The 7 Fundamental Elements of a Compliance Program

A Guide to Help You Build Your Compliance Program

Starting in 1998, OIG developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. The guidance provided in this document is based on those prior voluntary compliance program guidance documents. It is applicable to all healthcare provider types that participate in the Federal health care programs. In addition, recipients of grants from the U.S. Department of Health and Human Services may find these principles useful when establishing compliance programs for their organizations.

Compliance is the process an organization uses to ensure its activities conform with the organization's policies and procedures and applicable rules, including Federal requirements. Compliance is important for many reasons, but most importantly, it ensures funds are used to provide high-quality services to your community.

For healthcare providers with existing compliance programs, this guide may serve as a roadmap for updating or refining their compliance plans. For providers with emerging compliance programs, this guide may facilitate discussions among facility leadership regarding the inclusion of specific compliance components and risk areas.

While no single factor is conclusive of an effective compliance program, the following seven elements form a useful starting point for developing and maintaining an effective compliance program. For each element, you'll find questions to consider as you advance your program. The suggestions are not mandatory but are instead suggestions for healthcare providers to consider as beneficial compliance practices or relevant risk areas. For additional guidance beyond this guide, please find more resources on our website at https://oig.hhs.gov/.

Office of Inspector General
U.S. Department of Health and Human Services

Fundamental 1:
Establish Written Policies and Procedures

The purpose of compliance policies and procedures is to establish rules that help employees carry out their job functions in a manner that ensures compliance with Federal health care program requirements and furthers the mission and objective of the facility itself. Typically, policies and procedures are written to address identified risk areas for the organization. As healthcare facilities conduct a review of their written policies and procedures, some of the following factors may be considered:

- Are policies and procedures clearly written, relevant to day-to-day responsibilities, readily available to those who need them, and re-evaluated on a regular basis?
- Does the facility monitor staff compliance with internal policies and procedures?
- Have the standards of conduct been distributed to all directors, officers, managers, employees, contractors, and medical and clinical staff members?
- Has the facility developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?
- Does the risk assessment tool include an evaluation of Federal health care program requirements, as well as other publications, such as OIG's guidance, work plans, special advisory bulletins, and special fraud alerts?

Fundamental 2:
Designate a Compliance Officer and a Compliance Committee

The Compliance Officer and Compliance Committee are the backbone of the facility's compliance program. A Compliance Officer should have knowledge and experience in compliance and be empowered with what they need to run the program. The Compliance Officer should be a member of senior management and should report directly to the person at the top of the managerial hierarchy. The Compliance Officer may have to make some difficult recommendations, so they need to be at a level where other senior managers are colleagues and respect these recommendations. They also need to be able to go right to the top of the managerial structure so that their issues are heard. They should not be subordinate to the lawyers or the finance staff and should not have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions. Lawyers and finance staff have their own sets of duties that are different from a Compliance Officer's duties.

The Compliance Committee should be led by a well-qualified Compliance Officer. Compliance Committees will differ according to the size and scope of your organization, but key to the committee is that it is comprised of top leadership and management representatives from across the organization. The Compliance Committee's responsibility is to implement the facility's compliance program and to ensure that it complies with all applicable Federal health care program requirements. To ensure that the Compliance Committee is meeting this objective, each facility should conduct an annual review of its Compliance Committee. Some factors that the organization may wish to consider in its evaluation include the following:

- Does the compliance department have a clear, well-crafted mission?
- Is the compliance department properly organized?
- Does the compliance department have sufficient resources (staff and budget), training, authority, and autonomy to carry out its mission?
- Is the relationship between the compliance function and the general counsel function appropriate to achieve the purpose of each?
- Is there an active compliance committee, comprised of trained representatives of each of the relevant functional departments, as well as senior management?

- Are ad hoc groups or task forces assigned to carry out any special missions, such as investigating or evaluating a proposed enhancement to the compliance program?
- Does the compliance officer have direct access to the governing body, the president or CEO, all senior management, and legal counsel?
- Does the compliance officer have independent authority to retain outside legal counsel?
- Does the compliance officer have a good working relationship with other key operational areas, such as internal audit, coding, billing, and clinical departments?
- Does the compliance officer make regular reports to the board of directors and other facility management concerning different aspects of the facility's compliance program?

Fundamental 3:
Conduct Effective Training and Education

Employee training and education is a key part of an effective compliance program. The purpose of conducting a training and education program is to ensure that each employee, contractor, or any other individual that functions on behalf of the facility is fully capable of executing their role in compliance with rules, regulations, and other standards. In reviewing their training and education programs, healthcare facilities may consider the following factors:

- Does the facility provide qualified trainers to conduct annual compliance training for its staff, including both general compliance training and training specific to the staff's responsibilities?
- Has the facility evaluated the content of its training and education program on an annual basis and determined that the subject content is appropriate and sufficient to cover the range of issues confronting its employees?
- Has the facility kept up with any changes in Federal health care program requirements and adapted its education and training program accordingly?
- Has the facility formulated the content of its education and training program to consider results from its audits and investigations; results from previous training and education programs; trends in hotline reports; and OIG, CMS, or other agency guidance or advisories?
- Has the facility evaluated the appropriateness of its training format by reviewing the length of the training sessions, whether training is delivered via live instructors or via computer-based training programs, the frequency of training sessions, and the need for general and specific training sessions?
- Does the facility seek feedback after each session to identify shortcomings in the training program, and does it administer post-training testing to ensure attendees understand and retain the subject matter delivered?
- Has the facility's governing body been provided with appropriate training on fraud and abuse laws?
- Has the facility documented who has completed the required training?
- Has the facility assessed whether to impose sanctions for failing to attend training or to offer appropriate incentives for attending training?

Fundamental 4:
Develop Effective Lines of Communication

Open communication is essential to maintaining an effective compliance program. The purpose of developing open communication is to increase the facility's ability to identify and respond to compliance problems. Generally, open communication is a product of organizational culture and internal mechanisms for reporting instances of potential fraud and abuse.

Additionally, effective lines of communication can include tools such as monthly compliance reports. Such reports can, among other things, demonstrate a commitment to quality of care and foster an organizational culture that values compliance

When assessing a facility's ability to communicate potential compliance issues effectively, the facility may wish to consider the following factors:

- Has the facility fostered an organizational culture that encourages open communication, without fear of retaliation?
- Has the facility established an anonymous hotline or other similar mechanism so that staff, contractors, patients, visitors, and medical and clinical staff members can report potential compliance issues?
- How well is the hotline publicized, how many and what types of calls are received, are calls logged and tracked (to establish possible patterns), and is the caller informed of the facility's actions?
- Are all instances of potential fraud and abuse investigated?
- Are the results of internal investigations shared with the facility governing body and relevant departments on a regular basis?
- Is the governing body actively engaged in pursuing appropriate remedies to institutional or recurring problems?
- Does the facility use alternative communication methods, such as a periodic newsletter or compliance intranet website?

Fundamental 5:
Enforce Standards through Well-Publicized Disciplinary Guidelines

By enforcing standards of conduct, policies, and procedures, healthcare facilities help create an organizational culture that emphasizes ethical behavior. Healthcare facilities may consider the following factors when assessing the effectiveness of internal efforts:

- Are standards, policies, and procedures well-publicized and readily available to all facility personnel?
- Are standards, policies, and procedures enforced consistently across the organization?
- Is each instance involving the enforcement of standards, policies, and procedures thoroughly documented?
- Are officers, leaders, and supervisors held accountable for the foreseeable failure of subordinates to comply with standards, policies, and procedures?
- Are employees, contractors, and medical and clinical staff members checked routinely against government sanctions lists, including the OIG's List of Excluded Individuals/Entities (LEIE) and the System for Award Management (SAM)?

Fundamental 6:
Audit and Monitor

Effective auditing and monitoring plans will help healthcare facilities to address risks of fraud and abuse, such as the submission of incorrect claims to Federal health care program payors or the payment of kickbacks. Healthcare facilities should develop detailed annual audit plans designed to minimize fraud and abuse risks, including those associated with improper claims and billing practices and arrangements with referral sources. Some factors healthcare facilities may wish to consider include the following:

- Is the audit plan re-evaluated annually, and does it address the proper areas of concern? For example, does the audit consider findings from previous years' audits, risk areas identified as part of the annual risk assessment, and high-volume services?
- Does the audit plan include an assessment of billing systems--in addition to claims accuracy--in an effort to identify the root cause of billing errors?
- Does the audit plan include an assessment of arrangements with referral sources, including a review of payments made under those arrangements?
- Is the role of the auditors clearly established and are coding and audit personnel independent and qualified, with the requisite certifications?
- Is the audit department available to conduct unscheduled reviews and does a mechanism exist that allows the compliance department to request additional audits or monitoring should the need arise?
- Has the facility evaluated the error rates identified in the annual audits?
- If the error rates are not decreasing, has the facility conducted a further investigation into other aspects of the facility compliance program in an effort to determine hidden weaknesses and deficiencies?
- Does the audit include a review of all billing documentation, including clinical documentation, in support of the claim?

Fundamental 7:
Respond to Detected Offenses and Develop Corrective Action Initiatives

By consistently responding to detected deficiencies, healthcare facilities can develop effective corrective action plans and prevent further losses to Federal health care programs. Some factors a facility may wish to consider when evaluating the manner in which it responds to detected deficiencies include the following:

- Has the facility created a response team, that consists of representatives from the compliance, audit, and any other relevant functional areas, which may be able to evaluate any detected deficiencies quickly?
- Are all matters thoroughly and promptly investigated?
- Has the facility developed corrective action plans that consider the root causes of each potential violation?
- Does the facility conduct periodic reviews of problem areas verify that corrective actions were implemented successfully and eliminated existing deficiencies?
- Are overpayments promptly reported and repaid when a detected deficiency identifies an overpayment to the facility?
- If a matter results in a potential violation of law, does the facility make prompt self-disclosure or promptly disclose the matter to the appropriate law enforcement agency?

For more compliance resources, please visit our website at oig.hhs.gov.