

IEHP SUBCONTRACTOR MANUAL POLICY

Compliance Program Requirements

Introduction

- A. Inland Empire Health Plan (IEHP) is committed to conducting its business in an honest and ethical manner and in compliance with the law. IEHP, with the leadership and guidance from its Compliance Department, established and implemented a Compliance Program that promotes a culture of ethics, integrity and quality service. The Compliance Program Description sets forth the principles, policies, and procedures for how IEHP Team Members, Governing Board Members, as well as Subcontractors are required to conduct business and themselves. IEHP's Compliance Program is built upon and implemented in accordance with applicable Federal and State laws, regulations, and guidelines, including those set forth by the Federal Sentencing Guidelines (FSG) and the Office of Inspector General (OIG) Seven Elements of an Effective Compliance Program. This Compliance Program Description sets forth the requirements in which IEHP expects Subcontractors to develop their Compliance Programs.

Compliance Program Scope

- A. Subcontractors must adopt and implement an effective Compliance Program to provide a systematic process dedicated to ensuring that management, employees, business associates, subcontractors, and other associated individuals and entities comply with applicable healthcare laws, Federal and State requirements, and all applicable regulations and standards.^{1,2,3,4,5} Subcontractors must have a compliance plan that includes, at a minimum, the following:
1. Outlines the key elements of the compliance program;
 2. Includes reference to the standards of conduct or code of conduct (herein referred to as Code of Conduct), policies and procedures to support and sustain compliance program objectives;
 3. Allows the compliance program to act independently of operational and program areas without fear of repercussions for uncovering deficiencies or noncompliance;
 4. Details how it will implement and maintain elements of the compliance program;
 5. Includes the compliance reporting structure and positions of key personnel involved in ensuring compliance, including the compliance officer;
 6. References policies and procedures operationalizing the compliance program
 7. Is overseen by the Board and senior management levels;
 8. Is reviewed and approved by the Compliance Committee routinely, but not less than annually;
 9. Processes to report the outcomes of compliance activities to the Board, senior management, and IEHP (as required by policy and/or contract);
 10. Preventive practices to identify potential compliance issues and to implement actions that lower or mitigate risk; and Processes to evaluate the effectiveness of the compliance program on an annual basis.

¹ Medicare Managed Care Manual, Chapter 21 Compliance Program Guidelines

² Prescription Drug Benefit Manual, Chapter 9 Compliance Program Guidelines

³ 42 Code of Federal Regulations (C.F.R.) § 422.503 (b)(4)(vi)

⁴ 42 C.F.R. § 438.608

⁵ Centers for Medicare and Medicaid Services, Policy CMS 4182 Final Rule

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Written Standards/Codes of Conduct, Policies, and Procedures

- A. Code of Conduct –Subcontractors are required to implement a Code of Conduct (the Code) that demonstrates their commitment to compliance and articulates the core values and principles that guide the organization’s business practices and ensures that compliance with all Federal and State laws is the responsibility of all employees. The Code must be distributed to Employees (temporary and permanent), Providers, contractors, Board Members, and Volunteers at the time of hire or start and annually thereafter.
 - 1. The Code can be communicated by various methods, including:
 - a. Provided to new employees in the employee handbook upon initial employment.
 - b. Discussed and distributed during Compliance New Hire and Annual Training.
 - 2. Employees, contractors, volunteers are required to acknowledge their understanding of the Code of Conduct and their commitment to comply with its intent within 90 days of hire or start and annually thereafter.
 - 3. Subcontractors must also provide the Code of Conduct to their business associates and downstream subcontractors, that address their obligations toward conducting business at the highest level of moral, ethical, and legal standards.
 - 4. The Code of Conduct must include reporting requirements for compliance or FWA issues and concerns.
 - 5. The Code of Conduct must be approved by the Board annually.
- B. Policies and Procedures –Subcontractors should develop Policies and Procedures that:
 - 1. Detail how the compliance program is operationalized, including persons responsible for specific activities;
 - 2. Address their commitment to complying with all Federal and State standards;
 - 3. Provide direction on dealing with and reporting suspected or detected, compliance issues;
 - 4. Include a policy of non-intimidation and non-retaliation for good faith efforts to report potential compliance issues or concerns; and
 - 5. Detail how policies and procedures are reviewed on an annual basis, or more often to incorporate changes in applicable laws, regulations, or other program requirements, including how changes are disseminated to impacted operational areas.

Compliance Officer, Compliance Committee, and High-Level Oversight

- A. Compliance Officer – Subcontractors must designate a compliance officer who is an employee of the Subcontractor or the Management Services Organization (MSO) acting on behalf of the Subcontractor and reports directly to the highest level of the organization. The compliance officer must be a full-time employee and must be independent of serving in an operational role. The compliance officer must be responsible for:
 - 1. Developing, implementing, and ensuring compliance with regulatory and contractual requirements;

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2. Advising the organization and downstream subcontractors on policy requirements and the development, distribution, and implementation of policies;
3. Ensuring that policies are reviewed in accordance with the compliance plan and accurately and effectively communicate compliance and regulatory requirements;
4. Notifying Senior Management and of compliance issues;
5. Providing updates on the Compliance Program to the Board, which includes at a minimum:
 - a. Policy updates;
 - b. Issues of Non-Compliance; Fraud, Waste, and Abuse detection, monitoring, and reporting; and
 - c. Auditing and monitoring updates and outcomes.

B. Compliance Committee

1. Subcontractors must implement a Compliance Committee (Committee) that is accountable to senior management and the Board. The Committee must be a multidisciplinary body supports the Compliance Officer in the implementation of the Compliance Program. The Compliance Officer chairs the meeting. The Committee's membership must be comprised of individuals with a variety of backgrounds and reflect the size and scope of the delegate. Members of the Committee should have decision-making authority in their respective areas of expertise.^{6,7}
2. Duties of the Compliance Committee may include, but are not limited to:
 - a. Oversee the Compliance Program and compliance with regulatory and contractual requirements
 - b. Review the Compliance Plan on an annual basis;
 - c. Meet at least quarterly to oversee the Compliance Program;
 - d. Provide updates on the outcomes of compliance program activities to senior management, if members of senior management are not committee members; and
 - e. Review and address areas in which the Subcontractor is at risk of non-compliance or potential Fraud, Waste and Abuse (FWA), ensure the implementation of corrective actions, and monitor their development and effectiveness;
 - f. Review the results of the annual risk assessment;
 - g. Review the outcome of compliance activities;
 - h. Provide regular reports on the outcome of the Committee's activities to the Subcontractor's Board.

C. High Level Oversight – The Subcontractor's Board must exercise reasonable oversight with respect to the implementation and effectiveness of the Subcontractor's compliance program. The Board may delegate compliance program oversight to a compliance-based committee, however remains accountable for reviewing the status of the compliance program. The scope of the delegation from

⁶ 42 C.F.R. § 422.503(b)(4)(vi)(B)

⁷ 42 C.F.R. §423.504(b)(4)(vi)(B)

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the full Board to the a committee must be clear in the committee's charter or Subcontractors policies. The Board should:

1. Be knowledgeable about compliance risks and strategies;
2. Understand the measurements of outcome and be able to gauge effectiveness of the compliance program; and
3. Understand regulatory and/or contract changes, policy changes, health reform and the impact on the Subcontractor's compliance program.

Effective Training and Education

- A. Subcontractors must provide compliance program and FWA training and education to all Employees (Temporary and Permanent), Providers, Board members, contractors, vendors, and volunteers.
 1. Training must be provided within 90 days of hire or start, and annually thereafter. Training should be reviewed and updates when significant changes are made to the compliance program, upon changes in regulatory or contractual requirements related to specific job responsibilities, or when legislative updates occur, and at least on an annual basis.
 2. Subcontractor's may use a written test or develop other mechanisms to assess the effectiveness of the training.
 3. Subcontractors may also meet their FWA training requirements in the following way:
 - a. Adopt IEHP's General Compliance, FWA, and HIPAA Privacy & Security training; or
 - b. Incorporation of the content of the CMS standardized training modules related to General Compliance, FWA, and HIPAA Privacy & Security into the Subcontractor's existing compliance training materials/systems; or
 - c. Utilize the Health Industry Collaboration Effort (HICE) Fraud, Waste, and Abuse (FWA) training as an acceptable mode of completing the FWA requirement. See HICE FWA training for more information.⁸
 4. Subcontractors must be able to demonstrate that training requirements have been fulfilled. Documentation of education/training activities must be retained for a period of 10 years. Documentation may include sign-in forms, signed attestations, and the completion of testing results.
 5. Subcontractors must ensure that training information and requirements are communicated to downstream subcontractors.
 6. Training must include, at a minimum:
 - a. A description of the compliance program, including review of compliance policies and procedures and the Code of Conduct;
 - b. Emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;

⁸ [HICE Health Care Fraud, Waste and Abuse Training](#)

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- c. Review of the disciplinary guidelines for non-compliant or fraudulent behavior;
- d. Reinforcement of the organization's commitment to compliance.
- e. Laws and regulations related to FWA (i.e., False Claims Act, Anti-Kickback statute, etc.) Training should also include examples of FWA issues as well as regulatory updates, and recent healthcare compliance-related adverse actions such as penalties and settlements.
- f. Processes to report suspected FWA to the Subcontractor's compliance reporting mechanisms;
- g. HIPAA Privacy and Security and the Health Information Technology for Economic and Clinical Health (HITECH) Act regulations.
- h. Changes in compliance and regulatory requirements and updates on the consequences of non-compliance with these requirements.
- i. Responsibilities to report concerns, misconduct, or activities related to non-compliance.

Effective Lines of Communication

- A. IEHP has established effective lines of communication, that ensure confidentiality between the compliance officer, the compliance committee, employees, management, the Board, Subcontractors. The lines of communication are accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues. Subcontractors are required to report, and train their employees on reporting compliance concerns and suspected or actual violations as they're identified. The following reporting mechanisms are available to all, including Subcontractors and their employee:
 - 1. Compliance Hotline: (866) 355-9038, available 24 hours a day;
 - 2. E-mail: compliance@iehp.org;
 - 3. Secure Fax: (909) 477-8536; or
 - 4. Mail: Compliance Officer, PO Box 1800, Rancho Cucamonga, CA 91729.
- B. Subcontractors who have established their own system to receive reports of suspected or detected noncompliance or potential FWA must ensure the system:
 - 1. Records, responds to, and tracks reports;
 - 2. Maintains confidentiality (to the greatest extent possible), allow anonymity, and includes a policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the compliance program; and
 - 3. Ensures compliance concerns and suspected or actual violations are reported to IEHP in accordance with section A above.
- C. Subcontractors must adopt, widely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee or downstream subcontractor who in good faith reports suspected FWA. Employees and downstream subcontractors must be notified that they are protected from retaliation for False Claims Act complaints, as well as any other applicable anti-retaliation protections.

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- D. IEHP maintains a non-intimidation, non-retaliation policy for good faith reporting of compliance concerns and participation in the compliance program, including any investigation that may occur.

Well Publicized Disciplinary Standards

- A. Subcontractors must develop and implement disciplinary policies that reflect the organization's expectations for reporting compliance issues including non-compliant, unethical, or illegal behavior.
- B. Policies should provide for timely, consistent, and effective enforcement of established standards when non-compliance issues are identified.
- C. Disciplinary standards should be appropriate to the seriousness of the violation.

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

- A. Subcontractors must develop and maintain effective systems for routine monitoring and auditing, and identification of compliance risks, including but not limited to:
 - 1. Processes to conduct routine internal monitoring and auditing of compliance risks;
 - 2. Methods and tools for assessing whether the Subcontractor's activities required under its contract comply with Federal and State law, and contractual requirements. This includes having methods and tools to evaluate and trend an activity over time to assess noncompliance;
 - 3. Routine and periodic reporting of internal monitoring and auditing activities and results to the compliance officer and the compliance committee;
 - 4. Unannounced audits of downstream subcontractors to assess compliance with requirements relevant to their delegated function;
 - 5. The monitoring and auditing processes must be documented to show subject, method, and frequency; and
 - 6. Develop a monitoring and auditing work plan that addresses compliance risks.
- B. Subcontractors must establish and implement policies and procedures to conduct a formal risk assessment of their major compliance and FWA risk areas. Each operational area must be assessed for the types and levels of risks the area presents to Subcontractor's delegated function. The results of the risk assessment inform the development of the monitoring and audit work plan.
- C. IEHP utilizes both internal and external resources to conduct IEHP's audit program. IEHP expects that the individual or Subcontractor responsible for the audit content to cooperate with the audit process by providing access to documents and other information requested.
 - 1. Methods of review include, but are not limited to:
 - a. Provider/Contractor initial contract and annual Delegation Oversight Audits;
 - b. Quarterly Reporting;
 - c. External reviews of medical and financial records that support claims for reimbursement and Medicare cost reports; and
 - d. Trend analysis and studies that identify deviations in specific areas over a given period.

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- D. IEHP maintains the authority to conduct on-site audits and inspections, which can be announced or unannounced at the physical location of Subcontractors, for review of any Subcontractors' delegated function(s). Subcontractors must provide prompt and diligent cooperation, attention, and assistance, as reasonably necessary for IEHP to review and determine Subcontractor's compliance with applicable requirements including IEHP's Provider Manual.
- E. Subcontractors must implement process to verify employees, Board members, contractors, and business partners are eligible to participate in Federal and State healthcare programs. The process must include, but is not limited to:
 - 1. Prior to hiring or contracting and monthly thereafter, a review of the following lists:
 - a. Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE);^{9,10}
 - b. General Services Administration (GSA) System for Award Management (SAM);¹¹
 - c. Department of Health Care Services Medi-Cal Suspended and Ineligible Provider List;¹²
 - d. Department of Health Care Services Restricted Provider Database; and
 - e. CMS Preclusion List, as applicable.
 - 2. Criminal record checks when appropriate or as required by law.
 - 3. Reporting results to compliance committee, the Board, and IEHP as necessary.

Procedures and System for Prompt Response to Compliance Issues

- A. Subcontractors must develop and maintain effective systems for prompt response to compliance issues as they are raised or identified, and correction of such issues promptly and thoroughly to reduce the potential for recurrent and ongoing compliance. This includes policies and procedures for constructing and implementing effective Corrective Action plans, including root cause analysis and tailoring Corrective Action plans to address specific compliance concerns. Follow-up auditing and/or monitoring is conducted to assess the effectiveness of these processes.
- B. Subcontractors must develop and implement a system for reporting and prompt response to non-compliance and detected offenses.
 - 1. When potential and/or actual non-compliance is reported or suspected, the following steps should be taken:
 - a. The activity causing the non-compliance should be promptly halted and/or mitigated to the extent possible to prevent harm to individuals, entities, and/or IEHP.
 - b. Investigations should be promptly initiated in accordance with the Fraud, Waste, and Abuse Plan; the HIPAA Plan, the Compliance Plan, and/or in consultation with the IEHP Special Investigations Unit (SIU) or the Compliance Officer.
 - c. The implementation of Corrective Action Plans (CAP) should be based on the policy guidance that address the issue of non-compliance, as appropriate. These may include, but are not limited to:

9 42 United States Code (U.S.C.) § 1320a-7

10 42 C.F.R. § 1001.1901

11 Federal Acquisition Regulation (FAR) Subpart 9.4

12 Welfare and Institutions Code (W&I Code) §§ 14043.6 and 14123

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- 1) Initiation of corrective action plans and/or agreements.
 - 2) Repayment of identified overpayments.
 - 3) Initiation of Task Forces to address process and/or system deficiencies that may have caused or contributed to the non-compliance.
 - 4) Additional education and training.
 - 5) Modification of policies and procedures.
 - 6) Discipline or termination of Employees or contracts.
- d. Preventive measures should be implemented to avoid similar non-compliance in the future, including monitoring of corrective action plans.
- 1) Investigations may consist of an informal inquiry or involve formal steps such as interviews and document collection, depending on the circumstances involved.
 - 2) Investigations should be conducted in consultation with the Compliance Officer who has the final authority to determine this process.
 - 3) External investigations should be performed by the Special Investigation Unit (SIU) Team or related unit. Referrals to legal counsel and/or other external experts should be utilized as deemed appropriate by the Compliance Officer.
 - 4) The timeliness and progress of the investigation should be documented by the SIU Team or related unit.
 - 5) Documents and evidence obtained during investigations should be retained for a period of no less than 10 years.
- e. Reporting of these activities and their results should be provided to:
- 1) The Compliance Officer;
 - 2) The Compliance Committee;
 - 3) Chief Executive Officer;
 - 4) The Governing Body, if the Compliance Officer in consultation with the Chief Executive Officer deems there is a significant non-compliance finding;
 - 5) Governmental authorities, as determined by the Compliance Officer, if there is an obligation to report misconduct that violates criminal, civil, or administrative law within a reasonable time of discovery;
 - 6) Responses to government inquiries and investigations should be coordinated by the Compliance Officer; and
 - 7) IEHP Compliance Department.

Assessment of Compliance Effectiveness

- A. On an annual basis, Subcontractors must conduct a review of the compliance program to ensure the Program is effective in meeting applicable State and Federal regulations and preventing Fraud, Waste, and Abuse (FWA). The assessment should include, but is not limited to:
1. Written Policies and Procedures and Standards of Conduct.

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2. Designation of a Compliance Officer and High-Level Oversight.
3. Effective Lines of Communication.
4. Well Publicized Disciplinary Standards.
5. Ongoing Education and Training.
6. Effective System for Routing Auditing, Monitoring, and Identification of Compliance Risks;
and
7. Reporting and Prompt Response for Non-Compliance, Potential FWA, and Detected Offenses.

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