

Developing, Implementing, and Maintaining an Effective Compliance Program

An Effective Program Demonstrates an Organization's Good Faith Effort to Comply with Applicable Statutes and Regulations



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The development, implementation, and ongoing maintenance of an effective compliance and ethics program (“Program”) has become a necessity to protect any organization participating in the health care industry. At its core, the purpose of a Program is to protect an organization by detecting and preventing improper conduct and promoting adherence to the organization’s legal and ethical obligations. By and large the Federal Sentencing Guidelines Manual, first published in 1991 by the U.S. Sentencing Commission, established the “gold standard” for an effective Program within the Federal Sentencing Guidelines (FSG). The FSG are closely aligned with the principles set forth in compliance guidance that the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has developed over time for specific segments of the health care industry, including hospitals, physician practices, nursing homes, and pharmaceutical companies, among others (collectively, the “OIG guidance”).

In general, the FSG impose less stringent criminal penalties on organizations that have adopted an effective Program. To qualify for these less stringent penalties, an organization must demonstrate that the design, implementation, and enforcement procedures of its Program promote an organizational culture that encourages ethical conduct and a commitment to compliance.

It is well recognized that there is no single “best” or “one-size-fits-all” Program for every organization. In addition, no one factor is determinative of Program effectiveness. There are, however, several key elements that must exist to have an effective Program in any type of health care organization. These elements are discussed below.

ELEMENTS OF AN EFFECTIVE COMPLIANCE PLAN

Development of Written Policies and Procedures

The FSG and OIG guidance both recommend that organizations adopt clearly written policies and procedures relevant to the day-to-day responsibilities of their employees. An effective Program, however, only begins with the adoption of the policies and procedures. Organizations are urged to make the policies and procedures readily available to those who need them (*i.e.*, through the organization's Intranet).

These Program policies and procedures need to be reevaluated on a periodic, regular basis. Organizations need to develop and utilize a risk assessment tool to monitor employee compliance with internal policies and procedures as well as to identify and assess weakness and risks areas with the operation on a regular basis. The risk assessment tool should include an evaluation of federal health care program requirements as well as other publications, such as the OIG's compliance program guidance publications, work plans, advisory bulletins, and special fraud alerts.

Designation of a Compliance Officer and Compliance Committee

Both the FSG and the OIG guidance recommend that compliance departments have a clear, well-crafted mission statement. The compliance department should be led by a qualified chief compliance officer (CCO) who is a member of senior management. Organizations are also advised to allocate adequate resources (staff and budget), training, authority, and autonomy to the compliance department so that it can fulfill its mission. The relationship between the compliance department and the in-house legal department should be appropriate to enable each function to accomplish its goals and objectives. Organizations should supervise and support their compliance departments with an active compliance

committee, comprised of trained representatives of each of the relevant functional departments, as well as senior management.

The OIG guidance establishes that the CCO should have direct access to the governing body, the president or chief executive officer (CEO), and all senior management, including in-house counsel. OIG guidance also recommends that the CCO have independent authority to retain outside legal counsel. In addition to this independent authority to retain outside counsel, the degree of independence of the compliance department from the organization's in-house legal department and the nature of the relationship between the compliance department and the in-house legal department should be examined closely. In addition to the compliance department's relationship with the organization's legal department, the working relationship between the compliance function and other key operational areas that perform functions that have a clear nexus with the compliance function on a regular basis (*e.g.*, internal audit, coding, billing and clinical departments) should be evaluated.

Developing Open Lines of Communication

Organizations should foster a culture that encourages open communication without fear of retaliation. OIG guidance advocates that health care providers establish an anonymous hotline or other similar mechanism so that staff, contractors, patients, visitors, et cetera can report potential compliance issues.

Mere establishment of a hotline, however, does not meet this standard: its existence and availability must be publicized. The number of calls and the different types of callers provide a measure of outreach effectiveness. Upon receipt, calls should be logged and tracked (to establish possible patterns), and the caller should be informed of the organization's actions. Regardless of the communication channel, all reports of

potential fraud and abuse should be investigated and the results shared with the organization's governing body and relevant departments on a regular basis. The organization also should pursue appropriate remedies to any institutional or recurring problems.

Conducting Effective Training and Education of Various Constituencies

OIG guidance and industry "best practices" recommend annual compliance training for staff by qualified personnel regarding both general and specific training pertinent to the bodies of law and regulation relevant to that employee's duties and responsibilities. The FSG recommend that an organization should ensure that employees are trained on the Program's objectives and relevant policies, as relevant to their positions. OIG guidance encourages organizations to evaluate the content of training and education program on an annual basis and determine that the subject content is appropriate and sufficient to cover the range of issues confronting its employees, contractors, and vendors (including clinical personnel). The content should reflect changes in federal health care program requirements. The content also should reflect the results of the organization's audits and investigations; feedback from previous training and education programs; trends in hotline reports; and new advisories and bulletins from the OIG's Centers for Medicare & Medicaid Services (CMS) and other agencies.

Organizations also should evaluate the appropriateness of their 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. Organizations should seek feedback after each session to identify shortcomings. Organizations also should administer post-training testing to ensure attendees understand and retain the subject matter delivered. Industry standard

practices now include documenting the fact that individuals have completed the required training programs. Some organizations elect to impose sanctions for failing to attend training and/or offer incentives for attending such programs.

Many organizations mandate that attendance and participation in training programs is a condition of continued employment and that failure to comply with training requirements will result in disciplinary action, including possible termination, when such failure is serious. Adherence to the provisions of the Program's training requirements should be an important factor in each employee's annual performance review.

Internal Monitoring and Auditing

The FSG clearly document that an ongoing evaluation process is critical to a successful Program. An effective Program should incorporate thorough monitoring of its implementation and regular reporting to the board of directors and senior management. Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the CCO and shared with senior management and the compliance committee.

The FSG and the OIG guidance recommend that an organization's audit plan be evaluated on an annual basis to ensure that areas of concern with respect to billing matters and relationships with other institutions (particularly, referral sources) are properly addressed. This evaluation process should consider, for example, findings from previous years' audits, risk areas identified as part of the annual risk assessment, and high-volume services. As to the billing function, the audit plan should include an assessment of billing systems in addition to claims accuracy to identify the root cause of billing errors. Reviews of claims for accuracy should include a review of all billing documentation, including clinical documentation.

Recovery audit contractor (RAC) audits have become of significant concern to health care providers participating in the Medicare program. Organizations should create work groups to develop and refine action steps to be taken in connection with these audits, as they can be extremely disruptive to an organization in terms of resource consumption and cash flow challenges.

Responding to Detected Deficiencies

The OIG recommends that organizations create a response team, consisting of representatives from the compliance, internal audit, and any other relevant functional areas, to evaluate any detected deficiencies quickly. The team should promptly investigate all matters thoroughly and develop corrective action plans that take into account the root causes of each potential violation. In the wake of a corrective action plan, the team should conduct periodic reviews of problem areas to verify that the implemented corrective action successfully eliminated deficiencies. In addition, there should be protocols in place to address situations where a detected deficiency results in an identified overpayment, to ensure prompt and accurate repayment.

Organizations should have in place a procedure by which compliance officers and other responsible executives report probable violations of law to in-house counsel, or, in the event a conflict of interest exists within the in-house legal department, directly to the audit committee of their board so that the governing body can exercise its judgment with the advice of independent counsel when warranted to determine whether to disclose a matter to law enforcement.

If improper conduct has been detected, the FSG require that an organization take reasonable steps to both address it and to prevent further similar misconduct. The failure to prevent or detect improper conduct in and of itself does not mean that a Program is ineffective. However, the FSG

make clear that a “recurrence of similar misconduct creates doubt regarding whether the organization took reasonable steps to” achieve an effective Program. Thus, it is important for appropriate remedial measures to be taken. Such measures may include anything from disciplinary measures aimed at the person responsible for the improper conduct to modifying the Program that is currently in place.

ENFORCEMENT OF DISCIPLINARY STANDARDS

The OIG recommends that organizations broadly publicize disciplinary standards and make them readily available to all employees. Because enforcement of these policies helps to create an organizational culture that emphasizes ethical behavior, disciplinary standards must be enforced consistently across the organization. To achieve this, organizations must thoroughly document each instance involving the enforcement of disciplinary standards. Organizations also should check (at least annually) full and part-time employees, contractors, and clinical staff members against government sanctions lists, including the OIG’s List of Excluded Individuals / Entities (LEIE) and the General Services Administration’s Excluded Parties Listing System.

CONCLUSION

A successful compliance Program addresses the public and private sectors’ mutual goals of reducing fraud and abuse; enhancing organizations’ providers’ operations; improving the quality of health care services; and reducing the overall cost of health care services. Attaining these goals benefits the health care industry, the government, and patients alike. Compliance programs help health care organizations fulfill their legal duty to refrain from submitting false or inaccurate claims or cost information to the federal health care programs or engaging in other illegal practices.

It is highly unlikely that the implementation of a Program — even a highly effective

one — will completely eliminate improper or unethical conduct from the operations of health care organizations, given the industry's complex operating environment and constant state of flux. However, an effective Program demonstrates an

organization's good faith effort to comply with applicable statutes, regulations, and other federal health care program requirements and may significantly reduce the risk of unlawful conduct and corresponding sanctions.

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