

Elements of an Effective Compliance Program: Introductory Guidance

Background

The Federal Government has long sought to enlist members of the provider community in its efforts to uncover and deter fraudulent and abusive behavior that adversely affects federal health care programs. Working in collaboration with the Department of Justice and Federal Bureau of Investigation, the Department of Health and Human Services (“DHHS”), Office of Inspector General (“OIG”) is the agency charged with protecting the integrity of federal health care programs. The OIG has asserted that health care providers are responsible for policing their own actions as they relate to services and items furnished to program beneficiaries and payable by the Federal Government:

For many years, OIG has emphasized the importance of dealing with the Federal health care programs with integrity. All members of the health care industry have a legal and ethical duty to do so. This duty includes an obligation to take measures to detect and prevent fraudulent and abusive activities, including implementing specific procedures and mechanisms to investigate and resolve instances of potential fraud involving the Federal health care programs. Whether as a result of voluntary self-assessment or in response to external forces, participants in the health care industry must be prepared to investigate such instances, assess the potential losses suffered by the Federal health care programs, and make full disclosure to the appropriate authorities.¹

The OIG’s Compliance Program Guidance Documents

To assist health care providers in detecting fraud, waste, and abuse, the OIG issued a series of Compliance Program Guidance documents for different sectors of the industry describing how to develop and implement a comprehensive compliance program. The first of the OIG’s sector-specific guidance documents, issued on February 23, 1998, was targeted to [hospitals](#). Later Compliance Program Guidance documents included other sectors of the health care industry: [home health agencies](#), [clinical laboratories](#), [third-party medical billing companies](#), [durable medical equipment suppliers](#), [hospices](#), [Medicare+Choice organizations](#), [nursing facilities](#), [individual and small group physician practices](#), [ambulance suppliers](#), [pharmaceutical manufacturers](#), [recipients of Public Health Service research awards](#), as well as supplemental Compliance Program Guidance documents for [hospitals](#) and [nursing facilities](#).²

¹ [Updated OIG’s Provider Self-Disclosure Protocol](#), (April 17, 2013).

² All of the referenced Compliance Program Guidance documents are available in the Appendix to this Toolkit as well as on the [OIG website](#).

On October 5, 2000, the OIG published its Compliance Program Guidance for Individual and Small Group Physician Practices (“Physician Practice Guidance”).³ The Physician Practice Guidance reflects the OIG’s attempt to strike a compromise that permits implementation of cost-effective Compliance Program alternatives: “[a] compliance program can be an important tool for physician practices of all sizes and does not have to be costly, resource-intensive or time-intensive.”⁴

The Physician Practice Guidance recognizes the diversity in the size, complexity, and services offered by physician practices. For this reason, the OIG specifically refrained from defining “small group practice”:

[t]he difference between a small practice and a large practice cannot be determined by stating a particular number of physicians. Instead, our intent in narrowing the guidance to the small practices subset was to provide guidance to those physician practices whose financial or staffing resources would not allow them to implement a full scale, institutionally structured compliance program as set forth in the Third Party Medical Billing Guidance or other previously released OIG guidance.”⁵

The OIG has not developed a comparable Compliance Program Guidance for large group practices; however, larger health centers may find that the OIG Compliance Program Guidance for Hospitals⁶ and the OIG Supplemental Compliance Program Guidance for Hospitals⁷ contain guidance that is more relevant to their operations. The OIG also states that larger physician practices may want to use both the Physician Practice Guidance and the Compliance Program Guidance for Third Party Medical Billing Companies.⁸

Health centers with additional lines of business, such as home health care or managed care plans, should consult the OIG Compliance Program Guidance applicable to the sector of the health care industry for such line of business. Though each of the Compliance Program Guidance documents sets forth the same seven elements of an effective compliance program, the high risk areas described in each Compliance Program Guidance differ.

Health centers should note that of the Compliance Program Guidance documents, all are more stringent in their requirements for implementation of the seven elements than is the Physician

³ [Compliance Program Guidance for Individual and Small Group Physician Practices](#), 65 Fed. Reg. 59434 (Oct. 5, 2000) (“Physician Practice Guidance”).

⁴ [Id.](#) at 59435.

⁵ [Id.](#)

⁶ [Compliance Program Guidance for Hospitals](#), 63 Fed. Reg. 8987 (Feb. 23, 1998).

⁷ [Supplemental Compliance Program Guidance for Hospitals](#), 70 Fed. Reg. 4858 (Jan. 31, 2005) (“Supplemental Compliance Program Guidance for Hospitals”).

⁸ Physician Practice Guidance at 59436.

Practice Guidance. The Physician Practice Guidance offers suggestions that take into account the financial and staffing constraints characteristic of many smaller providers. The approach deviates significantly from other Compliance Program Guidance documents, which generally contemplate Compliance Programs consisting of a well-developed implementation of each of the seven elements. Indeed, the OIG in its Physician Practice Guidance acknowledges this deviation by suggesting that physician practices may begin to implement their Compliance Programs in steps, rather than being required to immediately establish processes for each of the seven elements. This flexibility, however, does not excuse well-established and developed health centers from taking appropriate measures to develop a complete Compliance Program.

The Seven Elements of an Effective Compliance Program

The OIG Compliance Program Guidance documents identify seven elements that should be included in every Compliance Program. These seven elements are based on criteria adopted by the Federal Government in the Federal sentencing guidelines.⁹ The sentencing guidelines set forth criteria by which courts determine corporate culpability and impose appropriate sanctions for organizations that are found, through the actions of their employees and agents, to have violated criminal law. If a court determines that an organization has an effective program in place to prevent and detect violations of law, it may impose a reduced fine.

Though the OIG's Compliance Program Guidance documents vary slightly by industry sector in describing how the seven elements should be implemented, each Compliance Program Guidance contains the same seven requirements.¹⁰

Element 1 - Designating a Compliance Officer or Contact

The designation of a single person to accept responsibility for the Compliance Program and manage its day-to-day operations is critical to ensuring that the Compliance Program remains visible, active, and accountable. In addition, the designation of a single person enables the health center's Board of Directors and CEO to have a single point of contact for receiving information about the activities of the Compliance Program without confusion regarding whose job it is to address particular aspects of the Compliance Program.

The designation of a single person to accept responsibility for the Compliance Program should be distinguished from a single person accepting responsibility for the organization's compliance with legal requirements. An organization's compliance is not solely the domain of the Compliance Officer, but the responsibility of Board members, employees, contractors, agents, consultants, volunteers, and any others who act on the health center's behalf (for simplicity, "Individuals Affiliated with the health center"). A health center should make clear that its

⁹ See [United States Sentencing Commission Federal Sentencing Guidelines Manual](#), Chapter 8.

¹⁰ For purposes of these materials, the Authors have sequenced the seven elements slightly differently from the order set forth in the Physician Practice Guidance.

Compliance Program applies to all Individuals Affiliated with the health center. To provide such notice, the health center may use methods that include (but are not limited to):

- Including compliance provisions in employee job descriptions,
- Including compliance provisions in contractors' contracts, even where a contractor's company has a compliance program of its own.

For more information regarding designating a Compliance Officer or Contact, see [Designating Compliance Personnel and the Role of the Board of Directors in the Compliance Program](#).

Element 2 - Implementing Written Standards and Procedures

The implementation of written standards and procedures ensures that a health center's expectations for Individuals Affiliated with the health center conduct are clearly communicated. Health centers should have written Standards of Conduct, or a "Code of Conduct," that:

- Expresses the health center's commitment to ethical and legal behavior;
- Describes the health center's conflict of interest policy; and
- Offers information on the health center's Compliance Program and compliance reporting mechanisms.

In addition, the health center should have written policies and procedures, particularly within the organization's principal risk areas, to ensure that legal requirements are distilled into clear, workable directions. Last but not least, the health center should have written policies and procedures that address each of the seven elements of its Compliance Program. For more information regarding implementing written standards and procedures, see [Developing and Implementing Compliance and Practice Standards](#).

Element 3 - Conducting Appropriate Training and Education

Training and education provide Individuals Affiliated with the health center with an understanding of the health center's Compliance Program, legal requirements applicable to the health center, and written policies and procedures. Annual training events create an important opportunity for a health center to convey its organizational values, including its commitment to ethical and legal conduct. Training on the health center's Compliance Program should explain the significant legal risks faced by the health center and the important role that Individuals Affiliated with the health center have for maintaining compliance. In addition, specific training should be provided to Individuals Affiliated with the health center whose job functions raise significant risks for the health center, e.g., coding and billing staff, practitioners, and finance staff. For more information regarding conducting appropriate training and education, see [Conducting Appropriate Training and Education](#).

Element 4 - Developing Open Lines of Communication

To facilitate detection of potential non-compliant conduct, it is necessary for all Individuals Affiliated with the health center to feel comfortable in reporting compliance issues. That is easier said than done. Individuals Affiliated with the health center may be concerned about how reporting potential compliance issues will reflect on them individually and will fear adverse reactions from colleagues and superiors. Consequently, it is critical that health centers create an environment in which Individuals Affiliated with the health center do not have reason to fear either retaliation for reporting or that reports will not be taken seriously. For more information regarding developing open lines of communication, [see Developing Open Lines of Communication.](#)

Element 5 - Conducting Internal Monitoring and Auditing

Monitoring is an ongoing process of reviewing the operations of the health center as they occur in the present. In contrast, auditing consists of conducting reviews of risk areas to determine compliance with legal requirements. An audit provides the health center with a “snapshot” of its compliance at a specific point in time, often in the past. For more information regarding conducting internal monitoring and auditing, [see Conducting Internal Monitoring and Auditing.](#)

Element 6 - Responding Appropriately to Detected Offenses

For a Compliance Program to be effective, the Compliance Officer must ensure that the health center has taken steps to correct any potential or actual occurrences of non-compliance. As part of this process, a health center Compliance Officer (or his or her designee) should investigate credible allegations to determine their scope, causes, and seriousness. If possible, non-compliant conduct should be halted immediately and the effects of non-compliant conduct should be mitigated. Any corrective actions taken to address non-compliance should aim to reduce the likelihood of similar instances of non-compliance occurring in the future. For more information regarding responding appropriately to detected offenses and developing corrective action, [see Responding Appropriately to Detected Offenses.](#)

Element 7 - Enforcing Disciplinary Standards through Well-Publicized Guidelines

In some cases, it will be appropriate to discipline individuals who violate standards or policies. Enforcing disciplinary standards gives the Compliance Program credibility as well as demonstrating a health center’s integrity, commitment to compliance and desire to prevent recurrence. For more information regarding enforcing disciplinary standards through well-publicized guidelines, [see Enforcing Disciplinary Standards through Well-Publicized Guidelines.](#)

Role of the Board of Directors

Boards of Directors of all health care entities are strongly encouraged by the OIG to play a role in their organization's Compliance Program:

[a]s appropriate, the OIG strongly encourages the participation and involvement of the hospital's board of directors ... in the development of all aspects of the compliance program.¹¹

For health centers, the Board of Directors' role in compliance is mandatory. Under Section 330 of the Public Health Service Act ("Section 330"), one of the duties of the Board of Directors of health centers is to ensure that the health center is operated in compliance with all applicable federal, state, and local laws and regulations.¹² Implementation of a Compliance Program is an effective, if not essential method of meeting this obligation.

- [Board resolution endorsing and authorizing the development and implementation of a compliance program: Sample language](#)

For additional information regarding the involvement of the Board of Directors in compliance, see [Designating Compliance Personnel and the Role of the Board of Directors in the Compliance Program](#).

Advice and Recommendations¹³

When developing a Compliance Program, each health center will need to determine for itself whether the Physician Practice Guidance or another of the OIG's Compliance Program Guidance documents is the applicable and appropriate guidance. Given the differences among health centers in terms of the number of individuals they employ, the budgets under which they operate, and the clinical and administrative functions they perform, the Authors believe that, similar to physician practices, no bright line between "small" and "large" health centers can or should be drawn.

Although the Physician Practice Guidance sets forth a step-by-step approach to implementing a Compliance Program, the Authors caution that the flexibility permitted by this approach should not imply that health centers may merely select a few elements for implementation from among the seven elements and deem the resulting Compliance Program to be sufficient. Every health center should strive to implement a Compliance Program consisting of all seven elements, with

¹¹ See Supplemental Compliance Program Guidance for Hospitals at 4874.

¹² See [42 C.F.R. § 51c.304\(d\)\(3\)\(v\)](#).

¹³ The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The advice and recommendations consist of general guidance based on federal law and regulations and do not necessarily apply to all health centers under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel.

active participation by their Board of Directors. Health centers that have been operating since the OIG published its Physician Practice Guidance are more likely to have better developed components of a Compliance Program. For new Section 330-funded health centers, compliance should not be a new concept, though such health centers are less likely to have more developed Compliance Programs.

Regardless of whether a health center is taking its first steps to implement a Compliance Program, or has implemented all seven steps (or is somewhere in between), the Authors recommend developing an annual Compliance Program work plan (“work plan”) to assist the health center in planning the activities related to the Compliance Program. Simply put, a work plan is a to-do list of projects or actions. It should list specific actions to be taken; the party responsible for each action; the date work is scheduled, conducted, and completed; and if possible, goals to measure effectiveness.

- [Compliance work plan: Sample](#)

In developing a Compliance Program where none existed previously, the work plan should contain activities that implement as many of the seven elements as possible, recognizing that the Physician Practice Guidance emphasizes a step by step approach to developing and implementing a voluntary compliance program.¹⁴ The Authors recommend that health centers consider the size of the health center and the complexity of the health center’s operations, in determining the extent to which, and when, they implement each of the seven elements.

For health centers that have implemented all seven elements of a Compliance Program, the work plan should include activities to strengthen the effectiveness of the Compliance Program as well as to focus on risk areas affecting the health center. The Authors recommend that a health center annually evaluate its Compliance Program in order to identify opportunities for improvement and, as appropriate, include activities to improve the Compliance Program in the work plan.

- [Evaluating a health center’s compliance program: Tip sheet](#)
- [Key considerations in evaluating a compliance program: Checklist](#)

¹⁴ OIG Physician Practice Guidance, 63 Fed. Reg. at 59434.