



A Public Entity

Inland Empire Health Plan

FIRST TIER AND DOWNSTREAM ENTITIES

COMPLIANCE PROGRAM REQUIREMENTS MANUAL



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1. INTRODUCTION

Inland Empire Health Plan (IEHP) is committed to conducting business in an honest and ethical manner, and always in compliance with the law. To promote our culture of ethical conduct and compliance, IEHP established and implemented a Compliance Program.

The Compliance Program sets forth the principles, policies, and procedures for how IEHP Team Members, Governing Board Members, and subcontracted entities—known as 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 the Office of Inspector General (OIG) Seven Elements of an Effective Compliance Program. This commitment extends to our business associates, delegated entities and identified FDRs that support IEHP's mission.

The intent of this manual is to provide guidance to IEHP's FDRs, to help them understand the specific contractual requirements that must be fulfilled and maintained when conducting business.

This manual is applicable to all delegated entities that meet the definition of an FDR as applied by the Centers for Medicare & Medicaid Services (CMS), as well as the definition of a Subcontractor as applied by the Department of Health Care Services (DHCS), which are found on page 4 of this manual.



2. IEHP'S MISSION, VISION AND VALUES

IEHP organizes and improves the delivery of quality, accessible and wellness-based health care services within our community. The heart of our organization is best represented within our Mission, Vision and Values statements.

Mission: We heal and inspire the human spirit.

Vision: We will not rest until our communities enjoy optimal care and vibrant health.

Values: We do the right thing by:

- Placing our Members at the center of our universe.
- Unleashing our creativity and courage to improve health and well-being.
- Bringing focus and accountability to our work.
- Never wavering in our commitment to our Members, Providers, Partners, and each other.



3. IEHP'S COMPLIANCE PROGRAM

The IEHP Compliance Program is designed to:

1. Ensure IEHP and its contracted FDRs comply with applicable laws, rules and regulations.
2. Reduce or eliminate Fraud, Waste and Abuse (FWA).
3. Prevent, detect and correct non-compliance.
4. Reinforce the commitment to a culture of compliance for which IEHP strives.
5. Establish and implement a shared commitment to honesty, integrity, transparency, and accountability.



4. WHAT IS AN FDR?

An FDR is defined by Centers for Medicare & Medicaid Services (CMS) as any party that enters a written arrangement—acceptable to CMS with a Medicare Advantage Organization (MAO) or Part D plan sponsor applicant—to provide administrative services or health care services to a Medicare-eligible individual under the Medicare Advantage (MA) program or Part D program.

A Subcontractor is defined by the Department of Health Care Services (DHCS) as an individual or entity that has a subcontract with the managed care health care plan (MCP) that relates directly or indirectly to the performance of the MCP’s obligations under the contract with DHCS.

A Downstream Entity is any party that enters a written arrangement—acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit—below the level of the arrangement between an MAO or applicant or a Part D plan sponsor, or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate Provider for both health care and administrative services.

A Related Entity refers to any entity that is related to a MAO or Part D sponsor by common ownership or control and:

1. Performs some of the MAO or Part D plan sponsor’s management functions| under contract or delegation.
2. Furnishes services to Medicare enrollees under an oral or written agreement.
3. Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Resource citation:

42 C.F.R. §, 422.500 - Scope and definitions
Department of Health Care Services (DHCS) APL 17-004



5. PURPOSE OF FDR COMPLIANCE REQUIREMENTS MANUAL

IEHP recognizes that FDRs play a critical role in the Plan’s success, as well as helping to provide certain services that help the Plan to fulfill its contractual obligations. IEHP is also committed to ensure its contracted FDRs are fully compliant with all laws, regulations and Compliance Program standards. In order to ensure FDRs understand and meet their obligations, the Vendor FDR Compliance Requirement Manual is provided. The purpose of the manual is to serve as a resource tool that provides important information on key elements and the steps needed to remain compliant.

Resource citation:

42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi).

42 C.F.R § 438.608 - Program integrity requirements under the contract.

Chapter 9 CMS Prescription Drug Benefit Manual, Compliance Program Guidelines Chapter 21. CMS Medicare Managed Care Manual, Compliance Program Guidelines.



6. EXAMPLES OF ADMINISTRATIVE SERVICES THAT FDRs PROVIDE FOR IEHP

Federal and State Regulatory requirements apply to FDRs/Subcontractors to whom the Plan has delegated administrative or health care service functions relating to the Plan's regulatory requirements. FDRs are also required to be compliant with CMS and the OIG of the U.S. Department of Health and Human Services (HHS) guidelines as applied to:

- Sales and marketing.
- Utilization management.
- Applications processing.
- Enrollment, disenrollment, membership functions.
- Claims administration, processing and coverage adjudication.
- Appeals and grievances.
- Licensing and credentialing.
- Pharmacy benefit management.
- Hotline operations.
- Customer Service.
- Bid preparation.
- Outbound enrollment verification.
- Provider network management.

Resource citation:

Chapter 21 CMS Medicare Managed Care Manual



7. FDR REQUIREMENTS

FDRs must provide and maintain a systematic process dedicated to ensuring they comply with applicable health care laws and Federal and State requirements. The process must include:

- Written policies, procedures, and standards of conduct that demonstrates commitment to compliance.
- A process to notify Compliance Officer, Compliance Committee, and High-Level Oversight of non-compliance issues.
- Effective training and education.
- Effective lines of communication to report compliance concerns.
- A well-publicized disciplinary standard that reflects the organizations expectations for reporting compliance issues, including non-compliant, unethical or illegal behavior.
- Complying with the Health Insurance Portability and Accountability Act (HIPAA) laws and regulations to safeguard the privacy and security of Members' Personal Health Information.
- An effective system for routine monitoring, auditing and identification of compliance risks.
- Procedures and a system for prompt response to compliance issues.

These required processes are further outlined within IEHP FDR policies. The policies set forth the principles, policies and procedures for how first tier entities are required to conduct business while contracted with IEHP.

Resource citation:

Monitoring of First Tier, Downstream and Related Entities Policy

Compliance Program Description Policy

IEHP Vendor FDR Manual Policy: Compliance Program Requirements

IEHP Vendor FDR Manual Policy: FWA Requirements

IEHP Vendor FDR Manual Policy: HIPAA Program Requirements

Attestation Requirement

To confirm that our FDRs are meeting their compliance obligations, IEHP will issue an FDR attestation upon initial contract and annually thereafter. An authorized representative from the FDR's organization is required to attest to compliance with IEHP's compliance program requirements. In addition to completing an annual attestation, IEHP may request the FDR provide supporting documentation for any of the requirements listed on the attestation to ensure compliance program requirements are being met. For those FDRs that fail to meet these requirements each calendar year, the issuance of a corrective action plan, retraining or possible termination of the contract may result. The requirements are as follows:

CODE OF CONDUCT/COMPLIANCE POLICIES

The FDR must ensure it has either implemented Standards of Conduct or has adopted IEHP's Code of Business Conduct and Ethics and maintain evidence that it has been distributed to its employees.

Resource citation:

Chapter 21 Medicare Managed Care Manual §50.1

[IEHP Code of Conduct](#)

[FDR Attestation](#)

FRAUD, WASTE AND ABUSE (FWA), GENERAL COMPLIANCE TRAINING (INCLUDING HIPAA)

WHAT IS FWA?

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

Waste includes the overuse of services or other practices that directly or indirectly result in unnecessary costs. Waste is generally not considered to be caused by criminally negligent actions but rather by the misuse of resources.

Abuse includes actions that may directly or indirectly result in unnecessary costs and improper payments or services. Abuse involves the payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

FDRs must complete general compliance training as well as fraud, waste and abuse (FWA) and HIPAA training. The FDR must fulfill at least one of the options below to ensure satisfaction with the general compliance and FWA training requirement:

Option 1. Adopt IEHP’s General Compliance, FWA, HIPAA Privacy Security training. This can be found on our Compliance page:
<https://www.iehp.org/en/about/compliance-program>.

Option 2. Incorporation of the content of the CMS standardized training modules related to General Compliance, FWA and HIPAA Privacy Security into the organization’s existing compliance training materials/systems. This may be subject to IEHP review and approval. <https://www.iehp.org/en/about/compliance-program>.

Frequency

Trainings must be distributed to employees within 90 days of hire or contracting and annually thereafter. All evidence must be retained and be provided to IEHP upon request. Evidence shall also contain employee names and dates of completion.

Resource citation:

Chapter 9 CMS Prescription Drug Benefit Manual, Compliance Program Guidelines & Chapter 21 CMS Medicare Managed Care Manual, Compliance Program Guidelines
Element III: Effective Training and Education

RECORD RETENTION AND ACCESS TO RECORDS

First tier and downstream entities must comply with Medicare laws, regulations and CMS instructions (422.504(i)(4)(v)) and agree to audits and inspection by CMS and/or its designees and to cooperate, assist, and provide information as requested, and maintain records for a minimum of 10 years. This includes all records related to the administration or delivery of benefits to IEHP Members and delegated activities.

Frequency

All evidence must be retained and be made available to IEHP upon request for an audit, monitoring and/or in the event IEHP is engaged with a regulatory audit.

Resource citation:

Chapter 11 CMS Medicare Advantage Application Procedures and Contract Requirements §100.4 – Provider and Supplier Contract Requirements
Chapter 9 CMS Medicare Prescription Drug Benefit §50.3.1 & 50.6.11

EXCLUSION MONITORING

Federal law prohibits Medicare and Medicaid health care programs from paying for items or services furnished, prescribed, or ordered by an individual, entity or downstream entity who has been excluded from these federal programs. IEHP and its FDRs are expected to conduct exclusion screenings to ensure none of its board members, employees, temporary employees, volunteers/interns, and downstream

entities are excluded/suspended or do not become excluded/suspended from participation in federal and state health care programs.

FDRs are expected to use the exclusion sources below when conducting exclusion reviews.

Exclusion sources:

- Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE) https://oig.hhs.gov/exclusions/exclusions_list.asp
- U.S. General Services Administration (GSA) Systems for Award Management (SAM) <https://sam.gov/content/home>
- DHCS Medi-Cal Suspended and Ineligible List (S&I) (as applicable) <https://files.medi-cal.ca.gov/pubsdoco/SandILanding.aspx>
- CMS Preclusion List (as applicable) <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Preclusion-List>

Frequency

Exclusion screenings must be conducted prior to contracting, prior to hiring and each month thereafter to prevent inappropriate payment to pharmacies, vendors, and other entities that have been added to exclusion lists since the prior month. Screenings shall include all employees, governing board members, temporary staff, volunteers, and consultants. All evidence must be retained and be provided to IEHP upon request.

Reporting

In the event the organization or an employee of the organization appears on an Exclusionary List or is otherwise not eligible to participate in the Medi-Cal and/or Medicare programs, the FDR shall notify IEHP within five business days and shall ensure that the employee does not participate in the care or services provided to IEHP or IEHP Members. FDRs are also expected to immediately remove any board members, employees, volunteers/interns, and downstream entities responsible for the administration or delivery of benefits to IEHP Members. Evidence of exclusion reporting shall contain the employee's name and date of completion.

IEHP DOES NOT PERMIT THE USE OF OFFSHORE SUBCONTRACTORS

CMS defines an Offshore Subcontractor as: Any organization that an MAO or Part D Sponsor contracts with to fulfill or help fulfill requirements in their Part C and/or Part D contracts.

Offshore subcontractors include all first tier, downstream, and/or related entities. The term “offshore” refers to any country that is not one of the 49 United States.

Offshore subcontracting that involves receiving, processing, transferring, handling, storing, or accessing Personal Health Information (PHI) and/or Personally Identifiable Information (PII) to an offshore location is not permitted by IEHP.

As of 2/1/2022 IEHP will no longer allow the use of offshore services or vendors that support delegated services, or any functions performed on behalf of IEHP. The term “offshore” refers to any state, country or territory that is not within the continental United States. The “continental United States” is further defined as the 49 States, including Alaska and the District of Columbia, but excluding Hawaii. This requirement applies to all IEHP vendors and subcontractors, including FDRs. Any service provided to IEHP pursuant to any agreement with IEHP must be performed within the continental United States for all lines of business. Any service provided to IEHP or performed on behalf of IEHP outside of the continental United States shall be considered a material breach of your contract with IEHP.

Note: Prior approval is required for the use of offshore subcontractors/downstream entities that will support the services first tier entities/subcontractors provide to IEHP.

Resource citation:

45 C.F.R Part 160 Subpart A – General Provisions §160.103 (Definitions) Personal Health Information (PHI)
2 C.F.R §200.79 Personally Identifiable Information (PII)
PII-and-PHI-Identifiers Reference-Guide

USE OF SUBCONTRACTORS/DOWNSTREAM ENTITIES

FDRs shall not utilize the services of any subcontractors in providing the services required without IEHP’s prior written approval. FDRs shall request approval by submitting a written description of the services to be subcontracted. If approved by IEHP, FDRs shall remain the prime contractor for the services and be responsible for the conduct and performance of each approved subcontractor. Please note that the use of subcontractor services may also require Department of Health Care

Services (DHCS) and Department of Managed Health Care (DMHC) approval prior to implementation.

In the event a first tier entity is in breach of this section, IEHP shall have sole discretion and right to immediately terminate its contract agreement.

REPORT COMPLIANCE AND FWA ISSUES/CONCERNS

FDRs are required to report suspected violations of any laws and regulations to IEHP. Based on IEHP policies, a zero-tolerance policy for retaliation or intimidation against anyone who is reporting suspected misconduct is enforced. IEHP has the following resources available for reporting fraud, waste, abuse, privacy issues, and other compliance issues:

Compliance Hotline: 1-866-355-9038

Fax: (909) 477-8536

E- mail: compliance@iehp.org

Mail:

IEHP Compliance Officer

P.O. Box 1800

Rancho Cucamonga, CA 91729-1800

Online:

[Report a Compliance Issue](#)



8. MONITORING AND AUDITING

MONITORING ACTIVITIES

Monitoring activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure corrective actions are being undertaken and are effective.

AUDIT ACTIVITIES

An audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

As a plan, IEHP must undertake monitoring and auditing to test and confirm compliance with regulatory requirements, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against noncompliance and potential FWA. To ensure IEHP's FDRs are in compliance with contractual and regulatory requirements, IEHP performs a risk assessment, which is structured around the FDRs delegated work functions. Doing so helps to confirm if contractual obligations and ongoing compliance are being maintained.

FDRs are also expected to conduct their own routine auditing and monitoring of the delegated work they do on behalf of IEHP. FDRs must be able to provide the results of these ongoing activities at any given time that IEHP requests them to ensure they are being maintained. Additionally, IEHP holds its FDRs accountable to ensure their downstream entities are also compliant in meeting contractual and regulatory obligations. IEHP, at any time, may request to see evidence of monitoring and auditing activities conducted on a downstream entity that is contracted to perform a delegated function.

If FDRs fail to comply with these requirements, a Corrective Action Plan (CAP) may be issued to address the identified deficiency(ies).

Resource citation:

42 CFR § 422.503(b)(4)(vi)(F) for MA

42 CFR § 423.504(b)(4)(vi)(F) for Part D

Chapter 21 Medicare Managed Care Manual, § 50.6.6



9. LIST OF APPENDICES

* FDRs must abide by the IEHP Vendor FDR Manual policies as well as all applicable state and federal requirements.

Appendix	Title
Appendix A	IEHP Vendor FDR Manual Policy Compliance Program Requirements
Appendix B	IEHP Vendor FDR Manual Policy FWA Requirements
Appendix C	IEHP Vendor FDR Manual Policy HIPAA Requirements

Compliance and FDR Program:

<https://www.iehp.org/en/about/compliance-program>

Reporting Information

IEHP has the following resources available for reporting fraud, waste or abuse, privacy issues, and other compliance issues:

COMPLIANCE HOTLINE:

(866) 355-9038

FAX:

(909) 477-8536

E-MAIL:

compliance@iehp.org

MAIL:

IEHP Compliance Officer

P.O. Box 1800

Rancho Cucamonga, CA 91729-1800

ONLINE:

[Report a Compliance Issue](#)



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