HCCA

**HEALTH CARE
COMPLIANCE
ASSOCIATION**

6500 Barrie Road · Suite 250 · Minneapolis, MN 55435 · (888)580-8373 · www.hcca-info.org

January 24, 2003

Dear HCCA Colleagues:

On behalf of the HCCA Board of Directors and the many volunteers from across the country who served on the HCCA Compliance Performance Measurement Initiative Task Force and its Steering and Drafting Committees, we are pleased to announce the release of the following document, "**Evaluating and Improving a Compliance Program, A Resource for Health care Board Members, Health care Executives and Compliance Officers.**" This resource is now available to all HCCA members and other interested parties on the public section of the HCCA website at **www.hcca-info.org**.

This document is the product of an extensive collaborative process and reflects hundreds of volunteer hours of research, meetings, drafting, collaborative discussions, decades of collective professional experience, as well as the important feedback received from the HCCA membership through surveys, interactions at meetings and finally, through comments received during a 45-day review and comment period.

We trust that this document will provide added value by identifying and sharing information and best practices regarding the operation and evaluation of compliance programs. While principally developed for the benefit of HCCA members, this reference is intended to be a useful guide to all health care compliance professionals. Nevertheless, it is important to note that this document is not intended nor should it be used as a "cookbook" or "list of standards." One size certainly does not fit all. As a reference, you should use and tailor this information to meet the specific needs of your organization and to better inform your board members, senior management and executives.

This document will also serve as the foundation for the next steps in HCCA's continued efforts to provide practical tools to you, our members, to assess the performance of compliance programs within health care organizations. Recognizing the complexity and variety of compliance issues within different health care industry sectors, the HCCA Board has assigned the task of developing specific performance measurement tools for different health care industry sectors to the HCCA Compliance Focus Groups (CFG's), e.g., Health Systems CFG, Home Health CFG, Pharmaceutical CFG, etc. The CFG's will provide an appropriate and useful forum to attract volunteers and their ideas to tailor and customize these tools to fit specific industry sector needs. We encourage you to volunteer your time and ideas and join the CFG that represents your sector of health care. *Become part of the solution – join a CFG today*! For more information on HCCA's CFG's, please contact HCCA at (888) 580-8373, via email at info@hcca-info.org, or visit the HCCA website at hcca-info.org.

With best regards,

L. Stephan Vincze, J.D., LL.M., CHC   Sheryl Vacca
Chairman, Compliance Performance Measurement   Immediate Past President, HCCA
Initiative Task Force   Chair, Drafting Committee
Chairman, HCCA Pharmaceutical Compliance Focus Group   HCCA Board Member
HCCA Board Member

Evaluating and Improving
A
Compliance Program

A Resource
For Health Care Board Members, Health Care Executives and Compliance Officers

Table of Contents

PREAMBLE

The goal of the HCCA Compliance Performance Measurement Initiative is to improve the quality and effectiveness of compliance programs by identifying and sharing information regarding the operation and evaluation of compliance programs.

Due to the complexity and volume of health care regulations and the relative infancy of compliance programs in health care organizations, management and governing bodies frequently have questions about compliance programs. Are we focused on the right issues? Is the program addressing our principal risks? How much should we spend? Are we deriving maximum value from our efforts? How do we evaluate the quality and effectiveness of our program? While this document does not provide definitive answers to these questions, it is intended to assist governing bodies, management teams, and compliance officers in health care organizations in evaluating and improving compliance activities. In short, this document is provided by the HCCA as a tool to help an organization determine whether the resources it devotes to compliance are effectively, efficiently and appropriately utilized.

Simply stated, the objective of a compliance program is to create a process for identifying and reducing risk and improving internal controls. Stated another way, from a legal enforcement standpoint, an effective compliance program reduces the likelihood that an organization will be found to have recklessly disregarded or deliberately violated the law. The aim of this document is to be a fluid guide to common indicators and recommended best practices for compliance programs, not a collection of rigid standards. In rare instances we have taken the position that a particular action or practice is an essential component of an effective compliance program. In most instances however, what the organization is advised to do depends on its size, resources, business activities, and past behaviors. We recognize and emphasize that "one size does NOT fit all." Compliance activities are best tailored to the unique needs and risks of the organization. The common indicators identified in this document will not be applicable or appropriate for every organization and even those common indicators that are relevant may need to be adjusted or modified by the organization to achieve the objective of compliance.

Nevertheless, investigative and enforcement entities have consistently stated that a compliance program should be judged, at least in part, by how it compares to programs of similarly situated organizations. The HCCA believes that this document will help governing bodies, management teams, and compliance officers effectively evaluate compliance programs and serve as a useful tool in the effort to improve the quality and efficiency of compliance activities.

While the HCCA initiative is conducted principally as a benefit and service to HCCA members, the work of this initiative will be shared with other interested public and private parties in a sincere effort to promote greater understanding and progress in the field of health care compliance.

The HCCA Compliance Performance Measurement Initiative Task Force and Committee Members are:

<u>Task Force</u>

Steve Vincze, Chair   Lori Richardson Pelliccioni
Odell Guyton   Roy Snell
William Heffron   Sheryl Vacca
Lewis Morris   Alan Yuspeh

<u>Steering Committee</u>

Lisa Murtha, Chair   Jeff Oak
Al Bothe   David Orbuch
Steve Brannan   Steve Ortquist
Suzie Draper   Dan Roach
Rory Jaffe   John Steiner

<u>Drafting Committee</u>

Fred Entin, Co-Chair   William Tillett
Sheryl Vacca, Co-Chair   Debbie Troklus
William Mitchelson   Mark Watson
Glen Reed   Howard Young
Brent Saunders

Introduction

We live and operate in an era of risk. Nowhere is this truer than in the health care industry. While we have decades of experience in the development of programs to address risks associated with patient care, infectious diseases, workplace injuries, and natural disasters, most health care organizations have only recently recognized the seriousness of the risk posed by non-compliance with the complex laws that govern business practices in health care, like the False Claims Act, fraud and abuse, tax and antitrust laws. Many organizations have begun implementing compliance programs to address these risks and to answer new challenges like those posed by the Health Insurance Portability and Accountability Act, "HIPAA."   Recent, highly publicized failures of corporate governance have raised questions regarding the role of governing bodies and increased the emphasis on promoting and enhancing board oversight.

Compliance programs play an important role in helping health care organizations fulfill their obligations to public and private payers, shareholders or bondholders, and the community at large. Health care organizations have recognized that such programs are important because the regulatory environment in which we operate is exceedingly complex, and we have a fundamental obligation to our patients and the public to ensure that our participation in government and private reimbursement systems and the operation of our health care organization is consistent with applicable laws and regulations.

What Is A Compliance Program?

In its simplest terms, a compliance program is <u>a systematic process aimed at ensuring that the organization and its employees (and perhaps business partners) comply with applicable laws, regulations, and standards</u>. In the context of health care, it usually includes a comprehensive strategy to ensure the submission of consistently accurate claims to federal, state, and commercial payers. It frequently includes an effort to adhere to other applicable laws and regulations relating to the delivery of health care products and services. Some programs go beyond these areas and address antitrust, environmental, tax and other laws as well. However, the principal focus of most compliance programs is on health care specific laws.

In a general sense, a compliance program has two basic components - <u>structural</u> and <u>substantive</u>.

- The <u>structural component</u> includes the basic framework necessary to build and operate an effective compliance program. The structural component includes those elements articulated by the Office of the Inspector General as necessary elements of a compliance program. These elements would typically be included in any compliance program, regardless of the substantive legal or regulatory issues the organization is trying to address. Generally, a program would include <u>standards (policies and procedures)</u>, <u>high-level oversight</u>, <u>reporting</u>, <u>employee screening</u>, <u>education</u>, <u>auditing/monitoring</u>, <u>enforcement</u> and <u>prevention</u>.

- The <u>substantive component</u> relates to the specific body of substantive law (Medicare, Medicaid, anti-kickback, Stark, insurance, ERISA, tax, antitrust, environmental, privacy, etc.) with which the organization is attempting to comply. Organizations frequently develop policies and education programs that explain to affected employees the obligations that the law imposes upon them in the performance of their particular job function. For example, if the Medicare program requires patient care providers to document patient care and treatment, an organization would seek to ensure that its patient care staff understands the documentation requirements. Similarly, where services must be provided by properly licensed and approved providers, care would be taken to ensure that providers

are properly qualified and enrolled. Also, health plans comply with laws governing mandated benefits, appeals and grievance procedures and timely claims payment.

A compliance program is much more than a policy communicating the organization's intent to comply with the applicable laws. In order to be effective, the compliance program must be designed in a manner which:

- Addresses the organization's business activities and consequent risks;

- Educates those persons whose jobs could have a material impact on those risks;

- Includes auditing and reporting functions designed to measure the organization's actual compliance and the effectiveness of the program, and to identify problems as quickly and as efficiently as possible;

- Provides for the prompt remediation of problems which are identified; and

- Contains enforcement and discipline components that ensure that employees take seriously their compliance responsibilities.

Creating an effective compliance program requires the commitment of the organization to comply with applicable laws. It also requires a systematic effort (scaled to the size, resources, and complexity of the organization) to understand its principal legal obligations and risks and to make employees aware of how the relevant laws and risks impact the performance of their job functions. In addition, employees will be made aware of their obligation to be an active participant in the organization's compliance effort.

Compliance Program Foundation

In its various guidance documents, the Office of the Inspector General, "OIG," has spoken authoritatively on the basic elements of an effective compliance program. The Federal Sentencing Guidelines have defined an effective compliance program as "a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct."[1] Clearly, this requires more than just policy statements reminding employees of their obligation to obey the law. In fact, the Sentencing Guidelines discuss seven elements of a compliance program.

1. <u>Compliance Standards</u> "The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct." Comment 3.(k)(1).

2. <u>High Level Responsibility</u> "Specific individual(s) within high level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures." Comment 3.(k)(2).

3. <u>Trustworthy Individuals</u> "The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities." Comment 3.(k)(3).

---

1 Federal Sentencing Guidelines, §8.A.2.Comment 3.

4. <u>Education</u> "The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required." Comment 3.(k)(4).

5. <u>Monitoring and Auditing</u> "The organization must have taken reasonable steps to achieve compliance with the standards, by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution." Comment 3.(k)(5).

6. <u>Enforcement and Discipline</u> "The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific." Comment 3.(k)(6).

7. <u>Response and Prevention</u> "After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses -- including any necessary modifications to its program to prevent and detect violations of law." Comment 3.(k)(7).

Evaluation and Measurement

In recent years compliance professionals Boards and executive leadership of organizations that have implemented compliance programs, and enforcement officials who have an interest in compliance effectiveness have all wrestled with how to evaluate an organization's compliance efforts. Due to the relative infancy of such programs there is scant data of measurable and objective criteria on which to build an evaluation process.

As a practical matter, and in order to create a starting point for efforts to improve the quality and efficiency of compliance programs, we believe that a compliance program can be evaluated by analyzing two dimensions: <u>effort</u> and <u>outcomes</u>.

<u>Effort</u> is the time, money, resources and commitment that an organization puts into building and improving a compliance program. While effort by itself will not guarantee compliance, it is unlikely that outcomes will improve if the organization devotes inadequate time and resources to the task. Particularly in the first several years of a program, effort is one measure of effectiveness that an organization can use to assess its compliance program. How do the resources devoted to the program compare to similarly situated organizations (size and complexity)? Are we addressing the issues that create the greatest risk for similar organizations engaged in similar activities? Are we promptly refunding overpayments? Have we addressed the issues that the OIG has identified in its guidance documents?

<u>Outcomes</u> are the impact that our efforts have on our level of compliance. As the compliance program matures, the principle measure of effectiveness moves from effort to outcomes. If our processes are appropriate, patients receiving non-covered services in an outpatient setting will have first received an Advanced Beneficiary Notice or "ABN".   If our education efforts are adequate, coding will improve over time. If our screening is consistent, the frequency with which we discover that we have employed or

contracted with an excluded individual decreases. If our processes are adequate we will have fewer instances where employees fail to receive required training. Our claim denial rates will decline, the number of payments to physicians without an appropriate contract will fall, and we will consistently have documentation that supports the claims we have submitted.

Obviously, progress will not always be linear. Staff turnover or personnel shortages will occur, something will fall through the cracks, the rules will change, new reimbursement methodologies will be adopted (APCs, RUGs, Home Health PPS, Medicare + Choice), new rules will be adopted (Stark), and new laws will be enacted (HIPAA). Each of these events may temporarily slow our improvement. Similarly, efforts will not always be perfect. An issue may be overlooked, an employee may ignore the rules, or systems may temporarily fail us. In these instances we must show that we have moved promptly to address an issue we missed in the past, appropriately disciplined the individual who disregarded the rules, and corrected the mistakes caused by human error or system failure.

However, a compliance program that cannot demonstrate improvement in mitigating risk areas cannot be deemed effective. Many providers are beginning to develop measurement tools to objectively evaluate compliance programs. This document reflects some of the benchmarks or indicators that are in use and the HCCA will continue to gather and share these tools with the health care industry. In doing so, it is our goal to improve the quality and efficiency of compliance programs in the organizations we are honored to serve.

Scalability

Provider groups and representatives are understandably concerned about the time and effort required to implement, maintain and improve a compliance program. In many segments of health care, margins are razor thin if they exist at all. Providers are struggling with new government mandates, declining reimbursement, increasing numbers of uninsured, professional shortages, and technology challenges. The resources that an organization can devote to a compliance program are directly linked to both its size and its margins.

While many of the specific activities discussed in this document – and even in the federal guidance documents noted above – are relevant to most organizations, we recognize some activities will not work in all organizations. For example, comment 3(k)(5) suggests that organizations must have reporting systems, which employees and other agents may utilize "…without fear of retribution." The OIG suggests, and many organizations utilize, hotlines (staffed either internally or externally) designed to preserve the anonymity of callers. As a practical matter, anonymity is difficult if not impossible in the context of a small physician practice, which employs only a handful of people. Even if the caller did not identify himself or herself, it is unlikely that the members of the clinic would not be able to identify the source of the call. However, while anonymity may be a good idea in many contexts, the important element is that the clinic has a process in place, which encourages employees to articulate their concerns (e.g., through a suggestion/question box). The clinic should also have a mechanism to reasonably evaluate and address the concern, and a culture that assures employees do not suffer retaliation as a result of participating in the process.

In short, with rare exceptions, the components of an effective compliance program described in this document can be altered if they are not relevant to the organization or if they are impractical given the organization's size and structure. This document frequently suggests multiple alternatives for achieving a specific objective. Finally, this is the HCCA's initial effort in this regard, but certainly not the last.

Accordingly, this reference should be used as a "living document"—one that will evolve over time with advances made and lessons learned in the compliance profession. This document has been formally issued by the HCCA only after the HCCA Board, HCCA members, other interested persons and organizations, and government had a meaningful opportunity to review the document, provide comments and feedback and participate in collaborative discussions about how to make the document more useful. We fully expect that the quality and utility of this document will improve as we continue to gather information and comments from our members and other interested persons, review our practices, measure our programs and improve our understanding of the laws, our organizations and our profession.

Questions are frequently raised regarding the respective roles of the Compliance Officer, management, and the Board of Directors (or relevant Board committee) in the compliance process. The HCCA believes that it is the Compliance Officer's job to oversee the development and/or implementation of the compliance program, to monitor adherence to the program, and to assess the impact of the program on the organization's compliance (outcome). These duties would include the program structure, content, education programs, monitoring processes and other pieces of the program working with those in operations in the organization and appropriate resources (e.g., legal, human resources, procurement, billing, coding, reimbursement, and accounts payable) within and/or outside the organization. In an era of resource constraints, it is also the Compliance Officer's job to ensure that the program developed is as efficient as possible.

The role of management is to ensure that the Compliance Officer is provided adequate resources (taking into consideration the organizations size, risk, and resources) and to ensure that the program, once developed, is effectively implemented. Fundamentally, it is management's job to ensure that the program developed by the compliance function is properly implemented.

The role of the Board is to ensure that the organization has implemented a compliance program that is reasonably calculated to be effective. One purpose of this document is to help the Board (and management) understand the components of an effective compliance program and enable the Board to more intelligently and efficiently fulfill its responsibility.

We hope that the document is useful. If you have questions, suggestions or concerns, you can provide your comments to the HCCA at the following address: Attention Tracy Hlavacek, HCCA, 5780 Lincoln Drive, Suite 120, Minneapolis, Minnesota 55436.

Indicator #1 – Policies and Procedures

A. <u>Rationale</u>

In order to effectively operate a compliance program, an organization must generally develop written standards, policies and procedures designed to address its principal risks. These written standards communicate organizational values and expectations regarding employee behavior, explain the operation of the compliance program, clarify and establish internal standards for compliance with laws and regulations, and help employees understand the consequences of non-compliance to both the organization and the individual.

Health care law and regulations are very complex. Providers and other health care organizations must comply with thousands of pages of laws, rules, manual provisions and other requirements that are specific to health care alone. Most health care organizations must also comply with the same tax, antitrust, employment, environmental and other laws that apply to business organizations generally. Meeting this obligation is most effectively accomplished in organizations that have developed policies designed to guide employee conduct. These policies will distill relevant laws and regulations into clear, understandable direction for employees. They will help focus the employee's attention on the principal compliance pitfalls or risks the organization faces.

B. <u>Relevant Issues</u>

Building an effective compliance program does not require the development of hundreds or even dozens of policies and procedures. However, most compliance programs include policies and procedures that fall into three broad categories: (i) a Code of Conduct; (ii) policies relating to the operation of the compliance program; and (iii) policies addressing the organization's principal legal (substantive) risks.

The Code of Conduct is typically a document that sets forth in general terms the organization's commitment to comply with the law. It varies from one or two to more than 30 pages in length. It frequently includes statements or guidelines addressing the organization's principal legal risks, expectations relating to employee conduct, information regarding the organization's compliance program and instructions on how an employee can access the organization's reporting mechanisms (see Indicator # 3). It may outline fundamental expectations regarding employee behavior applicable to all employees. It is typically distributed to all employees upon commencement of employment.

Operational policies and procedures address the operation of the compliance program itself. Policies may address issues such as the compliance reporting structure in the organization, compliance education requirements, the operation of the hotline or other complaint mechanisms, how the organization will investigate complaints or problems, and how the organization will institute remediation efforts when issues are identified.

Substantive policies address the principal legal risks of the organization. As noted above, the volume of laws applicable to health care organizations is immense, and precludes policies on every issue. Consequently, most health care organization policies are focused on addressing applicable risk areas that have already been identified in the context of OIG guidance, fraud alerts, OIG workplans, or frequent enforcement actions. Organizations may also develop policies in response to specific issues identified in the course of the organization's own audits, investigations or other reviews and assessments.

C. <u>**Implementation**</u>

<u>Policies and Procedures</u>

1. The organization develops policies and procedures designed to address its principal business risks.

    - The organization has evaluated its principal risks.

    - The organization's policies address issues identified in guidance documents (e.g., OIG guidance, fraud alerts) or enforcement actions by the OIG and other government agencies whose legal requirements are applicable to the organization.

    - The organization's policies address previously identified serious weaknesses in its practices.

2. The organization develops policies that describe how the organization's compliance program operates and the consequences of non-compliance.

    - The organization has developed and distributed a Code of Conduct or similar document to all employees.

    - The organization has communicated alternative complaint mechanisms to employees.

    - The organization has a process in place to promptly address and rectify employee non-compliance.

3. The organization ensures that relevant employees and agents are promptly oriented to applicable new and revised policies and procedures.

    - The organization ensures prompt orientation to applicable policies for new employees.
    - The organization ensures prompt distribution of revised policies to existing employees.

4. The organization's policies and procedures are periodically reviewed and are updated to reflect changes in laws, regulations or processes.

5. The organization monitors adherence to its policies and procedures (See Indicator #4).

    - The organization reviews policies and procedures at regular intervals.

    - The organization has a process to monitor significant changes in law and modify policies as appropriate.

6. The organization appropriately disciplines employees who do not adhere to the organization's policies or procedures (See Indicator #5).

D. <u>**Role of Compliance Officer, Management and Board**</u>

1. Compliance Officer: advises organization on policies that may be required; oversees development, distribution and implementation of policies; assures that policies accurately and effectively communicate legal and regulatory requirements; periodically reviews policies and initiates needed updates.

2. Management: provides adequate resources (taking into account the organization's size, risk, resources and scope of the compliance program); participates in policy development to assure that policies will be consistent with operations and capable of being implemented and followed; implements policies by conforming operations to policy requirements.

3. Board: may serve as originator or final adopter of some written standards, such as the Code of Conduct (Compliance Officer will generally develop for the Board's approval and adoption); may monitor to assure that legal risks are addressed.

E. Evaluation and Measurement

1. Effort

- Do policies and procedures exist for relevant topics and areas?

- Has a risk assessment been completed to identify the relevant risk areas?

- Are the policies comprehensive?

- Are policies understandable and capable of being fully applied?

- Have the requirements of the policies and procedures been communicated to employees?

- Have any audits been conducted to monitor compliance with the policies and procedures?

2. Outcome

- Have audits revealed fewer errors in areas where policies have been implemented?

- Upon testing, are the internal controls established by policies working?

- When interviewing employees during an audit or review, do they understand what the policies require?

Indicator #2 – Ongoing Education and Training

A. Rationale

Internal standards in the form of a Code of Conduct and compliance policies are useful in initiating the process of explaining health care laws and regulations, and establishing processes for compliance within an organization. However, to promote understanding of these internal standards and of the requirements of external laws and regulations, an organization's compliance program should include an active education and training program. An effective compliance training program will generally provide ongoing education and training specifically designed for management employees, non-management employees, and non-employed business associates. Training will generally be designed to provide an overview of compliance program activities and requirements that is appropriate to the audience (e.g., information needed by management is generally distinct from that needed by non-management employees).   Specific training is generally also provided to address legal and regulatory requirements that impact the performance of each significant category of job function within the organization (e.g., physicians, billing staff, admission staff), and provides information on how to raise questions.

The existence of an education and training program is an important component of compliance programs for a number of reasons, including the following:

- To promote understanding of and compliance with relevant federal, state and local laws and regulations.

- To enable implementation of the compliance program's policies and procedures and ensure that employees understand their role in the compliance process.

- To demonstrate the organization's commitment to compliance and ensure that commitment is carried out throughout the organization.

- To communicate the effect that industry standards and governmental requirements have on an organization's business activities and to improve skills for identifying potential compliance issues.

The overall benefit to an organization from an ongoing compliance education and training program is constant reinforcement of an organization's commitment to compliance and the expectation that everyone working for or affiliated with the organization is an integral part of the compliance effort. In addition, employees develop an understanding of the legal and regulatory requirements that most directly impact their specific job function.

B. Relevant Issues

Education and training programs typically include information regarding how the organization's compliance program operates (structure) and as well as information on specific laws and regulations (e.g., reimbursement, coding, prompt payment requirements, etc.) that impact the organization (substantive). Education also frequently includes a discussion of the consequences of non-compliance, (e.g. recoupment, fines, penalties, exclusion) for both the organization and the individual.

C. Implementation

1. Common Structural Education Topics

   - Why the organization is implementing the compliance program

   - The organization's commitment to compliance

   - The necessity of adhering to the organization's policies and procedures as well as applicable laws and regulations

   - The duty of employees to report concerns or misconduct

   - A description of the organization's compliance program including reporting/complaint mechanisms and the organization's commitment to non-retaliation

2. Substantive Education Components

   In the health care delivery, context education should include, a description of key substantive laws and regulations that affect the employee's job function. This education obviously varies for different employee groups but frequently includes information on such topics (as applicable and by way of example only) as:

   - admitting/registration requirements
   - documentation requirements
   - privacy/confidentiality issues
   - coverage and billing rules
   - cost report preparation

   - medical necessity
   - charge entry risks
   - coding requirements
   - EMTALA
   - licensure/qualification requirements

   In addition, employees are typically provided with information regarding the consequences of violations of the various laws (e.g., false claims act(s), Stark, anti-kickback) that may be imposed on individuals or organizations. This typically includes discussion of fines, penalties, exclusion and other remedies that may be imposed on an offending entity or individual.

   Those individuals in the management/administrative roles or those involved in negotiating, drafting or administering arrangements with other providers or business partners are also frequently provided education regarding laws which may impact provider relationships with referral and payment sources as well. These may include (as applicable and by way of example), anti-kickback laws, Stark laws, tax laws, and other laws.

   Compliance training strategies include the entire range of traditional and emerging education programs. Lectures, videos, interactive CDs or Internet training, and other self and group study methods are utilized. These training sessions typically are part of an ongoing process and repeated on a regular cycle. Training sessions typically occur for both new and existing employees with appropriate revisions to the training content as the rules change or at regular intervals. The frequency of the training or length of the training interval depends on the directness of the link between the employees' job and principal risks of the organization, the

frequency of rule changes in the context of the employee's job functions, and the level of non-compliance in the particular area to which the education applies.

Education can be one of the most expensive components of a compliance program. In addition, development of education and training programs can be difficult as some organizations lack the expertise to develop those training programs internally. However, for the small organization there are a number of resources where education can be obtained free of charge or at relatively nominal prices. In addition, hospitals and other larger providers are frequently willing to assist the small physician practices in a community in compliance education efforts, a practice encouraged by the OIG in its compliance guidance for hospitals.

D. Role of Compliance Officer, Management and Board

1. Compliance Officer: develops training programs that suit the unique needs of the organization, assuring that training accurately reflects and communicates legal and regulatory requirements; develops and implements tracking mechanisms to document attendance at and/or completion of required training.

2. Management: provides necessary funding to support compliance training program; enforces training requirements among the organization's staff; provides necessary accountability measures to support the mandatory nature of compliance training requirements.

3. Board: reviews periodic (e.g., annual) reports on status of completion of compliance training requirements throughout the organization; periodically reviews compliance training plan to confirm that necessary training is being provided.

E. Evaluation and Measurement

1. Effort

- Organizational policies require employees to receive periodic training and education regarding the organization's compliance program.

   - Percentage of employees who receive training regarding the organization's compliance program promptly following commencement of employment.

   - Percentage of employees in higher risk roles who receive specific, job related education designed to reduce the incidence of non-compliance in the department or function at intervals established by the provider.

- The organization evaluates the roles of its agents and provides education (or requires the agent's organization to provide education) if such agents directly impact the organization's compliance.

- The organization can demonstrate it has evaluated the role of non-employee agents and contractors and assessed the need to ensure they are adequately trained.

- The organization has a plan to train those non-employee agents or contractors who are determined to need training.

- The content of the education and training addresses the operation of the compliance program and the substantive legal issues that most directly impact the organization's risk and the employee's duties.

  - The organization has engaged in an assessment of its most significant risks by reviewing applicable OIG guidance, fraud alerts and work plans, through consultation with health care counsel or other experts, or by some other mechanism (consistent with the organization's size and resources) reasonably calculated to identify its principal risks.

  - The organization has a process to monitor changes in laws and regulations relating to its greatest risk areas and modifies education content as appropriate.

- The organization assesses the effectiveness of its education efforts by utilizing tests, which evaluate employee comprehension and measure impact on job processes, or some other mechanism designed to ensure the training is effective.

  - Failure to fulfill compliance education requirements is grounds for an employee's discipline up to and including termination.

- The organization consistently ensures that employees complete required education and takes appropriate steps where employees do not.

2. Outcome

- The organization has documentation that training and education of employees has occurred.

- The organization and its Compliance Officer have documentation that proves that policies and procedures and the Code of Conduct have been distributed to all applicable employees. Frequently, organizations will have a tear out sheet in the back of the Code of Conduct and will request that individuals simply sign the form and send it to the Compliance Officer upon receipt of the Code of Conduct.

- There is documentation in employee files showing discipline for employees who do not complete training or who do not return the receipt of the Code of Conduct.

Indicator #3 – Open Lines of Communication

A. Rationale

Compliance programs operate most effectively in organizations that encourage employees and business partners to report suspected wrongdoing so that it can be investigated and properly addressed. An organization's compliance efforts will be less effective if only a small number of individuals are willing to confront impropriety, than if the majority of employees are empowered to report their concerns. As an organization increases its numbers of employee-watchdogs, it will be better able to identify possible violations early and more immediately initiate investigation, determine the materiality of violations and, if necessary, implement the appropriate corrective action. An organization that encourages open communication will be more effective at identifying risk areas on which to concentrate its performance improvement efforts.

To achieve an open environment, employees at every level of the organization must believe that their good faith report of possible non-compliance will be taken seriously. They must be assured that the organization will not tolerate retaliation. They must be confident that if an investigation confirms impropriety, it will be appropriately addressed. Creating an environment where open communication about suspected misconduct is encouraged often requires ongoing affirmative efforts by those with leadership responsibility for the compliance program.

B. Relevant Issues

The creation and maintenance of mechanisms to encourage and facilitate candid communication are frequently components of an effective compliance program. The following issues are generally considered and addressed in an organization's compliance program strategy:

- Creation of an environment in every segment of the organization within which employees feel free to report concerns, questions, and instances of improper conduct without fear of retribution or retaliation.

- Provision of a mechanism for confidential or anonymous reporting for employees who are uncomfortable reporting concerns to a supervisor or to the compliance officer.

- Tracking, documentation and oversight mechanisms to ensure that reports of suspected non-compliance are fully and timely investigated and addressed.

- Mechanisms to assure that management and the board are properly and regularly apprised of, and can take appropriate action on, issues identified in investigations that resulted from reports of non-compliance.

The clearly articulated expectation of open communication needs to permeate all levels of the organization. Board members, executive leadership, and the Compliance Officer need to promote the message that they expect everyone to adhere to a "culture of compliance" and give the assurance that reported issues and concerns will be acted upon.

C. Implementation

1. Creating a Culture of Open Communication. To create a culture of open communication, organizations typically address some or all of the following issues in compliance program literature, organizational policies, training programs or otherwise:

   - Organizations often require employees and other associates at all levels of the organization to report compliance concerns, significant legal risk questions, and suspected or actual misconduct, and to allow this reporting requirement to be satisfied by a report to a supervisor, a compliance officer, or to the organization's confidential reporting mechanism.

   - Organizations with compliance programs communicate and publicize the existence, intent, process, and mechanisms available for raising compliance concerns.

   - Communication mechanisms used for clarification (both external and internal), questions or education can be the same mechanisms as those used for reporting potential concerns and issues.

   - Compliance programs typically explain how employees and those affiliated with the organization can expect reported concerns to be handled.

   - The Compliance Officer and compliance department staff often publicize their availability to receive reports of non-compliance from employees and others affiliated with the organization.

   - Managers and supervisors receive formal communication on their responsibility to respond appropriately and honestly when possible wrongdoing is brought to their attention. They are often trained on how to respond to questions and concerns and their responsibility to relay reports of non-compliance to the Compliance Officer.

   - Generally organizations adopt, publicize and enforce a no-tolerance policy for retaliation or retribution against an employee or associate who reports suspected compliance violations or misconduct.

2. Establishing Confidential/Anonymous Reporting Mechanisms.
   Establishing a variety of reporting mechanisms can be an effective way to demonstrate the organization's desire that potential compliance issues be reported. Independent, confidential mechanisms outside of more traditional reporting methods (i.e., directly to supervisor, human resources, etc.) may give reluctant employees greater assurance when making reports.

   - Independent mechanisms may include hotlines, suggestion boxes, employee exit interviews, e-mails, and other forums that promote information exchange.

   - Reporting mechanisms need to be convenient to employees and those associated with the organization. This may mean having at least one mechanism that is available at all times.

   - Assurance of confidentiality, except where disclosure of identity is required by a legal obligation to resolved discovered non-compliance may also be important.

- Those reporting should be provided with clear information about what they may expect after reporting a suspected compliance issue (i.e., timely response, striving to preserve confidentiality, progress reports if appropriate).

3. Documentation of Compliance Related Reports. Compliance Officers will be able to more efficiently and accurately manage the compliance program if they have developed a formalized means to document and track reported questions and concerns.

   - Establishing a process to document and track reported concerns, including the status of related investigations and corrective action, may improve an organization's efficiency in resolving reports and preventing or correcting ongoing non-compliance.

   - Confidential intake forms can be used to record an initial report of a potential compliance issue.

   - Thorough documentation of corrective actions implemented, disciplinary measures imposed, and any overpayments returned should generally be maintained in conjunction with the organization's tracking mechanisms.

   - The tracking process may be housed and maintained manually or may be automated to facilitate referral, trending and reporting.

4. Reporting to Board and Executive Leadership. Regularly informing an organization's Board and executive leadership of reported concerns will foster the culture of open communication, and will allow organizational leaders to respond appropriately to risks or improprieties that are identified through the organization's reporting mechanisms.

   - An organization's executive leadership, compliance committee, and Board of Directors often receive statistical and trending information on reports or inquiries received through compliance reporting mechanisms. Reports and inquiries may be categorized by area of concern, seriousness of allegation, and otherwise, to allow organizational leaders to assess whether trends in use of the reporting mechanisms or in organizational operation or behavior suggest that improvements may be required.

   - Reports to executive leadership and/or to the Board often include specific reports on areas of material legal risk or significant breaches of policy or misconduct that have been identified, and the status of necessary corrective action steps.

   - An aging of reports and inquiries, from date of receipt by the compliance office, to date of resolution, may be maintained and reported periodically to organizational leaders to assure that inquiries and reports are investigated and addressed in a timely manner.

D. Role of Compliance Officer, Management and Board

1. Compliance Officer: establishes and maintains reporting mechanisms; manages response to reports, including determining when investigation may be required; reports regularly to the

Board and executive leadership on reports and inquiries received; assists in setting a tone and creating a culture of open communication.

2. Management: primarily responsible for creating a culture of open communication by responding appropriately when reports are received; works with the compliance officer as needed to investigate reported concerns; executive leadership and/or compliance committee provides oversight and receives regular reports on trends or issues identified.

3. Board: provides oversight and receives regular reports on trends or issues identified; assists in setting a tone by mandating a culture that promotes open communication and assures effective response.

E. **Evaluation and Measurement**

1. Effort

- Do the necessary communication policies exist and have they been implemented and maintained?

- Are reporting mechanisms appropriate to the size of the organization (i.e., suggestion boxes in smaller facilities vs. continuously available hotlines in larger, more geographically diverse, organizations)?

- Is the reporting mechanism available to all levels of the organization and to those affiliated with the organization?

- Are reporting mechanisms publicized throughout the organization?

2. Outcome

- Is analysis being conducted on reports to determine whether response is timely and thorough?

- Is there a trending of questions, issues raised or potential misconduct to direct where the organization should be focusing its efforts?

- Have employees been surveyed to evaluate their knowledge of the reporting mechanism?

- Does evidence show that there is a confidence in the reporting mechanism?

Indicator #4 – Ongoing Monitoring and Auditing

A. Rationale

Effective compliance programs include proactive monitoring and auditing functions that are designed to test and confirm compliance with legal requirements and with the organization's written compliance standards. These functions serve to test compliance with internal policies and procedures and with federal, state and local laws, regulations and rules. As such they may assist an organization's compliance activities by identifying possible misconduct or criminal activity.

Self-evaluation that occurs as a result of a compliance auditing and monitoring program is often critical in identifying areas where compliance standards have not been fully understood or fully implemented. An effective monitoring and auditing program may allow an organization to correct any oversight or resulting non-compliance before it creates significant risk to the organization.

The auditing and monitoring function of the compliance program can also be used to test the completion and effectiveness of functions at the heart of the compliance program, such as compliance training programs, employee and vendor screening, or whether disciplinary action is occurring and is appropriate. This function also provides a unique opportunity for a compliance program to measure and benchmark its own effectiveness.

Compliance audits are typically structured to test compliance in a finite cross section or functional area of the organization. It is, therefore, generally possible to repeat the same audit periodically, and thereby to measure not only the organization's current level of compliance, but also its progress in attaining higher levels of compliance as the compliance program matures.

B. Relevant Issues

Compliance guidance documents often use a variety of terms when referring to the auditing and monitoring components of a compliance program. An *audit* is typically a more formal review of compliance with a particular set of internal (e.g., compliance policies) or external (e.g., laws and regulations) standards. Audits are typically conducted by individuals who are independent from the area being audited—usually compliance department staff or outside auditors. *Monitoring* refers to reviews that are repeated on a regular basis during the normal course of operations. An organization may monitor its activities as part of a corrective action plan, to assure that corrections implemented continue to be effective. Monitoring may also be initiated when no specific problems have been identified to confirm and document ongoing compliance.

Prospective audits occur before billing, allowing an organization to correct discovered errors before submitting the bill. *Retrospective audits* occur after billing and may require an organization to correct discovered errors by re-billing or self-disclosing to a payer or to the government. A *baseline audit* is typically the initial audit in a series of identical audits, and as such establishes the baseline against which progress measured by future audits is compared. A *risk assessment* is typically a broad based audit that may be used to identify opportunities for improvement either before development of the compliance program or workplan or periodically thereafter.

Critical issues to consider in developing an auditing and monitoring program include:

- Comprehensive programs typically include a variety of both auditing and monitoring functions.

- Properly trained and independent audit resources are key to a successful compliance audit program. Will the organization use internal or external resources? Does the organization have existing internal resources with necessary expertise and independence from the areas to be audited? At what level will the organization support budget allocation for a compliance audit program?

- Compliance auditors must be given authority to conduct audits and access to documents and other information needed to complete the audit process.

- The most effective compliance audit programs review operations in areas where the organization is at risk. The results of past internal reviews may help identify what risk areas an organization should focus on, or which areas may no longer require the same amount of attention. Patient/member satisfaction surveys can quickly point to risk areas, as can patient/member complaint logs, payment denial logs and other indicators. An organization should also review its compliance plan within the context of recent government issuances such as the OIG's annual Work Plan, Fraud Alerts, Bulletins and other guidance documents.

C. Implementation

1. Developing an auditing and monitoring plan.
   Organizations typically develop an auditing and monitoring plan, setting out the areas that will be the focus of auditing or monitoring activity for a given period of time, such as a calendar or fiscal year.

   - An Organizations' monitoring and auditing plans are often constructed based upon a review of risk areas that are generic to all health care organizations, in addition to those risk areas specific to the organization itself.

   - Past organizational performance, patient complaints or satisfaction surveys, and guidance from the Office of Inspector General (e.g., OIG Work Plans and Fraud Alerts) are examples of resources that an organization uses to identify issues for audit.

   - Consideration of the organization's audit budget and audit staff resources are critical to developing a workable auditing and monitoring plan.

   - Issues that have previously been discovered and corrected by the compliance program should generally be included in the organization's monitoring and/or auditing plan, especially in periods immediately after they were discovered and corrected.

   - The auditing and monitoring plan may include review of compliance with substantive internal (e.g., compliance policies) and external (e.g., an intermediary's local medical review policies) standards; and of operational components of the compliance program (e.g., the OIG database screening process).

- The methods used for each monitoring and auditing activity should be documented so that auditing and monitoring functions can be repeated in the future if that becomes necessary.

2. Conducting auditing and monitoring activities.

- To the extent practicable, an organization's compliance audit activities should be conducted by audit personnel who have expertise in the areas being audited, and who are independent from the activities being reviewed.

- Monitoring activities may be conducted by independent audit staff or by operational staff responsible for compliance in the area that is being audited.

- Findings from auditing and monitoring activities should be reported as appropriate to the compliance officer, to the organization's management, and to the board.

3. The method of review.
   Organizations may collect information using a variety of methods to increase their ability to identify improper procedures or activities. Methods of review that organizations might use include:

- Site visits

- Interviews of personnel in areas such as management, operations, coding, claim development and submission, patient care and other activities

- Questionnaires given to a cross-section of employees

- Reviews of records and source documents, such as medical and financial records that support claims for reimbursement and Medicare cost reports

- Reviews of written materials and documentation prepared by departments not included in the current review or audit.

- Trend analyses or longitudinal studies that identify deviations, positive or negative, in specific areas over a given period of time

4. Addressing adverse findings.

- When auditing or monitoring activities identify opportunities for improvement or compliance failures, it is often appropriate and/or necessary to take corrective action to address the findings. When corrective action is taken, follow-up auditing and/or monitoring should be conducted to confirm the effectiveness of the corrective action.

- Findings of significant noncompliance are generally promptly reported to the organization's internal management and the Board of Directors.

- Organizations promptly evaluate (usually in consultation with legal counsel) whether there is an obligation to report the existence of misconduct that may violate criminal, civil or administrative law to the appropriate governmental authority within a reasonable time after discovery. (In some instances, violations may be so serious, as to warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation.)

- Not all instances of errors necessitate the initiation of a formal disclosure process. For example, clerical or inadvertent billing errors with no apparent pattern are different from intentional "upcoding" or deliberate overbilling.

D. **Role of Compliance Officer, Management and the Board**

1. Compliance Officer: establishes auditing and monitoring plan; oversees compliance audit functions; continuously reviews organizational risk areas to identify necessary auditing and monitoring activities; assists management with formulation of corrective action plans and oversees and/or verifies implementation of corrective action.

2. Management: works cooperatively with compliance officer to facilitate compliance audit activity; conducts or oversees monitoring activities of operations in manager areas; works with compliance officer to implement corrective action as required by adverse audit findings.

3. Board: is accessible to receive reports of severe adverse audit findings from the compliance officer; periodically reviews summary reports of audit findings; assures that compliance officer has adequate resources to conduct an adequate auditing and monitoring program.

E. **Evaluation and Measurement**

1. <u>Effort</u>

- Is the organization conducting a regular auditing and monitoring program consistent with the size, complexity and scope of its business operations?

- To the extent possible, are audit staff responsible for conducting compliance audits independent from the areas of the organization that they are auditing?

- Does the organization have a written compliance auditing and monitoring plan that includes subject, method, and frequency of audits?

- If any major findings were made, was senior management and/or the Board notified as appropriate in a timely manner?

- When appropriate, have government agencies been notified of adverse finding in a timely manner?

- Have written corrective action plans been produced and followed when adverse findings were made?

- Are overpayments promptly refunded?

- Are audit plans built on organizational history?

- Have audit results been disseminated to the appropriate groups for corrective actions?

2. Outcome

- Do the results of audits indicate that the organization understands and is complying with internal and external laws, regulations, rules and policies?

- Does analysis of the results of repeat audits indicate an upward trend of improvement in the organization's understanding of and compliance with internal and external standards?

Indicator #5 - Enforcement and Discipline

A. Rationale

There are significant risks when health care organizations fail to meet the requirements and legitimate expectations of their stakeholders. Compliance programs play a key role in helping organizations to fulfill this obligation in the legal, regulatory and policy arenas. In so doing, an effective compliance program can assist an organization in earning and maintaining public trust.

The effectiveness of an organization's compliance effort is generally tied directly to its ability to affect the conduct of each individual in or associated with the organization. In many instances the compliance program's success will be achieved one individual at a time. Building and maintaining meaningful structures of accountability is critical to this effort. When compliance failures occur, there must be a process for enforcing compliance standards and for disciplining responsible individuals when discipline is appropriate. Enforcing standards and disciplining the individuals who violate them underscores the organization's commitment to compliance.

B. Relevant Issues

- There are a number of relevant issues to consider when building enforcement mechanisms and disciplinary procedures. To assist in enforcement of standards, effective compliance programs generally include a process for identifying individuals and organizations whose background indicates a tendency toward improper conduct. Effective organizations generally avoid employing or contracting with such individuals or entities.

- A communication strategy that results in clear communication of enforcement and disciplinary standards throughout the organization will bolster the effectiveness of a compliance program.

- Communicating a commitment to compliance is most credible when this commitment clearly states that *all* individuals involved in the work of the organization—regardless of position or status—are accountable for compliance, are subject to the same disciplinary standards, and are expected to fully participate in the compliance effort. One important element of full participation that should be emphasized is that reporting potential compliance failures is a duty of all employees and business partners.

- Enforcement of standards generally requires establishing an effective working relationship between the compliance program and the functional areas of the organization that have primary responsibility for administering discipline.

- Effective enforcement and discipline requires an investigative process capable of substantiating alleged compliance failures (see Indicator #6).

- Oversight by an organization's compliance committee or another appropriate body may bolster effectiveness by enhancing the organization's ability to demonstrate that discipline is proportionate, and is administered fairly and consistently.

C. **Implementation**

1. Screening employees and business partners. Effective compliance programs include a process for avoiding relationships with individuals or entities that have a tendency toward inappropriate conduct. This process generally includes some or all of the following:

   - Review of Office of Inspector General's (OIG) list of individuals and entities that are excluded from participation in government health care programs, and of the General Service Administration's (GSA) list of individuals and entities that are excluded from participating in government contracts.

   - Criminal record checks when appropriate or as required by state law.

   - Standard reference checks.

   - Review of the National Practitioner Databank.

2. Tying compliance standards to existing disciplinary processes. Because discipline is generally carried out by, or in accordance with, standards developed by other functional areas within the organization, compliance standards are typically tied to existing disciplinary processes.

   - Compliance program documents and an organization's disciplinary policy for employees generally cross-reference each other to facilitate progressive discipline of employees pursuant to existing human resources policy and procedure.

   - Medical staff bylaws, credentialing/privileging programs and vendor contracts are often written or amended to require compliance with an organization's compliance standards, and to facilitate temporary or permanent removal from an organization's medical staff upon violation of compliance standards.

   - Medical staff bylaws, credentialing/privileging programs vendor contracts, and the organization's policies allow an organization to immediately terminate any medical staff member, vendor or employee who is excluded by either the OIG or GSA. Generally these same documents require any individual or organization that is excluded on the OIG or GSA lists to immediately notify the organization of the exclusion.

3. Communication of enforcement and disciplinary standards. The compliance program includes processes for communicating enforcement and disciplinary standards to employees and business partners.

   - An expectation that all employees and business partners will report suspected unlawful activities or compliance violations is generally communicated throughout the organization.

   - Employees and business partners are informed that violation of compliance standards may result in appropriate discipline, up to and including termination, of employment, medical staff or contract relationship with the organization.

4. Oversight of compliance discipline.

- Records of discipline for compliance violations are generally maintained and reviewed periodically by the organization's compliance committee or other appropriate oversight body to promote consistency and fairness.

D. Role of the Compliance Officer, Management and the Board

1. Compliance Officer: assists organization in developing appropriate standards for discipline and enforcement, and in tying compliance standards to functional areas within the organization that are responsible for administering discipline; establishes and implements a communication strategy to assure that enforcement and discipline standards are understood throughout the organization; maintains records of discipline resulting from compliance violations and reports periodically to the compliance committee and/or other oversight body.

2. Management: assists compliance officer in communicating standards for enforcement and discipline throughout the organization; works with compliance officer to assure that contracts, policies and procedures, and other controlling documents include appropriate ties to compliance standards so that the organization will be able to take appropriate disciplinary action when needed; generally responsible for carrying out discipline of employees and others within their area of responsibility.

3. Board: may periodically review aggregate data on enforcement and discipline to verify that compliance standards are being followed within the organization.

E. Evaluation and Measurement

1. Effort

- Does the organization have policies and procedures addressing enforcement of compliance standards and discipline of individuals who violate them?

- Does the organization screen employees and business partners before initiating a relationship and periodically thereafter to assure that they have not been excluded by the OIG or GSA?

- Are enforcement and disciplinary standards communicated throughout the organization?

- Is compliance an element of performance reviews and incentive compensation decisions?

2. Outcome

- Percentage of success in meeting the reporting requirements of Corporate Integrity Agreements (CIA's)

- Percentage of success in meeting audit recommendations

- Does a review of disciplinary actions taken as a result of compliance failures indicate that discipline is consistently and fairly administered

- Percentage of employees who satisfy the compliance elements of their performance reviews and incentive compensation decisions

Indicator #6 – Investigation, Response and Prevention

A. Rationale

While compliance programs are intended to promote adherence to applicable substantive laws and regulations, situations may still arise where conduct inconsistent with legal requirements is reported, suspected or even confirmed. An effective compliance program will include a process by which the organization can respond to these actual or potential violations.

B. Relevant Issues

When an instance of potential non-compliance is reported or suspected, an effective compliance program will generally take some or all of the following steps:

- Promptly halt the non-compliance and halt or mitigate to the extent possible any ongoing harm caused by the suspected non-compliance.

- Fairly and expediently investigate to determine the existence, scope and seriousness of the non-compliance, and to identify the underlying conduct or process that caused the non-compliance.

- Respond with appropriate corrective action to confirmed non-compliance.

- Implement preventative measures to avoid similar instances of misconduct in the future.

This document outlines a number of proactive measures that an organization can take to promote and facilitate compliance with laws and regulations. However, an organization's timely and thorough response to discovered impropriety may be the most accurate barometer of the organization's compliance culture.

C. Implementation

The following practices related to response and prevention of non-compliance are often found in effective compliance programs:

1. An investigation protocol outlining how the organization will respond to reported, suspected, or confirmed non-compliance. The term "investigation" is often used as shorthand to describe the various responses an organization might take to address known or suspected misconduct. Depending on the circumstances involved in the suspected misconduct, an investigation may be merely an informal inquiry, or it may involve more formal steps like a detailed audit of claims. As part of its compliance efforts, an organization should consider establishing and operating according to written protocols or policies for conducting investigations. Such protocols or policies may address some or all of the following:

    - Who in the organization is responsible for and authorized to determine (1) whether the suspected non-compliance and related circumstances warrant an investigation, and (2) what form the investigation will take.

- A system of checks and balances to ensure that decisions to abstain from initiating a formal investigation are reviewed by other objective individuals.

- The role and/or qualifications of those who may be involved in conducting an investigation, including:

  - Requirements for requisite experience and/or substantive knowledge level, and
  - Requirements for assuring the objectivity of investigators and avoiding conflicts.

- Guidelines or policies for determining when legal counsel or external experts should be involved in an investigation.

- A requirement that investigations be conducted in a timely fashion and a process for accountability and oversight to assure that this requirement is met.

- A process for tracking progress on and the status of an investigation.

- Proper safeguards for preventing the inappropriate or inadvertent disclosure of confidential information that is obtained in or is part of the investigation.

- Processes for securely maintaining evidence obtained in an investigation.

- Requirements for documentation that internal investigators must maintain, which generally should include a description of the issue(s) investigated, the source of the allegation(s), a summary of evidence considered, and the final disposition of the investigation.

- Record retention requirements for investigative reports and files. (Reports summarizing the investigation's findings along with the underlying evidence relied upon to reach investigative conclusions should be governed by the organization's document retention policies.)

- Clear delineation of who has the authority to close an internal investigation.

- The organization's processes for reporting findings of investigations to appropriate oversight or governing bodies.

2. <u>Responding to discovered non-compliance with appropriate corrective actions</u>. Appropriate response to discovered non-compliance might require an organization to take affirmative steps to address the non-compliance and to correct any harm that may have been caused by the non-compliance. Corrective actions steps that are frequently used in health care organizations include any or all of the following:

- Discipline or termination of employees or agents who intentionally or recklessly caused the non-compliance (see Indicator #5);

- Repayment of identified overpayments; and

- Self-reporting of the non-compliance to law enforcement or regulatory officials.

In developing a compliance program, an organization may want to develop written protocols that set out specific steps to be followed in each of these broad categories of corrective action. These protocols may include a process to enable independent verification that necessary corrective actions have been completed, and a requirement that all corrective action taken must be appropriately documented.

3. <u>Responding to discovered non-compliance with preventative measures and monitoring</u>. After determining the causes of discovered non-compliance, measures should be developed and implemented to prevent future recurrences, and appropriate monitoring is instituted to assure that preventative measures are operating effectively. Preventative measures may include some or all of the following:

- Identification and repair of any internal control or management deficiencies that may have caused or contributed to the non-compliance;

- Additional education in those departments that contributed to the deficiency.

- Identification of and appropriate response to any deficiencies in competency or qualifications that may have contributed to the non-compliance;

- Development and/or modification of policies, procedures or systems to address the deficiencies involved in the non-compliance; and

- Identification and repair of similar deficiencies that may be causing risk of similar non-compliance in other areas of the organization.

In addition to any other preventative measures, an effective response to identified non-compliance will include appropriate monitoring of ongoing activities to assure that preventative measures have effectively eliminated recurrence of the non-compliance. This monitoring may be incorporated into the organization's auditing and monitoring program (see Indicator #4 above) or may be addressed separately. Generally, the Compliance Officer or his designee will be directly involved in monitoring for compliance during the months immediately following implementation of preventative measures.

4. <u>Reporting investigation findings and outcomes to appropriate oversight bodies.</u>
Findings of investigations and outcomes of corrective action and prevention plans should be regularly reported to appropriate managerial and governing bodies. Compliance programs generally include one or more of the following reporting protocols:

- Regular reports to a compliance committee composed of individuals from upper management on the status and progress of ongoing investigations;

- Regular reporting to key members of upper management (e.g., CEO, CFO) who are not members of the compliance committee on the status and progress of ongoing investigations;

- Tracking and reporting to appropriate managerial and/or governing bodies on the amount of time that elapses between the opening and closing of an investigation;

- Periodic reporting to the Board of Directors or to a designated committee of the Board (e.g., the Audit Committee) of the status and progress of ongoing investigations that involve serious violations of law or significant risk to the organization.

The minutes of all governing or managerial bodies receiving reports on the findings, status and outcomes of compliance investigations should appropriately reflect oversight of the compliance program's investigative activity.

5. Involving legal counsel in response and prevention.
   The purpose of a compliance program is to prevent violations of law and to ensure that if inadvertent violations occur the organization responds appropriately. Competent legal counsel can assist an organization in achieving these ends by providing legal advice, and by assisting in the development of the investigative plan and the organization's subsequent response to an investigation's findings. Organizations should consider involving legal counsel any time that suspected non-compliance may involve criminal misconduct, civil law violations, or significant overpayment liability.

   One benefit of involving legal counsel in response and prevention is that communications between the attorney and the organization may be subject to the attorney-client privilege, and investigative work conducted at the direction of counsel may be protected by the attorney work product privilege. These privileges should not be used by the organization to avoid taking necessary corrective action steps. However, they may prove valuable in assuring that resolution of discovered problems is equitable and just.

6. Appropriate response to government inquiries and investigations.
   Effective compliance requires that an organization respond in a lawful and appropriate manner upon learning of a government investigation of the organization's activities. Appropriate response to government investigations requires:

   - Preserving (i.e., preventing alteration or destruction of) any written or electronic materials that are or could reasonably be known to be the subject of a government investigation;

   - Notification of organizational leaders when a government inquiry is initiated;

   - Appropriate response by employees who are contacted directly by government investigators. (Employees should be advised that they may speak with investigators but are generally not obligated by law to do so; that they may be entitled to have an attorney present if they do speak with investigators; and that the organization is willing to work with investigators and the employee to schedule an interview at an appropriate time. The organization should never direct employees not to speak with government investigators.)

   An organization may wish to develop written policies or protocols that address each of these areas of response to government investigation or inquiry.

D. Role of Compliance Officer, Management and Board

1. Compliance Officer: primarily responsible for overseeing or performing independent investigations and for documenting investigative efforts; reports findings of investigations to management and the Board as required by organizational policy; recommends corrective action and prevention strategies for adoption and implementation by management and/or the board as appropriate.

2. Management: responsible for cooperating in investigations of reported non-compliance; commits appropriate resources to conduct of investigations and to corrective action and prevention measures.

3. Board: oversees compliance efforts by receiving and assessing reports of findings and progress of internal investigations, and of corrective action and prevention measures; assures that it benefits both from the recommendations of the Compliance Officer and from the advice of counsel when corrective action may require report of the non-compliance to outside parties including the government.

E. <u>Evaluation and Measurement</u>

1. <u>Effort</u>

    - Has the organization developed a process for investigating reports of suspected non-compliance?

    - Has the organization developed a process for responding appropriately to discovered non-compliance?

    - Are the findings, status and outcomes of internal investigations reported regularly to appropriate oversight and management bodies? Do these bodies record their oversight of the organization's investigation, response and prevention activities in their respective minutes?

    - Has the organization developed written policies or protocols for responding to government investigations?

2. <u>Outcome</u>

    - Can the organization demonstrate that ongoing harm is halted promptly upon discovery of confirmed non-compliance?

    - Does an aging of closed and ongoing investigations demonstrate that the organization is promptly resolving reports of suspected non-compliance?

    - Are the organization's corrective action responses to investigations consistent with legal requirements and with the recommendations of relevant regulatory agencies?

- Do the organization's monitoring efforts indicate that preventative measures taken in response to non-compliance are effective in eliminating future instances of similar non-compliance?

—