

THE 7 ESSENTIAL ELEMENTS OF A HEALTH CARE COMPLIANCE AND ETHICS PROGRAM

The delivery of health care in the U.S. is complex and expensive. In 2022, the federal government spent approximately \$1.485 trillion on health care costs, while state governments spent \$675 billion.¹

Both federal and state governments pass regulations and laws designed to reduce health care costs and improve health care quality by reducing fraud, abuse, and waste. Organizations that do not comply with these rules can face stiff financial penalties and other risks, such as being excluded from federal programs like Medicare. Today, health care entities are required to have effective compliance programs that demonstrate compliance with these regulations and laws.

A **compliance program** is a system designed to ensure that organizations, their employees and their agents are following applicable laws and regulations. An effective compliance program can reduce risk and improve care.

Read on to get a thorough understanding of what goes into an effective compliance and ethics program.

Elements of Compliance and Ethics Program

Every health care organization must have a Compliance and Ethics Program (the Program) to ensure ethical business conduct. The Program applies to the board of directors/governors, company officers, all other employees, contractors, subcontractors, all agents, and anyone who performs services for or acts on behalf of the company.

The Compliance and Ethics Program must include the following:

1. Written Standards, Policies, and Procedures

These written standards include the following:

- Code of Ethics
- Code of Conduct
- Policies that address specific risk areas, depending on the organization's business
- Procedures that implement the policies, so that compliance can be verified

Compliance with the Code of Ethics and Code of Conduct and all policies and procedures is typically a condition of employment and a part of evaluating the performance of employees/contractors/agents.

2. Compliance Leadership and Oversight:

The Program is led by a chief compliance officer (CCO) who should report directly to the CEO (with independent access to the board) or directly to the board. If the CCO reports to the CEO, then the CCO should be able to meet with the board at any time, and the board should sign off on CEO actions to discipline or fire the CCO or change the CCO's compensation.

The CCO should have sufficient funding, resources, and staff to operate a compliance program capable of identifying, preventing, and mitigating the entity's compliance risks.

The CCO should also chair a compliance committee composed of other company leaders from different departments, which could include billing and coding, clinical and medical, finance, internal audit, IT, HIM, human resources, legal, quality, risk management, and sales and marketing. The duties of the compliance committee include supporting the CCO in addressing risks, developing a work plan, and overseeing compliance.

There should also be a board-level compliance committee charged with overseeing the compliance function and reporting its status to the full board.

3. Training and Education

All board members, officers, employees, contractors, and medical staff (if applicable) should receive training at least annually about the organization's compliance program and potential compliance risks. Otherwise, training is offered when and where it is needed in addition to the annual training. Some training will be strictly for the board or senior leaders, while some training will be company-wide and take place periodically, such as training related to the Codes of Conduct and Ethics. Some training must occur only when needed and by function—such as when a new billing policy is implemented.

Trainings should:

- Include assessments to confirm employee understanding
- Keep track of who has and has not been trained

Failure of employees to comply with training requirements will result in disciplinary actions.



4. Open Communications/Disclosures

The compliance department should have an open-door policy and welcome questions. Employee exit interviews should specifically ask about any concerns or situations that may raise compliance issues.

The Program should have at least one anonymous reporting system (such as a hotline). All reports of compliance concerns should be recorded in a log maintained by compliance. All reports should be logged, whether made anonymously, directly to compliance, or eventually reported to compliance by a third party.

The log should include the:

- Date received
- Individual or department who investigated the complaint
- Investigation's findings
- Actions taken
- Date resolved
- If necessary, whether there was communication or disclosure to governmental authorities

5. Enforcing Standards

The organization should publicize its procedures for identifying, investigating, and remediating compliance violations and adopt progressive disciplinary actions that are fair and reasonable for compliance violations. Discipline should be applied evenly and consistently. By the same token, the organization should develop appropriate incentives to encourage participation in strategic compliance activities.

6. Risk Assessments and Auditing/Monitoring

A formal risk assessment is a fundamental part of a compliance program. Compliance, audit, quality, and risk management functions should perform a joint risk assessment at least annually. Then, the CCO/compliance committee can develop a work plan, including audits and monitoring of risks identified in the assessment. This may also drive changes in policies and training as the program works to address risk. In addition, the compliance function should monitor legal and regulatory changes, enforcement actions, and Office of Inspector General (OIG) work plan developments. It should also examine new entity acquisitions and company strategies or initiatives and evaluate internal audits or investigations for risk.

It is impossible to know if a compliance program is effective if it is not audited or monitored. The Program should plan a schedule of periodic audits based on risks identified by the annual risk assessment. Routine monitoring examples include monthly screening of the List of Excluded Individuals and Entities (LEIE) and State Medicaid exclusion lists, regular screening of state licensure and certification databases, and annual review of policies and procedures.

7. Responding to Detected Offenses and Developing Corrective Action

The CCO must act promptly upon learning of noncompliance to determine whether a material violation of applicable law has occurred. To do this, the CCO usually would need to include legal and potentially other organization leaders.

Noncompliance allegations should be investigated. Part of the investigation is to determine whether it is necessary or advisable to report the situation to a governmental authority. Most investigations will require reviewing documents and interviews. It may be necessary to search emails or other records and data.

When conducting an investigation, it is important to:

- Ensure all documents, including emails and notes pertaining to the topic investigated, are preserved
- Depending on the scope and severity, organizations must determine whether to use outside counsel, outside auditors, or other experts to assist in the investigation
- If investigators believe employees may impede the investigation, it may be appropriate to remove them from their current work assignments

The HHS Office of Inspector General (OIG) states that, if the compliance officer or counsel has reason to believe, after the investigation, that the misconduct may violate criminal, civil, or administrative law, then the organization should promptly (not more than 60 days after the determination that credible evidence of a violation exists) notify the appropriate government authority of the misconduct.

Some violations may be so serious that OIG states they warrant immediate reporting prior to or when starting an internal investigation. Examples of these serious violations are:

- A clear violation of criminal law
- A violation that has a significant adverse effect on either patient safety or the quality of care provided to patients
- A violation that is evidence of a systemic failure to comply with applicable laws, an existing corporate integrity agreement, or other standards of conduct, regardless of the financial impact on federal health care programs

Cut Through Compliance Complexity and Forge Ahead in Health Care

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1. Retrieved June 7, 2024, from [cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet](https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet)