Generation of claims data
- Pharmacy benefit management
  - Processing of pharmacy claims at the point of sale
  - Administration and tracking of enrollees' drug benefits, including TrOOP balance processing
  - Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs
- Appeals and grievances
- Hotline operations
- Customer service
- Bid preparation
- Provider network management
  - Licensing and credentialing
  - Network adequacy analysis
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs

### Pre-Delegation Assessment

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Prior to delegating a core service to an FDR/Subcontractor, the Corporate Compliance Department and the Contract Administrator shall perform, when appropriate, an FDR/Subcontractor pre-delegation assessment and review. The review will cover topics such as the FDR/Subcontractor's experience in the delegated area, its operational performance, policies and procedures, compliance program infrastructure and adherence, compliance monitoring and auditing, HIPAA Privacy and Security, record retention, reportable metrics, and proof of concept demonstration.

In determining whether to conduct the review, the Corporate Compliance Department and the Contract Administrator shall assess the FDR/Subcontractor's specific functions, the risks associated with the FDR/Subcontractor and functions, and the size and magnitude of the contract.

### Compliance Program Dissemination

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Within **90 days** of contracting, and on an annual basis, the Contract Administrator, working in conjunction with the Corporate Compliance Department, shall distribute PacificSource's Compliance Program and Standards of Conduct to all applicable FDR/Subcontractors. The FDR/Subcontractors may

be required to sign an acknowledgment of receipt of the Corporate Compliance Program.

### **FDR/Subcontractor Compliance Program**

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PacificSource also requires certain high-risk FDR/Subcontractors to maintain its own effective compliance program consisting of the 7 core elements. The Corporate Compliance Department will (based on our risk assessment) review the FDR/Subcontractor's compliance program at the time of contracting, and annually thereafter. PacificSource may require the FDR/Subcontractors to provide signed attestation/certification of their compliance with this requirement, subject to validation for compliance.

### **Federal & State Laws**

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Applicable FDR/Subcontractors must comply with applicable laws and regulations that pertain to government programs, such as HIPAA, Federal False Claims Act, and the Social Security Act. Please see *Policy Number C-1: Compliance with Federal & State Laws* for a detailed list of such laws.

### **Training**

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Applicable FDR/Subcontractors must administer effective training and education to all applicable employees who are responsible for the administration or delivery of a government programs at the time of hire and annually thereafter. Training and education must cover general compliance training, and FWA training. Please see *Policy Number C-3: Compliance Training* for a detailed description of the training requirements.

### **Compliance Investigation & Reporting**

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Applicable FDR/Subcontractors are expected to disclose to PacificSource potential issues of noncompliance and FWA in a timely manner. FDR/Subcontractors are also expected to cooperate with PacificSource in the investigation and resolution of such issues. Upon discovery of an incident or report of a potential noncompliant or FWA issue, the FDR/Subcontractor is expected to initiate a thorough investigation of the incident. Identified deficiencies and instances of noncompliance must be tracked and monitored to ensure that they are remedied and are not likely to reoccur. Please see *Policy Number C-4: Effective Lines of Compliance Communication, Reporting & Non-Retaliation* for a detailed description of the reporting process.

In addition, the FDR/Subcontractor must maintain effective lines of communication within its organization to ensure that its employees understand their obligation to raise compliance issues, and provide a means for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

Lastly, the FDR/Subcontractor must support a non-intimidation and non-retaliation environment that allows individuals to make good faith reports without repercussion or fear of retaliation. Those who retaliate against an individual who makes a good faith effort to report a compliance or FWA issue will be subject to the FDR/Subcontractor's disciplinary actions.

## Disciplinary Standards

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Applicable FDR/Subcontractors must maintain disciplinary standards to ensure that their employees who commit a compliance or FWA violation are subject to disciplinary and corrective actions, up to and including termination.

## Monitoring & Auditing

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PacificSource requires applicable FDR/Subcontractors to conduct self-monitoring and self-auditing of their operational performance, remedy all identified areas of deficiency, and disclose them to PacificSource. In addition, the Contract Administrator is obligated to oversee and routinely monitor the FDR/Subcontractor's work performance and compliance relative to its delegated functions.

The Corporate Compliance Department also routinely monitors and assesses the FDR/Subcontractor's operational performance as it relates to compliance measures. Please see *Policy Number C-6: Compliance Monitoring & Auditing* for a detailed discussion of the monitoring and oversight activities.

## General Oversight

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Performance Metrics: Applicable FDR/Subcontractors are required to provide and report to the Contract Administrator (and the Corporate Compliance Department as appropriate) operational performance metrics that reflect the FDR/Subcontractor's compliance with regulatory and business standards.

Routine Meetings: Applicable FDR/Subcontractors are expected to maintain regular operational or management meetings with the Contract Administrator (and the Corporate Compliance Department when appropriate) to ensure issue resolution, process enhancements, and coordinated communication.

Post-Implementation: On a risk basis, the Corporate Compliance Department may conduct a post-implementation review approximately **60 days** after the initial go-live date. This is done to ensure that the FDR/Subcontractor is performing in accordance with State, Federal and PacificSource standards and business expectations, and that issues are identified and remediated early in the contract relationship.

## References

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§40)
- Chapter 21: Medicare Managed Care Manual – Compliance Program Guidelines (§40)
- Policy Number C-1: Compliance with Federal & State Laws
- Policy Number C-3: Compliance Training
- Policy Number C-4: Effective Lines of Compliance Communication, Reporting & Non-Retaliation
- Policy Number C-6: Compliance Monitoring & Auditing Policy

## POLICY NUMBER C-7: COMPLIANCE INVESTIGATION & CORRECTIVE ACTION PLAN

### POLICY

Upon discovery of an incident or report of a potential noncompliant or fraud, waste and abuse (FWA) issue, the Corporate Compliance Department will initiate a thorough investigation of the incident. All applicable deficiencies and instances of noncompliance are tracked through an investigation form or corrective action plan (CAP) as appropriate to ensure remediation.

#### Applicability

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This policy applies to all applicable PacificSource leased employees, officers, and directors, including applicable contractors and first tier, downstream and related (FDR) entities and subcontractors (hereafter “covered person(s)”).

### PROCEDURE

#### Sources of Incident Reporting

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The Corporate Compliance Department investigates all incidents and reports of noncompliant or FWA issues that may come from formal and informal communication channels. In addition, incidents and reports of noncompliance or FWA issues may also come from various sources, including:

- Regulatory agencies such as CMS, OHA, OIG, NBI MEDIC, DOJ, law enforcement, and state insurance divisions
- National fraud alerts
- Complaint Tracking Module (CTM)
- Prospective claim review
- Retrospective data mining
- Employee reporting
- Member reporting
- First tier, downstream and related entity (FDR/Subcontractor) reporting
- Compliance monitoring/audit findings
- Opt-out & exclusion list screening
- Employer client reporting
- NAVEX Global (formerly EthicsPoint)
- HR exit interviews or questionnaires

To that end, PacificSource maintains these open lines of communication channels and routinely monitors them for reports of potential incidents.

## Investigative Process

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Investigation of all incidents and reports are initiated within **2 weeks** of the date the incident was identified or reported. If a department or individual (other than the Corporate Compliance Department) receives a reported incident, that department or individual is responsible for gathering the relevant facts and referring the matter over to the Corporate Compliance Department when applicable.

Upon initiating an investigation, the issue or incident will be assigned to a member of the Corporate Compliance Team. The applicable team member will complete a Compliance Investigation Form to document the course of action. During the investigation process, the Corporate Compliance Department may utilize any of the following methods:

- Interviews
- Review of process and system
- Review of policies and procedures
- Risk analysis
- Root cause analysis
- Beneficiary, financial, or operational impact analysis
- Validation of sample cases

Cases are resolved as expeditiously as possible depending on the complexity and issue at hand. Complexity is based on factors such as the risks involved, amount of data and facts to be researched and confirmed in order to form a conclusion, clarity of issue and root cause, actions needed to resolve the issue, and the available resources. Every case varies by fact, circumstance, complexity, and resource availability. Thus, it is sometimes not possible to close out a case within a strict and defined timeframe because doing so will compromise the integrity, quality and thoroughness of an investigation. To that end, we adopt a “reasonable” approach to timely resolution of cases.

If a case qualifies as Fraud, Wast or Abuse it will be noted as such and referred to the FWA Staff/Committee for tracking, evaluation and mangement.

## Referral, Disclosure & Coordination with External Agencies

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PacificSource will refer matters over to Federal and State regulatory agencies and law enforcement, including the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC), under certain circumstances, including:



- Incidents it does not investigate due to resource constraints
- Potential criminal, civil, or administrative law violations
- Allegations involving multiple health plans, multiple states, or widespread schemes
- Allegations involving known patterns of fraud
- Pattern of fraud or abuse threatening the life or well-being of beneficiaries
- Scheme with large financial risk to the Medicare and Medicaid program or beneficiaries

The referral will include certain information, if it is available, such as:

- Organization name and contact information
- Summary of the Issue
  - Information on who, what, when, where, how, and why
  - Any potential legal violations
- Specific Statutes and Allegations
  - List of civil, criminal, and administrative code or rule violations, state and federal
  - Detailed description of the allegations or pattern of FWA
- Incidents and Issues
  - List of incidents and issues related to the allegations
- Background information
  - Contact information for the complainant, the perpetrator or subject of the investigation, and beneficiaries, pharmacies, providers, or other entities involved.
  - Names and contact information of informants, relators, witnesses, websites, geographic locations, corporate relationships, networks.
- Perspectives of Interested Parties
  - Perspective of Plan, CMS, beneficiary
- Data
  - Existing and potential data sources
  - Graphs and trending
  - Maps
  - Financial impact estimates
- Recommendations in Pursuing the Case
  - Next steps, special considerations, cautions

When possible, cases to the NBI MEDIC are referred within the timeframe given or if not specified, within **30 days** of the date the incident was identified or reported.

**NBI MEDIC:**

Attn: NBI MEDIC  
 28464 Marlboro Avenue  
 Easton, MD 21601-2732  
 Phone: 1-877-7SAFERX (1-877-772-3379),  
 Fax: (410) 819-8698  
 Email: [NBIMEDICCompliance@healthintegrity.org](mailto:NBIMEDICCompliance@healthintegrity.org)

To ensure compliance with all applicable laws, do not send Protected Health Information (PHI) via email.

<http://www.healthintegrity.org/contracts/nbi-medic/referring-fraud-waste-or-abuse-cases.html>

[http://www.healthintegrity.org/contracts/nbi-medic/documents/NBI\\_Contract\\_HI\\_MEDIC\\_ComplaintForm\\_20160212.pdf](http://www.healthintegrity.org/contracts/nbi-medic/documents/NBI_Contract_HI_MEDIC_ComplaintForm_20160212.pdf)

PacificSource will provide additional information pursuant to the MEDIC's request within **30 days**, or within a timeframe required by the MEDIC. The Corporate Compliance Department may also disclose incidents of significant or serious compliance and FWA violations to CMS, the NBI MEDIC, the OIG, and the Department of Justice when appropriate and warranted.

In addition, the Corporate Compliance Department will refer, report and coordinate with State Medicaid Fraud Control Units (MFCU) on issues impacting Medicaid. PacificSource shall refer member and provider fraud cases, including those referred by the member or provider, to the following agencies:

**General:** <https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/index.asp>  
<https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/files/contact-directors.pdf>

**Oregon:** Medicaid Fraud Control Unit (MFCU)  
Oregon Department of Justice  
100 SW Market Street  
Portland, OR 97201  
Phone: 971-673-1880  
Fax: 971-673-1890  
<https://www.doj.state.or.us/>

OHA Fraud Investigation  
PO Box 14150  
Salem, OR 97309  
Hotline: 1-888-FRAUD01 (888-372-8301)  
Fax: 503-373-1525 Attn: Hotline

OHA Provider Audit Unit  
3406 Cherry Ave. NE  
Salem, OR 97303-4924  
Phone: 503-378-8113  
Fax: 503-378-2577  
Hotline: 1-888-FRAUD01 (888-372-8301)  
<https://www.doj.state.or.us/consumer-protection/sales-scams-fraud/medicaid-fraud/>

If PacificSource is aware that there are credible allegations of fraud for which an investigation by MFCU is pending against a provider, PacificSource shall suspend payments to the provider unless OHA determines there is good cause not to suspend payments or to suspend payments in part. If the act does not meet the good cause criteria, PacificSource shall work with the MFCU to determine if any participating provider contract should be terminated.

### **Fraud Alerts**

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Upon receipt of a fraud alert from CMS, OIG, the MEDIC, or any State and Federal government agency, the Corporate Compliance Department shall investigate the matter, analyze the claim system for potential impact, and deny, reverse and recoup impacted claims based on internal analysis. Compliance will work with Pharmacy Services and the PBM to identify potential fraudulent claims and correct PDE data submissions.

Provider Network, working in conjunction with the Corporate Compliance Department, shall review the contractual agreements with the identified providers and may initiate termination if law enforcement has issued indictments against those providers.

### **Coordination with Human Resources**

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For issues that have an impact on personnel matters, Human Resources will be engaged appropriately to handle compliance or FWA issues that impact such personnel matters.

### **Documentation & Provider File Maintenance**

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The Corporate Compliance Department will retain documentation of investigations, including the original documentation of reports of noncompliance and FWA violations. The Corporate Compliance Department will retain investigative documents on providers who were the focus of an internal investigation. In addition, we will also maintain files on applicable providers who have been the subject of complaints, investigations, violations, and prosecutions stemming from enrollee complaints, fraud alerts, NBI MEDIC investigations, OIG and/or DOJ investigations, US Attorney prosecution, and any other civil, criminal, or administrative action for violations of Federal health care program requirements.

PacificSource shall permit CMS, the MFCU or OHA or both to inspect, evaluate, or audit books, records, documents, files, accounts, and facilities maintained by or on behalf of PacificSource or by or on behalf of any FDR/Subcontractor, as required to investigate an incident of fraud and abuse.

PacificSource shall cooperate, and requires its FDR/Subcontractor to cooperate, with CMS, the MFCU and OHA investigator during any investigation of fraud or abuse.

In the event that PacificSource reports suspected fraud or abuse by an FDR/Subcontractor, or learns of a CMS, MFCU or OHA investigation of an FDR/Subcontractor, PacificSource should not notify or otherwise advise it's FDR/Subcontractor of the investigation. Doing so may compromise the investigation.

PacificSource shall provide copies of reports or other documentation, including those requested from the FDR/Subcontractor regarding the suspected fraud or abuse at no cost to CMS, MFCU or OHA during an investigation.

## **Investigative Findings**

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At the conclusion of the investigation into the incident, the Compliance investigator will document the findings. All investigations, regardless of outcome, will be documented on the Compliance SharePoint site within either the Internal Monitoring and Auditing list or the FWA list so that it will be reportable should it be requested during a CMS Program Audit. A description of any needed corrective action as a result of an investigation is documented here as well. If it is determined that corrective action cannot be completed immediately, but will require a period of time for implementation, a corrective action plan (CAP) will be entered into the CAP tracking tool on SharePoint and will be tracked until implementation is complete.

## **Corrective Action Plan (CAP)**

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CAPs are generated due to deficiencies and incidents of noncompliance, and may arise from various sources, including:

- Routine monitoring and oversight
- Internal audits
- External audits
- Investigations
- Self-disclosures
- Reporting
- Regulatory agency initiatives

Upon discovery of a potential compliance or FWA issue, the Corporate Compliance Department will initiate an investigation into the matter. Compliance will then determine whether the issue warrants corrective action.

Corrective actions can range from simple to complex in nature. Simple corrective actions are those that can be implemented promptly and typically don't require additional testing or validation. Examples of simple corrective actions include:

- Sending a reminder about a process step to a particular staff member
- Making a small revision to a documented policy or procedure

More complex corrective actions typically require some time and resources to implement. Complex corrective actions also require testing and validation to ensure the actions implemented corrected the original problem. Examples of complex corrective actions include:

- Reprogramming a core operational system

- Implementing a new process that will require intensive training to multiple individuals and/or a full operational team.

Simple corrective actions do not typically require formal tracking and validation. Any corrective action taken will be documented within the original investigation notes or final audit report.

Complex corrective actions will be logged within the CAP database so that they can be appropriately tracked until all findings are fully resolved and not likely to reoccur.

Considerations for logging a CAP in the database for tracking and validation include, but are not limited to:

- Complexity of the action needed to correct the issue
- Amount of time and resources needed to correct the issue
- Whether or not the issue warranted a self-disclosure to either CMS or OHA
- Nature of violation
- History of violation or recurrence
- Risk to beneficiary access to care and protection
- Risk of government sanctions, fines, and corrective actions
- Likelihood of recurrence
- Root cause (i.e., manual/human error, process/systemic problem)

## CAP Creation

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If a CAP is determine to be complex, the Corporate Compliance Department will enter all relevant information into the CAP Database. The CAP will then follow the following process:

1. Each CAP will have an assigned business owner. The person assigned to the CAP is typically the person with the most overall ownership of the impacted process, even if the root cause may have occurred downstream in a supporting area. In most cases, Compliance will assign a single business owner to a CAP. The assigned business owner will be responsible for collaborating with other business owners in other areas that have a role in the overall process. In limited circumstances, Compliance may assign more than one business owner if the need arises.
2. Corporate Compliance will notify business owners of the opening of a CAP by sending an email with a link to the SharePoint site and a partially-complete CAP form. Once the CAP form is initiated by Corporate Compliance, business owners must investigate the errors or deficiencies and notify Compliance so that the remaining sections of the CAP form can be completed within the following timeframes:
  - a. **7 days** from receiving the CAP form from Corporate Compliance. This standard timeframe applies to most issues.
  - b. **30 days** from receiving the CAP form from Corporate Compliance. This exceptional timeframe applies only to a small number of highly complex issues, and must only be used on a limited basis, such as:
    - i. When the resolution is highly complex or unknown and will require additional time to investigate.

- ii. When the resolution is co-dependent on substantial resource allocation, or system/software enhancement or purchase and will require additional time to investigate.
- iii. When there are other good business rationales.

The business owner will be largely responsible for completing the Interim Activities and Corrective Action Plan sections of the form. By the form due date, these sections, and any other sections requiring business owner input, should be completed. This allows Corporate Compliance to ensure that the root cause of the non-compliance will be addressed and that the corrective action is appropriate.

- 3. Corporate Compliance may log multiple Corrective Actions if numerous deficiencies are found within the same business area. When possible, Corporate Compliance will combine issues into one CAP form. However, for clarity, tracking and documentation purposes multiple CAP forms may be needed.
- 4. The CAP is sent electronically to the business owner of the affected area, and may also be distributed to the associated supervisor, manager and/or executive. This electronic communication will contain a link to the SharePoint site and CAP form.
- 5. Once the CAP form is completed, it is then reviewed by the compliance owner for appropriateness and completeness of the proposed corrective actions and timelines. If any adjustments to the CAP are required, the Corporate Compliance owner will discuss the issue(s) with the business owner(s) and reach agreement on appropriate corrective action. If the CAP form is not completed timely, follow-up requests will be made to management of the affected area. All follow-up attempts for information will be documented by the Corporate Compliance owner within the comments section of the CAP form. If the CAP form is not complete, the CAP will be reported as at risk as described in the reporting section below.

### CAP Timelines

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The standard timeline for issue resolution of a complex CAP will default to **30 days**. However, there may be operational and other circumstances which will require longer timelines. It is up to the business owners to designate an appropriate timeline (that may exceed 30 days to resolve) at the time the complex CAP is logged. Timelines that exceed **90 days** will be subject to greater scrutiny and will be reported to the Corporate Compliance Committee as a potential risk. In determining the appropriate timeline, the business owners must make a good faith effort to calculate a reasonable, achievable and realistic timeline to resolve the CAP based on objective criteria. Corporate Compliance will work with the business owners on a mutually-acceptable, achievable and realistic timeframe while being mindful of the potential risks and urgencies created by the non-compliance.

In situations where highly complex CAPs will require a significant timeframe to fully resolve, such as purchase of new software or substantial reprogramming of existing systems, the expectation is that an

acceptable interim process will be put into place that will bring the current finding into compliance.

### CAP Timeline Revision

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The original timeline may be revised after the CAP has been opened for good cause. Examples of good cause may include:

- The resolution becomes more apparent in complexity or impact during the CAP process, and this was not foreseeable when the CAP was first opened.
- Resource, staff or system constraints that were not foreseeable when the CAP was first opened.
- Other good business rationale.

Requests to revise the CAP timeline must be made before the original CAP timeline expires. The CAP timeline will not be revised for the following reasons:

- Lack of good faith due diligence in resolving the CAP during the original timeline.
- Inadequate administration of resource or timing to resolve the CAP.

Revising the original CAP timeline has the effect of keeping the CAP at *On Track* status.

### CAP Extension

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Business owners may request an extension to a CAP. An extension differs from a revised timeline in that an extension provides a short-term period to resolve minor, low risk issues that may prevent the CAP from being resolved in its entirety, while a revised timeline is a long-term period that is needed to resolve the fundamental essence of the CAP.

Business owners may request an extension for good cause. Examples of good cause may include:

- Minor resource, staffing or system issues that prevent the CAP from being closed in its entirety.
- Other good business rationale.

Requests for extension must be made before the CAP timeline expires. Extensions will not be made for the following reasons:

- Lack of due diligence in resolving the CAP during the original timeline.

An extension has the effect of keeping the CAP at *On Track-Extension* status. All requests for CAP Timeline Revisions and CAP Extensions must be documented in the actual CAP status and comments section.

### CAP Tracking

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Corporate Compliance will track the CAP progression on a continuous basis. CAPs are tracked based on Stage and Status:

**Stage:** This tracks where the CAP is in its lifecycle:

- **Stage 1 [Corrective Action in Progress]:** The issue is currently being worked on to be resolved.
- **Stage 2 [Issue Resolved/Validation]:** The issue is resolved from an operational perspective. While the issue may be resolved, the CAP may still be open pending validation. The issue is being validated to confirm that it has been resolved. Depending on risk, some issues require validation before it can be closed, through monitoring or auditing.
- **Stage 3 [Closed]:** The CAP is fully resolved and is closed.

**Status:** This tracks where the CAP is in its deadline:

- **On Track:** The CAP is on-track to be resolved timely based on its original deadline.
- **On Track-Extension [number of extensions taken]:** The CAP is on-track to be resolved timely based on its extended deadline. The status will show the number of extensions taken on the CAP.
- **Late:** The CAP is in late status. Late status will be applied when the CAP is past its set deadline and there are no agreed upon extensions in place.
- **At risk:** This indicates that the CAP will likely not meet the resolution deadline due to lack of form completion, business owner attention or other circumstances.

Compliance will work with business owners to update the CAP as issues are resolved. The SharePoint system will generate due date reminders 7, 3 and 1 day prior to the resolution due date. These reminders will be sent to the business owner, the applicable EMG member, and the compliance owner. Once the plan has been effectuated, all errors and deficiencies addressed, and validation (if applicable) is successful, the CAP form will be marked as completed and closed.

### CAP Escalation

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CAPs that are untimely and in *Late* status will be escalated to the next level of management, including the EMG member overseeing the business area. Untimely and high-risk *Late* CAPs will also be escalated and reported to the Corporate Compliance Committee. Failure to resolve a CAP timely and in its entirety may result in disciplinary action up to and including termination or dismissal of the responsible party, or termination of contract.

### CAP Reporting

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The Corporate Compliance Officer will report to the Corporate Compliance Committee relevant open and closed CAPs that were initiated within the last 30 days. Special emphasis will be given to those CAPs that are in *On Track-Extension*, *At Risk* or *Late* status.

### CAP Closure

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If it is determined that the issue has been remediated, the Corporate Compliance Department will close out a CAP. Prior to closing a CAP, we will analyze the CAP against the 7 elements of an effective compliance program as appropriate:



- **Element 1:** We will assess whether operational and compliance policies and procedures existed before the issue occurred, and whether they have been created or revised to address the issue.
  - The revised operational and compliance policy will be uploaded to the CAP database. An acceptable rationale must be provided if no revision was made.
- **Element II:** We will report high-risk CAPs to the Corporate Compliance Committee and Audit Committee as appropriate.
  - For each committee, documentation is maintained separately in its respective SharePoint documentation folder.
  - All issues are presented to the Corporate Compliance Committee.
  - Recognizing that the Audit Committee and the Board of Directors function at a higher level, if the issue is not reported to them (such as due to low risk or low impact), an acceptable rationale must be documented.
  - Directives and follow-up instructions from the Board of Directors or Audit Committee related to the issue are documented in their respective minutes.
- **Element III:** We will require business owners to conduct operational training and education with staff on any new processes. An acceptable rationale must be provided if no training was conducted.
- **Element IV:** Evidence of communication may be emails from the Corporate Compliance Officer/Department to business owners, and issues log and final audit report dissemination.
- **Element V:** We will assess whether the business owner took disciplinary actions against personnel due to the CAP. An acceptable rationale must be provided if such actions did not occur.
- **Element VI:** We will conduct a risk assessment of the issue to determine what level of validation (monitoring/auditing) is needed before closing out a CAP:
  - *Low/Moderate Risk:* The CAP has marginal impact on members or compliance. The CAP can be closed without documentation of routine monitoring.
  - *Moderate/High Risk:* The CAP has significant member or compliance impact, or is a repeat finding, and requires documentation of routine monitoring and auditing before it can be closed.

If the issue was not previously identified in our initial risk assessment (and thus not incorporated into the compliance work plan), the CAP will document a new risk assessment to determine if it needs to be incorporated into the compliance work plan as a new addition.

- **Element VII:** The actual CAP articulates the prompt response to compliance issues. The CAP documents the following:
  - Root cause analysis.
  - Corrective actions taken.
  - Timeline of corrective actions.

Documentation and rationale for each element will be documented in the actual CAP database under their respective element data fields. If an element does not apply, or an activity was not performed in support of the element, the rationale will be noted in the element data field. With the exception of Element II, a CAP cannot be closed until all elements have been assessed. Due to timing, issues may be reported to the Corporate Compliance Committee and Audit & Compliance Committee at a later date.

If an issue has a negative member impact, the member shall be made whole when appropriate. If the issue has a negative impact to CMS, OHA, or a State or Federal regulatory agency, those entities shall be made whole when appropriate.

Violations that stem from an employee or FDR/Subcontractor's failure shall be handled in accordance with the disciplinary guidelines and enforcement standards.

### **Ongoing Monitoring & Auditing**

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Depending on the nature, extent and risk of the issue, the Corporate Compliance Department may conduct, or require business owners to conduct, ongoing monitoring reviews to measure the effectiveness of the resolution and to ensure that the issue is not likely to reoccur.

### **References**

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- Chapter 9: Prescription Drug Benefit Manual-Compliance Program Guidelines (§50.1.6, 50.7)
- Chapter 21: Medicare Managed Care Manual - Compliance Program Guidelines (§50.1.6, 50.7)
- Corporate Compliance CAP Database (Sharepoint Site)
- [OIG Self-Disclosure Policy](#)
- Appendix I