IEHP VENDOR FDR MANUAL POLICY
Compliance Program Requirements

Introduction

IEHP is committed to conducting its business in an honest and ethical manner and in compliance with the law. IEHP has established and implemented a Compliance Program to promote our culture of ethical conduct and compliance. The Compliance Program Description sets forth the principles, policies, and procedures for how IEHP Team Members, Governing Board Members, as well as subcontracted entities (First Tier, Downstream, and Related Entities (FDRs) 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 Office of Inspector General (OIG) Seven Elements of an Effective Compliance Program. This Compliance Program Description sets forth the requirements in which IEHP expects Delegated entities to develop their Compliance Programs.

Compliance Program Scope

A. Delegated entities must implement a Compliance Program to provide a systematic process dedicated to ensuring that management, employees, business associates, Downstream Entities, Subcontractors, and other associated individuals/entities comply with applicable health care laws, Federal and State requirements, and all applicable regulations and standards.

B. Delegated entities must implement an effective compliance program that meets regulatory guidelines. The Compliance Program must include:

    1. Standards of conduct, policies and procedures to support and sustain Compliance Program objectives.
    2. Be overseen by the Board of Directors/Governing Body ("Board") and senior management levels.
    3. Process to report compliance activities and outcomes to the Board of Directors/Governing Board, senior management, IEHP, and applicable regulatory agencies.
    4. Screening of employees, Board Members, business associates, Downstream Entities, Subcontractors, and other affiliated individuals/entities for the presence/absence of program-related adverse actions and/or sanctions.
    5. Education and training: General training on health care regulatory requirements; specific training on job functions; and training to business associates, Downstream Entities, Subcontractors, and other external affiliates.
    6. Ongoing auditing and monitoring of the organization's compliance performance, including preventive practices identifying potential compliance issues.
    7. Enforcement measures, including implementation of corrective action plans (CAP), enacted when issues of non-compliance are identified.
    8. Preventive practices to identify potential compliance issues and to implement actions that lower or mitigate risk.
    9. Evaluation to determine the effectiveness of the compliance program.

Written Policies, Procedures, and Standards of Conduct

A. Code of Conduct – All Delegated entities are required to implement and maintain a Code of Conduct 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 and laws is the responsibility of all employees. The Code must be communicated to Employees, (Temporary and Permanent), Providers, Downstream Entities, Contractors, Board Members, and Volunteers.

1. The Code can be communicated by various methods, including:
    a. Provided to new Employees in the Employee Handbook upon initial employment.
    b. Discussed during Compliance New Hire and Annual Training.
2. Employees, Providers, Contractors, Volunteers/Interns, Board Members/Governing Body Members are required to acknowledge their understanding of the Code of Conduct and their commitment to comply with its intent within ninety (90) days of initial employment/start and annually thereafter.
3. Delegated entities should also provide a Vendor Code of Conduct to their business associates that address their obligations toward conducting business at the highest level of moral, ethical and legal standards.
    a. The Vendor Code of Conduct should include reporting requirements for any issue of non-compliance.

B. Policies and Procedures – All Delegated entities must develop Policies and Procedures that:
1. Address commitment to complying with all Federal and State standards.
2. Provide direction on dealing with suspected, detected or reported compliance issues.
3. Provide guidance on reporting compliance issues.
4. Identify how to communicate compliance issues to appropriate compliance personnel.
5. Include a policy of non-intimidation and non-retaliation for good faith efforts to reporting potential non-compliance issues, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials; and
6. Are reviewed on an annual basis, or more often to incorporate changes in applicable laws, regulations, or other program requirements.

Compliance Officer, Compliance Committee, and High-Level Oversight

A. Compliance Officer – The Compliance Officer is an employee of the Delegated entity and should report directly to the highest level of the organization.
1. The Compliance Officer must have express authority (oral or written) to make in-person reports to the CEO and Board of Directors/Governing Board in the Compliance Officer's sole discretion.
2. The Compliance Officer must provide updates on a periodic basis of the Compliance Program for presentation to the Governing Board, which includes at a minimum:
    a. Policy updates.
    b. Issues of Non-Compliance.
    c. Fraud, Waste and Abuse detection, monitoring and reporting.
    d. Auditing and Monitoring Program Updates.
    e. Outcome of Compliance Program Activities.
3. The responsibilities may include, but are not limited to:
    a. Advising the organization and Downstream Entities on policy requirements and the

development, distribution and implementation of policies.
   b. Ensuring that policies accurately and effectively communicate compliance and regulatory requirements.
   c. Periodically reviewing policies and initiating needed updates.
   d. Notifying Senior Management and IEHP of non-compliance issues.

B. Compliance Committee
   1. Delegated entities must establish a Compliance Committee that oversees the Compliance Program. The Compliance Committee must be accountable to and must provide regular compliance reports to the Delegate's Senior-most Leader and Governing Body.
   2. The Compliance Committee should include individuals with a variety of backgrounds and reflect the size and scope of the Delegate.
   3. Members of the Compliance Committee should have decision-making authority in their respective areas of expertise.
   4. Duties of the Compliance Committee may include, but are not limited to:
      a. Meeting at least on a quarterly basis, or more frequently as necessary to enable reasonable oversight of the compliance program.
      b. Developing strategies to promote compliance and the detection of any potential violations.
      c. Reviewing and approving compliance and FWA training and ensuring that training and education are effective and appropriately completed.
      d. Assisting with the creation and implementation of the compliance risk assessment and of the compliance monitoring and auditing work plan.
      e. Assisting in the creation, implementation and monitoring of effective corrective actions.
      f. Developing innovative ways to implement appropriate corrective and preventative action.
      g. Reviewing effectiveness of the system of internal controls designed to ensure compliance with regulations in daily operations.
      h. Supporting the Compliance Officer's needs for sufficient staff and resources to carry out his/her duties.
      i. Ensuring that the Delegate has appropriate, up-to-date compliance policies and procedures.
      j. Ensuring that the Delegate has a system for employees and Downstream Entities to ask compliance questions and report potential instances of noncompliance and potential FWA confidentially or anonymously (if desired) without fear of retaliation.
      k. Reviewing and addressing reports of monitoring and auditing of areas in which the Delegate is at risk for noncompliance or potential FWA and ensuring that corrective action plans are implemented and monitored for effectiveness; and
      l. Providing regular and ad hoc reports on the status of compliance with recommendations to the Delegate's Governing Board.

C. High Level Oversight – The Delegated entity's Governing Board should be responsible for:
   1. The annual review and approval of the Compliance, Fraud, Waste and Abuse, and HIPAA Programs.
   2. Adoption of written standards including the Delegated entity's Code of Conduct.
   3. Monitoring and support of the compliance program; and
   4. Understanding regulatory and/or contract changes, policy changes and health reform and the

impact on the Delegated entity's Compliance Program.

Effective Training and Education

A. IEHP requires Delegate's to provide Compliance Training to all Employees (Temporary and Permanent), Providers, Board Members/Governing Body, Contractors, Vendors, and Volunteers/Interns.

B. Compliance Training must be provided within ninety (90) days of initial employment/start, whenever 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 on an annual basis.

C. Training must include, at a minimum:

1. Reinforcement of the organization's commitment to compliance.
2. Defines Fraud, Waste and Abuse (FWA) and how to recognize it.
3. Reviews of conflicts of interest and disclosure of conflict of interest.
4. Privacy/confidentiality issues, as well as regulatory updates and recent health care compliance related adverse actions such as penalties and settlements.
5. Fraud, waste and abuse issues as well as regulatory updates and recent health care compliance related adverse actions such as penalties and settlements.
6. HIPAA Privacy and Security and the Health Information Technology for Economic and Clinical Health (HITECH) Act regulations.
7. Laws that may directly impact job related functions such as anti- kickback laws, privacy breaches, the False Claims Act and, the consequences of non-compliance.
8. Changes in compliance and regulatory requirements and updates on the consequences of non-compliance with these requirements.
9. Responsibilities to report concerns, misconduct, or activities related to non-compliance.
10. Reporting requirements and available methods for reporting non-compliance and potential FWA.

D. Delegated entities may use a written test or develop other mechanisms to assess effectiveness of the training.

E. Delegates who have met the Fraud, Waste and Abuse (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 FWA but must provide an attestation to IEHP of deemed status. Delegates may also meet their FWA training requirements in the following way:

1. Option 1, Delegates can adopt IEHP's General Compliance, FWA, HIPAA Privacy & Security training.
2. Option 2, Incorporation of the content of the CMS standardized training modules related to General Compliance, FWA, HIPAA Privacy Security into the organization's existing compliance training materials/systems.
3. Option 3, Delegates may also utilize the Industry Collaboration Effort (ICE) Fraud, Waste and

Abuse (FWA) training as an acceptable mode of completing FWA requirement.

F. Documentation of education/training activities must be retained for a period of ten (10) years. Documentation may include sign-in forms, signed attestations and the completion of testing results, Learning Management System (LMS) records.

Effective Lines of Communication

A. IEHP requires all Delegates, Subcontractors, Vendors, and other business associates to report compliance concerns and suspected, or actual, misconduct regarding delegated functions, IEHP Members, and Providers. This requirement is communicated through:
   1. Provider Manuals, newsletters and bulletins. Providers and Delegated entities are required to submit signed acknowledgement of their receipt of the Provider Manual or Vendor FDR Compliance Program Requirements Manual which delineates compliance reporting responsibilities.
   2. Annual Compliance training for all Downstream Entities and Subcontractors; and
   3. The IEHP Code of Business Conduct and Ethics.

B. IEHP has the following mechanisms available for reporting Compliance issues:
   1. Compliance Hotline: (866) 355-9038.
   2. E-mail: compliance@iehp.org;
   3. Secure Fax: (909) 477-8536; or
   4. Mail: Compliance Officer, PO Box 1800, Rancho Cucamonga, CA 91729.
   5. Web: IEHP.org About Us – Compliance Program

C. Delegates must:
   1. Implement and maintain mechanisms that allows compliance and FWA issues to be reported (hotline, drop box, email, etc.).
   2. Ensure mechanisms that allows compliance and FWA issues to be reported (hotline, drop box, email, etc.) are well-publicized for employees.
   3. Ensure reporting mechanisms allow for anonymous reporting of potential compliance or FWA issues.
   4. Implement and maintain a system to receive, record, respond, and track compliance questions or concerns and reports of potential FWA from Employees, Members of the Board of Directors/Governing Board, Downstream Entities, and Providers.

D. Delegates are required to develop similar mode of referring compliance issues, including reporting non-compliance issues to IEHP.

Well Publicized Disciplinary Standards

A. Delegated entities 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 must 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. Delegated entities must develop a monitoring and auditing component of the Compliance Program to test and confirm compliance across functional areas with contractual, legal and regulatory requirements to ensure compliance of their delegated function. The monitoring and auditing processes must be documented to show subject, method, and frequency.

B. Definitions:
   1. Audit - a formal review of compliance with a set of standards (e.g., policies and procedures, laws and regulations) used as base measures.
   2. Monitoring - regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.
   3. Risk assessments - broad based audits used to identify opportunities for improvement.

C. IEHP utilizes both internal and external resources to conduct the audit program. It is IEHP's expectation that the individual or Delegated entity's responsibility for the audit content cooperate with the audit process by providing access to documents and other information requested.

D. Methods of review include, but are not limited to:
   1. Provider/Contractor initial contract and annual Delegation Oversight Audits.
   2. Quarterly Reporting.
   3. External reviews of medical and financial records that support claims for reimbursement and Medicare cost reports; and
   4. Trend analysis and studies that identify deviations in specific areas over a given period.

E. Delegates must:
   1. Implement a system for identification of compliance risks including auditing and monitoring the organization's delegated function(s) and reporting findings to appropriate oversight body and taking corrective actions.
   2. Conduct a risk assessment of major compliance and risk areas in operational areas annually and ensure the risk assessment is periodically re-evaluated at least annually.
   3. Develop and implement an annual Audit Plan to schedule and prioritize audits to be performed.
   4. Ensure the outcome of auditing and monitoring activities are documented and reports are developed.
   5. Ensure reports of the outcomes of auditing and monitoring activities are communicated to the appropriate oversight body, Senior Leadership, and/or Governing Body as deemed appropriate by the Compliance Officer.
   6. Ensure corrective actions are developed and implemented in response to issues identified through auditing and monitoring activities.

Eligibility to Participate in State and Federal Healthcare Programs

A. Delegated entities must implement a screening program for Employees, Board Members/Governing Board, Contractors, Volunteers/Interns, Downstream Entities, Subcontractors, and business partners

to avoid relationships with individuals and/or entities that tend toward inappropriate conduct. This program includes:

1. Prior to hiring or contracting and monthly thereafter, review of the Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE) that are excluded from participation in government health care programs.
2. Prior to hiring or contracting and monthly thereafter a monthly review of the General Services Administration (GSA) System for Award Management (SAM).
3. A monthly review of the Department of Health Care Services (DHCS) Medi-Cal Suspended and Ineligible list and Centers for Medicare and Medicaid Services Preclusion List, as applicable.
4. Criminal record checks when appropriate or as required by law.
5. Review of the National Practitioner Databank (NPDB) as applicable.
6. Review of professional license status for sanctions and/or adverse actions, as applicable.
7. Reporting results to Compliance Committee, Governing Board, and IEHP as necessary.

Procedures and System for Prompt Response to Compliance Issues

A. Adverse findings routinely require corrective action plans, designed to identify the root cause of compliance failures; to implement actions directed at improving performance and/or eliminating risk; and, to ensure that desired results are being sustained. Follow-up auditing and/or monitoring is conducted to assess the effectiveness of these processes.

B. Delegated entities must develop and implement a system for reporting and prompt response to non-compliance and detected offenses.

C. When potential and/or actual non-compliance is reported or suspected, the following steps should be taken:
   1. Promptly respond to compliance and FWA issues as they are raised, but no less than two (2) weeks after identification.
   2. Investigate potential compliance problems and potential FWA as identified in the course of self-evaluations and audits.
   3. Timeliness and progress of investigations are documented by the responsible Compliance employee or Compliance Officer.
   4. Preventive measures are implemented to avoid similar non-compliance in the future, including monitoring of corrective action plans.
   5. Documents and evidence obtained during investigations are retained for a period of no less than ten (10) years.
   6. The activity causing the non-compliance must be promptly halted and/or mitigated to the extent possible to prevent harm to individuals, entities and/or IEHP.
   7. Investigations must be promptly initiated in accordance with the First Tier Entity's Fraud, Waste and Abuse Program; the HIPAA Privacy Program, or the First Tier Entity's Compliance Program, and, or, in consultation with the IEHP Special Investigations Unit (SIU).
   8. 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:
      a. Initiation of corrective action plans and/or agreements.

   b. Repayment of identified over-payments.
   c. Initiation of Task Forces to address process and/or system deficiencies that may have caused or contributed to the non-compliance.
   d. Additional education and training.
   e. Modification of policies and procedures.
   f. Discipline or termination of Employees or contracts.
9. Preventive measures must be implemented to avoid similar non-compliance in the future, including monitoring of corrective action plans.
   a. Investigations may consist of an informal inquiry or involve formal steps such as interviews and document collection, depending on the circumstances involved.
   b. Investigations should be conducted in consultation with the Compliance Officer who has the final authority to determine this process.
   c. The timeliness and progress of the investigation should be documented by the First Tier Entity's SIU Team, Compliance Department, or related unit.
   d. Documents and evidence obtained during investigations must be retained for a period of no less than ten (10) years.

D. 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 Board, 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. IEHP Compliance Department, as applicable.

Assessment of Compliance Effectiveness

A. On an annual basis, Delegated entities 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.
   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.

REFERENCES:

A. Medicare Managed Care Manual, Chapter 21 Compliance Program Guidelines.
B. Prescription Drug Benefit Manual, Chapter 9 Compliance Program Guidelines.
C. General Provisions 42 CFR § 422.503 (b)(4).
D. Program integrity requirements under the contract 42 CFR § 438.608.
E. Centers for Medicare and Medicaid Services, Policy CMS 4182 Final Rule.
F. (OIG) List of Excluded Individuals and Entities (LEIE).
G. Scope and Effect of Exclusion 42 CFR § 1001.1901

INLAND EMPIRE HEALTH PLAN		
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