

An Overview of Methods to Assess Compliance Program Effectiveness

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The Compliance Auditing and Monitoring Focus Group of the Health Care Compliance Association (HCCA) and Association of Healthcare Internal Auditors (AHIA) members continue to explore opportunities to improve compliance auditing and monitoring capabilities. Their goals are to clarify the roles and responsibilities of compliance and internal audit functions, achieve greater leverage of combined resources, and improve effectiveness as they address issues within their health care organizations. The focus group has developed guidance and reference materials on key aspects of healthcare auditing and monitoring processes, including the Seven Component Framework for compliance auditing and monitoring, which comprises the following activities:

- Perform a risk assessment and determine the level of risk
- Understand laws and regulations
- Obtain and/or establish policies for specific issues and areas
- Educate personnel on policies and procedures and communicate awareness
- Monitor compliance with laws, regulations, and policies
- Audit the highest risk areas
- Re-educate staff on regulations and issues identified in the audit

Assessment of Compliance Program Effectiveness

This article is intended to provide an overview of the history and importance of compliance program effectiveness assessment and to outline methods currently available to measure, benchmark, and improve the overall effectiveness of your organization's

compliance program. There will be a companion article in HCCA's *Compliance Today* that will provide an in-depth focus on practical tools, techniques, and peer review methods that can be used to complete an assessment or self-assessment of compliance program effectiveness.

Organizations should commit to assessing the effectiveness of their compliance program.

Compliance programs play an important role in helping health care organizations fulfill their obligations to governing boards, senior management, public and private payers, lenders and bondholders, and the organization at large. Compliance programs are important because:

- The regulatory environment in which health care organizations operate is exceedingly complex and constantly changing;
- Organizations have a fundamental obligation to patients and the public to ensure participation in government and private reimbursement systems; and
- Healthcare organizations have a duty to operate in a manner consistent with applicable laws, regulations, and contractual obligations.

Creating an effective compliance program requires the ongoing commitment of the organization,

including its leadership, people, information systems, and processes, to comply with applicable laws and invest the necessary resources for compliance-related activities.

Why is Effectiveness Important?

All organizations need to know if the resources invested in their compliance program activities are sufficient and are, in fact, working effectively to identify and mitigate risks outlined in the organization's compliance plan, compliance committee charter, and other key documents. The effectiveness of an organization's compliance program is of increasing interest to the governing boards, the organization's senior management team, and the corporate compliance committee, as well as the employees, medical staff, and volunteers of the organization. Additionally, the organization has many external entities interested in the effectiveness of the compliance program, including external (independent) auditors, the Department of Health & Human Services Office of Inspector General (OIG), financial rating agencies, the media/public, accrediting bodies, and the patients being served.

Government Emphasis on Compliance Program Effectiveness

The federal government has promoted the importance of compliance program effectiveness over the past eight years via several agencies and written guidance. From 1998 through 2004, OIG issued compliance program guidance for a number of health care-related service lines. The *Supplemental Compliance Program Guidance for Hospitals*, issued by the OIG in January 2005, further recommended that hospitals review the implementation and execution of their compliance program elements at least annually and outlined specific risks and

mitigating actions to check for under each of the seven elements.

In 1999, the Government Accounting Office (GAO) issued a key report to Congress titled *Medicare: Early Evidence of Compliance Program Effectiveness is Inconclusive* that started the effectiveness ball rolling. The report concluded:

“In addition to stepping up enforcement actions, HHS-OIG, HCFA [Health Care Financing Administration (renamed CMS in 2001)], and Justice have all encouraged the adoption of compliance programs in the hopes of reducing improper Medicare payments. The voluntary compliance of hospitals and other Medicare providers is crucial to reducing the improper payments that continue to plague the program. Although determining the prevalence of such programs is difficult, there is a consensus among providers and agencies that these programs are becoming more widespread. Furthermore, despite the investment of time and resources that compliance programs entail, many hospitals believe the benefits of these programs—particularly reduced liability under the fraud and abuse statutes—outweigh their costs. Finally, while the effectiveness of compliance programs is difficult to determine with certainty, HHS-OIG, HCFA [Health Care Financing Administration, now part of CMS], Justice, and providers themselves believe that compliance programs can reduce improper Medicare payments.”¹

In 2004, the United States Sentencing Commission amended the Federal Sentencing Guidelines and strengthened the criteria for an effective compliance and ethics program in order to synchronize the guidelines with best practices as reflected by more than a decade of guidelines’ application within organizations, the Sarbanes-Oxley Act of 2002, and other relevant regulatory and administrative initiatives. Highlights of these revisions included strengthening the linkage between compliance and ethics, updating and strengthening the criteria for an effective compliance and ethics program, and addressing the needs of small organizations. Increased emphasis was placed on risk assessments and their relevance to each of the seven key components of an effective compliance program. The 2004 amendments also articulated compliance program responsibility for the organization’s governing authority

and spelled out compliance training requirements. The Commission also made it explicit in the 2004 amendments that the implementation and successful maintenance of an effective compliance and ethics program requires that organizations periodically assess the risk of criminal conduct.²

The Centers for Medicare and Medicaid Services (CMS) *Pilot Project on Compliance Program Effectiveness* was launched in 2004 with sixteen hospitals in six states volunteering to participate. The study was designed to assess the effectiveness of hospital compliance programs by tying the elements of a compliance program to data outcomes. The CMS pilot endeavors to show whether particular actions by a health care provider, such as aggressive auditing and monitoring, have a direct impact on their billings resulting, for example, in lower claim denial rates. At the end of the pilot, CMS will issue best practices guidance detailing the findings of the pilot and educating the provider community on effective compliance practices identified through the pilot.³ Some preliminary observations from site visits and completion of a survey tool are available on the CMS Web site (<http://www.cms.hhs.gov>) in a 2005 presentation titled *CMS’ Compliance Effectiveness Pilot*. Formal results of the pilot project were unveiled at the April 2007 HCCA Compliance Institute in Chicago.

HCCA Resource Paper: Evaluating and Improving a Compliance Program (January 2003)

At the same time the healthcare compliance industry was learning more about how the federal government viewed compliance programs, HCCA issued a key resource paper⁴ entitled *Evaluating and Improving a Compliance Program, a Resource for Health Care Board Members, Health Care Executives, and Compliance Officers*. As stated on HCCA’s Web Site, the intention of the document was to provide added value by identifying and sharing information and best practices regarding the operation and evaluation of compliance programs. The document was not intended to be a list of standards but was viewed to be a reference that could be tailored to meet the specific needs of one’s organization.

Six indicators are defined in the paper:

1. Policies & Procedures,
2. Ongoing Education & Training,
3. Open Lines of Communication,
4. Ongoing Monitoring & Auditing,
5. Enforcement & Discipline, and
6. Investigation, Response & Prevention.

For each of the six indicators the following is discussed:

- Rationale
- Relevant issues
- Implementation
- Role of compliance officer, management, and board
- Evaluation and measurement

For evaluation and measurement, the paper advocates analyzing two dimensions: effort and outcomes. Effort is defined as the time, money, resources, and commitment that an organization puts into building and improving a compliance program; outcomes are the impact that the efforts have on the organization’s level of actual compliance.

Current Assessment Options

Periodic evaluation of a compliance program’s effectiveness is well established and, in fact, is expected by an increasing number of governing boards. Several options are available for conducting an assessment. One of the challenges is recognizing that generally accepted standards for compliance program effectiveness are still in their infancy and none are *universally* accepted, either by healthcare compliance organizations or by the government. Options currently available include:

- Internal review — self-assessment or conducted by the Internal Audit department
- Professional consulting firm
- Peer review
- Government review — voluntary
- Government review — involuntary

Self Assessment or Internal Audit

Having your organization’s Internal Audit department review the compliance program’s effectiveness has advantages

¹ GAO/HEHS-99-59 Corporate Compliance Programs: Medicare: Early Evidence of Compliance Program Effectiveness is Inconclusive. 1999.

² Paula Desio: An Overview of the Organization Guidelines. Deputy General Counsel, United States Sentencing Commission. 2004.

³ CMS Press Release: *CMS Strengthens Efforts to Reduce Fraud and Abuse in Medicare, Medicaid*. August 27, 2004.

⁴ HCCA: *Evaluating and Improving a Compliance Program, a Resource for Health care Board Members, Health care Executives and Compliance Officers*, 2003. Available at: <http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/EvaluationImprovement/default.htm>

and disadvantages. Having internal audit professionals from your own organization perform the review will generally be easier to coordinate and complete and will likely be less costly than hiring outside professionals. Internal audit staff's familiarity with your organization's operations provides two advantages. First, the internal auditor can interact directly with other departments, such as Human Resources and Counsel's Office,

Creating an effective compliance program requires the ongoing commitment of the organization.

to obtain the needed information to perform the review. With external groups, the compliance department would be required to take on a more active role in coordinating all meetings and assisting with providing information required for the peer review. Secondly, the internal auditors may be better able to provide recommendations for improvement that are more realistic for your organization. External auditors often do not understand how or why some operations are centralized or decentralized, so the recommendations made can be unrealistic, based on a misunderstanding of how an organization operates.

The primary disadvantage to having internal audit perform the compliance peer review is that they will not likely be as knowledgeable of compliance best practices as a compliance professional from a consulting firm or a compliance peer professional who has knowledge across the industry of similar and dissimilar organizations. The specifics of required compliance program elements, the myriad of external regulations, and the non-financial aspects of an effective compliance program require a knowledge base that your internal auditors may not have. In addition, having internal auditors perform some of the compliance-related audits may cause independence issues, because they would have to audit themselves. Internal audit professionals

focus on risks across the financial, operational, information technology, and compliance spectrum, and therefore, often have a broader, less detailed knowledge of compliance risks. It is likely that resources from the compliance program would be required to educate the internal audit staff on the functions of an effective compliance program.

Engaging a Consulting Firm

Various healthcare consulting firms offer services that include conducting compliance program effectiveness reviews. Conducting an Internet search for *compliance program effectiveness* brings up a lengthy list of possible companies. These consultant reviews may vary in name from a Compliance Program Effectiveness Evaluation or simply a Compliance Program Assessment. Although the intent of this article is not to convince readers to use or not use a consulting firm to review your compliance program, we have included some practical tips and lessons learned, based on the experience of members of our compliance auditing and monitoring focus group. The primary advantage of engaging a consulting firm is the breadth of industry knowledge they can provide. The primary disadvantages are less familiarity with your organization and cost.

A starting point to identify possible firms is to consult with your peers in the industry and find out who they have used and why, as well as who they did not use and why. When you have narrowed down the list to a few possible consulting firms, there are several important facts to consider before making the final selection:

- Do the firm's personnel have the requisite qualifications to assess your organization? For example, do they have relevant experience for your organization's lines of service?
- What is the firm's level of experience in conducting compliance program reviews? Were their customers pleased with the process and deliverables? Ask for references and check them.
- Does the firm have established and tested methods to adequately assess program effectiveness? Can you review the components of the assessment before engaging the firm?

Preparation for review will most likely require providing compliance

program-related materials for the firm to review prior to coming on site. The on-site review will typically last three to five days and usually will include interviews with key individuals and stakeholders.

The benefits of having a consulting firm conduct an external compliance program review include (1) the undisputed independence of the assessment, (2) an enhanced level of assessment credibility, if the review is conducted by a reputable firm, and (3) knowledge of best-practices from the organizations they have reviewed, depending on the experience level of the firm selected, including how these organizations effectively structured their programs. This breadth of knowledge about multiple compliance programs, including what works and what doesn't work, should allow the consultants to provide recommendations and that will actually enhance your program.

The disadvantages in using an outside consulting firm include the selection process itself, the due diligence, and time required to ensure that the best firm for your organization is selected. The other major potential disadvantage is the cost of an external review, especially compared to an internal review or peer review that will have comparably very little cost. The determination of the return on investment for the external assessment may be difficult to calculate.

Using Peer Review

Dictionary.com defines peer review as: *evaluation of a person's work or performance by a group of people in the same occupation, profession, or industry.*⁵ NonprofitHub.com has a slightly different definition: *a peer review is the review of a product by an individual or agency with similar backgrounds as the creator of the product.*⁶ Conducting a peer review using experienced compliance professionals brings first-hand knowledge of the most current compliance processes, techniques, and best practices. Advantages of peer review are two-way in that the review can address the interests of the reviewer(s), as well as those being reviewed. Peer reviews have also been used relatively successfully in both the external and internal audit professions, and are required by the standards governing those professions.

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⁵ Peer Review. Dictionary.com Unabridged (v 1.0.1). Random House, Inc. 11 Dec. 2006. <Dictionary.com [http://dictionary.reference.com/browse/peer review](http://dictionary.reference.com/browse/peer+review)>.

⁶ Peer Review. NonprofitHub.com. <http://www.nonprofitHub.com/peer-review.htm>

out the insurer on their promise to pay? If a supplier or GPO does not provide the cost savings it claims, would failing to call them out on their claim of savings not be equivalent to allowing an insurer to pay less for a procedure they agreed to cover?

In any business venture there are only two ways to protect the bottom line: sell more at a higher price or spend less. Increasing reimbursement is difficult and hospitals cannot exactly create more business by causing pileups on the interstate. Meanwhile, the worker shortage and increasing union activity is pushing up the cost of labor. Most hospitals are severely underutilizing their supply chain savings potential. By providing a check on savings claims the internal auditor can help their management see through the smoke and

Sources of Cost Savings

Definition

1. Product Cost
2. Rebate
3. Supplier Grants
4. Outsourcing
5. Product Cost Avoidance
6. Value Analysis
7. Inventory Reduction
8. Other Savings

Data Source

- Supplier Invoice
- Rebate Check
- Grant Check
- Department P and L
- Proof of Increase
- Supplier Invoice
- Calculation of Carrying Costs
- Financial Analysis

understand the urgency in fully exploiting the real savings opportunities in their supply chains. **NP**

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Peer review of a compliance program is a viable option, which the author has personally participated in, and will be the subject of the next focus group article.

Governmental Review—Voluntary or Involuntary

As described earlier, sixteen hospitals have voluntarily subjected their compliance programs to review as part of the *CMS Pilot Project on Compliance Program Effectiveness*, launched in 2004. Compliance programs can also be involuntarily reviewed when an organization is dealing with a government agency on a significant compliance issue(s) or as part of a self-disclosure of provider misconduct. Resolution of the issue may lead to imposition of a Corporate Integrity Agreement (CIA) or Certification of Compliance Agreement (CCA). During settlement negotiations, the organization will no doubt be asked to provide information about the compliance program. The organization's goal is to prove that their program is effective.

The relevant considerations for whether an entity may be permitted to enter into a CCA instead of a

comprehensive CIA include those set forth in the November 20, 2001 Open Letter to Health Care Providers.⁷ This letter directed that eight criteria be considered when determining whether to require a corporate integrity agreement, including "(7) whether the provider has an effective compliance program..."

Conclusion

An effective compliance program is an expectation of governing boards and senior management, as well as a clear articulation by the federal government. It is a significant business risk for an organization to have an ineffective compliance program and not know it. Organizations should commit to assessing the effectiveness of their compliance program this year to help set expectations and as a governance process best practice. One way to formalize such an assessment would be to add a requirement for a periodic assessment of the compliance program to the corporate compliance committee charter.

About the AHIA/HCCA Focus Group

The AHIA/HCCA focus group will continue to address compliance auditing

and monitoring directives through white papers, articles, and educational initiatives. The focus group welcomes your feedback and requests to address particular matters related to auditing and monitoring. Please submit your request directly to any member of the focus group. **NP**

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⁷ "An Open Letter to Health Care Providers". DHHS, Office of Inspector General. November 20, 2001.