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Refocusing the compliance paradigm

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The U.S. Sentencing Commission performed a great service for corporate America when they laid out seven elements of an effective compliance program. These seven elements have been a fundamental component of the Federal Sentencing Guidelines since its introduction in 1991, and throughout the years, have become an integral part of the health care culture. In 2004, the Federal Sentencing Guidelines were amended to include more detailed and stringent requirements, which further emphasized the importance of the seven elements when designing and implementing an effective compliance program.[1] The Department of Health and Human Services' Office of Inspector General (OIG) has used these seven elements as the basis for their compliance guidances issued for various health care entities that conduct business with the federal government. The seven elements have become the backbone for an effective compliance program and the benchmark against which health care organizations evaluate their compliance programs.

Based on our experience working within OIG and through numerous consulting engagements, including various clients ranging from small skilled nursing facilities to large hospital systems, we observe firsthand the importance of the seven elements. However, we have also observed the need for the seven elements to be framed in a slightly refocused paradigm. In this article, we will discuss why we believe there should be a refocus and lay out how this new paradigm should be structured.

Need for refocus

Our perceived need for refocus is primarily based on our years of experience with health care clients who have indicated that they need a clearer, more practical path in order to successfully accomplish the seven elements. OIG provides guidance to help health care entities identify significant risk areas and evaluate their compliance efforts. However, many of our clients have voiced their questions and concerns about implementing the information available in the various guidances.

- **Clients Overwhelmed/Confused**
  We hear from compliance officers on a daily basis that it is almost impossible to keep up with all the regulatory risks within their facilities. The 100 to 200-plus risk categories that are identified by reviewing OIG and other federal agency issued documents and through canvassing their own health care staff, need to be reviewed, prioritized, and mitigated.
  - ❑ How do we begin to put all these risks in some workable format that makes sense?
  - ❑ How then do we remediate, audit, and report on the risks?
- **Categories and Priorities Not Clear**
  Compliance officers frequently ask if, instead of the 100-200 risk areas, there are10-15 risk categories that can subsume all the other risk areas.
  - ❑ Do some areas have more priority than others?
  - ❑ Are all the risk areas of equal weight or do some have more weight than others?
  - ❑ Each facility will have its own unique risks, but are there some OIG/CMS areas that are priorities?
- **Chronology Not Apparent**
  The various written guidances outline seven separate elements, and many clients have questions about the chronology of those elements, especially what should be done first.
  - ❑ Do the seven elements flow in chronological order?
  - ❑ Why is risk assessment mentioned under developing policies and procedures? Don't we have to assess our risks before writing policies and procedures?
  - ❑ Isn't conducting a risk assessment different than developing a policy for cost reports?

In discussing these types of questions with clients and working with them to provide practical advice on how to solve these issues, we have come up with a slightly refocused compliance paradigm. We have taken the seven elements of an effective compliance program and matched them against two major functions, namely (1) the appropriate structure of the compliance program and (2) an effective compliance process.

Structure of compliance program

From both a rational and practical standpoint, a compliance program needs to be appropriately structured in order for the compliance process to run efficiently and effectively. Thus, the designation of a compliance officer and compliance committee, the first compliance element as outlined in the OIG Supplemental Compliance Program Guidance for Hospitals,[2] is a prerequisite for the other six elements to function optimally. This structure includes:

- Board oversight committee that meets regularly with the chief compliance officer and asks questions as outlined in the three documents included in a series of educational resources co-sponsored by the OIG and American Health Lawyers Association on corporate compliance and health care quality
- Corporate compliance committee represented by all the various department heads
- Chief compliance officer and staff who have sufficient resources and authority to carry out their responsibilities

The structure of the compliance program aligns well with the first element (Designation of a compliance officer and compliance committee). With this type of structure in place, the other six elements, related to the compliance process, are much more obtainable.

Compliance process

The remaining six elements, as laid out in the supplemental guidance for hospitals, are best incorporated as part of a cyclical process for compliance that is developed around risk areas and consists of four functional steps:

- **Step 1: Risk assessment**

  This function is discussed within the second element (Development of compliance policies and procedures), but we believe it is quite different from developing a policy for a given risk area and deserves specific attention. Thus, we believe that a risk assessment is the first necessary step in the compliance process that subsequently identifies the risks that need to be remediated, audited, and reported on for that year. A risk assessment should lead organizations to create an attainable risk auditing and remediation plan. In order to effectively manage the countless risks, we have found it is best to first organize the risks into fairly broad categories, such as anti-kickback, claims development, EMTALA, etc. Therefore, we identify 10-12 broad risk categories and then select targeted areas within those categories. Otherwise, it is very difficult and overwhelming to try to deal with 100-200 separate risk areas.
- **Step 2: Risk remediation**

  We identify the second (Development of compliance policies and procedures), third (Developing open lines of communication), and fourth (Appropriate training and education) elements of compliance effectiveness as part of risk remediation. After the risks have been identified in the risk assessment process, necessary steps need to be taken to install the proper internal controls to mitigate the organization's vulnerability to those risks. The primary internal controls are usually clear, well-written policies and procedures. We urge clients to employ a criteria/condition matrix that compares all the applicable laws and regulations to a given risk area (e.g., EMTALA), and compares the requirements with policies in place at the client's facility. Sometimes there is a perfect match and at other times, polices need to be amended or new policies need to be developed. In addition to facilitating risk remediation, this process also helps in evaluating your organization's policies and procedures.

  Risks are also identified and remediated through the reporting hotline, other internal communication mechanisms, and investigations. Additionally, risks are considerably lessened when staff are trained and educated on compliance risks and on the proper protocols for identifying and alleviating those risks.
- **Step 3: Risk auditing**

  This function, which is congruent with the fifth element (Internal monitoring and auditing), requires an effective monitoring and auditing function that verifies whether the internal controls, established as a result of risk remediation efforts, are working properly in reducing vulnerabilities. The results of these audits should also be reviewed during the next risk assessment process. Furthermore, any detected deficiencies brought to light through this step should be appropriately handled through the next step of the compliance process.
- **Step 4: Risk response and reporting**

  Just as with risk assessment, this last step has not received the kind of attention it deserves. Part of the reason for this inattention is that this step encompasses a part of multiple elements: (1) The first element, when the compliance staff provides necessary and continuous feedback to the Board so they may take appropriate action, (2) the third element, when suspected wrong-doing is reported through the hotline or through other communication channels in good faith, (3) the sixth element, (Response to detected deficiencies), when potential issues are promptly investigated and corrective action plans are developed, and (4) the seventh element (Enforcement of disciplinary standards), when disciplinary action is taken when it should be and enforced consistently throughout the organization. We view this function as critical in responding to problems as they arise, and an important prevention measure to mitigate potential compliance violations.

The guidance provided by the U.S. Sentencing Commission, OIG, and other federal agencies has been invaluable in assisting clients with their compliance programs. The seven elements are particularly instructive and provide a great framework for health care entities. Nevertheless, clients have difficulty accomplishing the seven elements and have expressed the need for a clearer process to follow. We believe that after establishing a solid compliance structure, health care entities can follow a logical, four-step process that will assist them in meeting the seven elements of an effective compliance program. ■

1 United States Sentencing Commission Organizational Guidelines http://www.ussc.gov/orgguide.htm
2 OIG Supplemental Compliance Program Guidance for Hospitals www.oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf