



A Look Inside Harmonia's Compliance Plan

Generally, an agency such as ours instructs its employees, vendors and contractors on certain duties and any standard parameters around the performance of their duties through policies and procedures. Specifically, through written policies and procedures, we provide a roadmap for “relevant individuals” (What is a relevant individual? A person whose responsibilities or activities are within the scope of the code or policy including employees, clients, vendors, contractors. Each entity must determine for itself who their relevant individuals are), outlining their duties within the organization, imposing documentation requirements and implementing controls agency-wide to mitigate compliance risks specific to Harmonia.

Let's Review the Required Elements of Harmonia's Compliance Plan:

Code of Conduct & Ethics

A code of conduct & ethics along with compliance policies are critical elements of any compliance program. The code of conduct and compliance policies and procedures are developed under the direction of the compliance office with input from the Compliance Committee. The Code and applicable policies and procedures should be made available to all employees of the agency and part of the performance evaluations of all employees.

A code of conduct is important to communicate our mission, goals, and ethical requirements central to our operations. It articulates our commitment to comply with all Federal and State laws and regulations. It defines our ethical standards necessary to fulfill our mission and govern the conduct of our board members, employees and others who work with or on behalf of Harmonia.

Element 1 – Policies and Procedures

Compliance policies should encompass at least two areas: (1) the implementation and operation of an organization's compliance program, including the required elements; and (2) process to reduce risk caused by noncompliance with Federal and State laws. Entities should assess how their operations may present risk areas specific to them and design policies to address these risks.

Come common compliance risk areas are:

- Billing
- Quality of Care
- Coding
- Conflict of Interest

The Compliance Committee must ensure that a system exists to ensure Harmonia's policies and procedures foster rather than undermine our compliance culture or impair our risk-mitigation efforts.

Up-to-date policies and procedures are a critical element of a compliance program. The OIG recommends that entities establish a schedule for annually reviewing and revising, as necessary, all policies and procedures to ensure they reflect any modifications to applicable regulations.

Element 2 – Compliance Leadership and Oversight

Boards and senior leadership are vital to effective compliance programs. To be effective, a compliance program should have a board and senior leadership that understand its value and are committed to its success.

Every entity should designate a leader as the entity's compliance officer. This is a key indicator of the board and senior leadership's commitment to compliance. Designating a compliance officer with the authority, access, and resources necessary to lead an effective compliance program is essential. To fulfill their duties, the compliance officer should be empowered, and independent of other duties to the entity that might impair their ability to maintain compliance with Federal and State requirements. *The Compliance officer should not report to the entity's legal or financial functions. The compliance office should report directly to the CEO and/or the board.*

The compliance officer should have the authority to review all documents, data, and other information that are relevant to the agency's compliance activities. This includes, but is not limited to client records, billing records, and records concerning the agency's arrangements with other parties, including employees, independent contractors, suppliers, and health care professionals. The compliance officer also should have the authority to interview anyone within or connected to the agency in connection with a compliance investigation.

- **The Compliance Committee's purpose is to aid and support their compliance officer in implementing, operating and monitoring the Compliance Program. Their primary duties include analyzing any legal and regulatory requirements applicable to the agency, assessing developing, and regularly reviewing policies and procedures, monitoring and recommending internal systems and controls, conducting annual risk assessments and assessing training needs.**
- **The compliance officer should be the chair of the Compliance Committee. The committee should be comprised of the relevant leaders of both operational and supporting departments. All members should have the authority and the ability to speak for the department they represent.**
- **Board Compliance Oversight**

The United States Sentencing commission Guidelines require that an entity's "governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exert reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.

- **The Board should meet with the compliance officer on a regular basis and no less than quarterly (based on General Compliance Program Guidance for 2023).**
- **Another important component of the board's compliance role is Compliance Committee oversight.**

Element 3 – Training and Education

The compliance officer should develop an annual training plan that includes the training topics to

be delivered and the target audience for each topic. The annual training plan should incorporate material addressing any concerns identified in audits and investigations.

All board members, employees, contractors, and vendors (if applicable) should receive training at least annually on HCC's compliance program and potential risks.

Training should assert HCC's commitment to complying with Federal and State standards and review the applicable fraud and abuse standards (False Claims Act, the Federal anti-kickback statute). Training sessions should be developed and assigned based on an individual's roles and responsibilities and any compliance risks specific to those roles and responsibilities.

Education should not be limited to annual formal training requirements. The compliance officer should seek and develop opportunities to provide education on compliance topics and risks throughout the year.

Element 4 – Effective Lines of Communication

Open lines of communication between the compliance officer and entity personnel is critical to the successful implementation of the compliance program and the reduction of fraud, waste, and abuse. There are several channels of communication, while not all anonymous, whereby an employee can directly report to the compliance officer -- the Agency hotline, office "suggestion" boxes, email, anonymous letter, etc. We always encourage employees to first approach their supervisor if practical.

HCC has a written confidentiality and non-retaliation policy which is reviewed with all employees during NHO and in the agency newsletter.

All disclosures of compliance concerns, including potential violations of agency policies or Federal and State requirements should be recorded in a log maintained by the compliance officer.

Element Five – Enforcing Standards: Consequences and Incentives

For a compliance program to be effective, the agency must establish appropriate consequences for instances of noncompliance, as well as incentives for compliance.

- Consequences, as used here, are the result of noncompliant actions. Consequences may be educational (re-train), non-punitive or they may be punitive, or they may involve both. Consequences must be appropriate where a responsible individual's failure to detect or report a violation is attributable to their ignorance, negligence, or reckless conduct.
- Harmonia will follow the disciplinary guidelines as stipulated in our Handbook. The Handbook identifies the various steps that may be imposed under specific circumstances involving non-compliance with Agency policies, procedures, Federal or State regulations and our Code of Conduct.
- To deter noncompliant conduct, the consequences of noncompliance must be consistently applied and enforced. Employees at all levels of the agency are subject to the same consequences.
- Incentives -- Entities should develop appropriate incentives to encourage participation in HCC's compliance program. The Compliance Officer, Compliance Committee, and other employees should thoughtfully consider the compliance activities and behaviors they would like to incentivize (the "props pail" lends itself to this task).

- Although an entity may not be able to publicly recognize an individual who raises a substantial concern that results in the mitigation of harm or risk, the entity should find a way to recognize this in the performance appraisal of individuals. This of course is not possible for people who wish to remain anonymous. Also, this does not apply to individuals who raise compliance or legal violations for which they themselves committed or were responsible.

Element Six – Risk Assessment, Auditing, and Monitoring

1. Risk assessment, auditing, and monitoring each play a role in identifying and quantifying compliance risk. In recent years OIG and other stakeholders have come to recognize and place increasing emphasis on the importance of a formal compliance risk assessment process as part of the compliance program. Risk assessment best practice is to conduct an annual assessment

Risk assessment is the process of identifying, analyzing, and responding to risk. A risk assessment is a process that looks at risk in every area of the organization stemming from violations of policy, procedure, violations of law, regulations, or other legal requirements, risks stemming from violations of Medicare/Medicaid requirements.

A formal assessment process should pull information about risks from a variety of external and internal sources, evaluate and prioritize them, and then decide which risks to address and how to address them. Each risk should also be assessed against HCC's strategic plan. The results of department/program assessments are incorporated in the Compliance work plan and are used to identify training needs.

2. Auditing and Monitoring should be included in the Compliance Committee's work plan/schedule. Examples of routine monitoring of known risks include:

- Monthly screening of the Medicaid exclusion list
- Regular screening of State licensure and certification databases; and
- Annual review of the Agency's policies and procedures
- Other areas appropriate for routine monitoring based on the risk assessment and interaction with Federal health care programs, such as high-value billing codes, medical record documentation, medical necessity or business need.

Element Seven – Responding to Detected Offenses and Developing Corrective Action Initiatives.

No matter how strong our commitment to compliance or how effective the policies and procedures, training, and risk assessment, it is inevitable the compliance officer will receive audit or monitoring results that raise concerns or receive a report through the disclosure program that requires investigating. Compliance programs should include processes and resources to thoroughly investigate compliance concerns, take steps necessary to remediate any legal or policy violations that are found, including reporting to any Government program agencies or law enforcement where appropriate, and analyze the root cause(s) of any identified impropriety to prevent a recurrence. How an entity responds when it finds a violation resulting in a substantial overpayment or serious misconduct sets apart those organizations that have a strong compliance program.

- Investigations of Violations: Violations of an entity's compliance program. Failures to comply with applicable Federal or State law, and other types of misconduct threaten HCC's

status as a trustworthy organization capable of participating in federal health care programs. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the agency.

- Allegations of noncompliant conduct should be investigated and the outcome of the investigation should determine whether, and what kind of, reporting is necessary.
- Most internal investigation will require interviews and a review of relevant documents. Data review, email searches, examination of files and audits may also be required.

Regardless of the size or severity of the violations being investigated, a contemporaneous record of the investigation should be maintained, so that a record of the investigation can be compiled. The record should include:

- Documentation of the alleged violation;
- Description of the investigative process;
- Copies of interview notes and key documents;
- A log of witnesses interviewed and the documents reviewed;
- The results of the investigation; and
- Any disciplinary action taken or corrective action implemented.
- Prompt reporting will demonstrate the Agency's good faith and willingness to work with governmental authorities to correct and remedy the problem.

Some violations may be so serious that they warrant immediate notification to governmental authorities, prior to, or simultaneous, with commencing an internal investigation.

OIG believes in the importance of self-reporting. OIG takes into consideration an entity's good-faith voluntary disclosure when resolving violations submitted through one of the programs.

Element 8 – Non-Intimidation and Non-Retaliation

Good faith participation in the Compliance Program means an individual makes sincere efforts to comply with the standards and provisions set forth in the Compliance Plan, Code of Conduct, policies, procedures, rules, regulations, and laws.

Good faith reporting of a compliance concern is made with honest intent and motive – that the employee, contractor, or other agent had a sincere and reasonable belief that a violation may have occurred. Reporting can be made in good faith but be wrong about the facts. Good faith participation and reporting includes, but is not limited to: • Reporting actual or potential compliance issues such as fraud, waste, or abuse

Three Purposes of a Compliance Program

Prevention – Detection -- Correction

- Bucket #1: Prevention
 - Written Policies and Procedures
 - Compliance Officer and oversight
 - Training/education
- Bucket #2: Detection
 - Communication/Reporting hotline
 - Monitoring/auditing and internal reporting
 - Non-intimidation/ non-harassment
- Bucket #3: Corrective Action
 - Investigation/remediation
 - Disciplinary policies

