Interview with Gene DeLaddy

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REGISTER TODAY!
FOR THE HCCA COMPLIANCE INSTITUTE, CHICAGO, IL–APR 25-28, 2004 - For registration info go to the HCCA Website, www.hcca-info.org, or see page 31 of this issue.
Dear Colleagues:

Welcome to the 2004 Compliance Institute, and for those of you that could not make it, we hope to see you in New Orleans in 2005.

The compliance profession continues to remain in the spotlight in health care, but we are now beginning to see more fortune 500 companies discussing the cost associated with the development of compliance programs. It is important for you to know that HCCA is doing what it can to make sure compliance continues its growth as a profession. Most recently, HCCA’s Executive Committee submitted comments to the United States Sentencing Commission on proposed amendments to the U.S. Sentencing Guidelines. As you know HCCA does not participate in any advocacy activities, but in this instance we were able to respond to the commission’s request for comments and provide them with our observations as the nation’s largest association of compliance professionals.

Given that compliance-related topics are appearing frequently in all types of news media, I would encourage each of you to make sure you are taking advantage of this opportunity to promote your compliance program within your own organization. As Boards and their respective committees consider their response to Sarbanes-Oxley, make sure you have a place at the table. Without question, both for-profit and non-profit organizations are making changes in response to Sarbanes-Oxley and compliance programs can provide the infrastructure to implement those changes. When I first started in this profession and people asked what I did for a living I would always get a strange look when I answered, but more recently the response has been a nod of recognition.

As we all work to establish compliance as a profession, HCCA needs your help. As you know there is strength in numbers not only for the opportunities and benefits it provides you as a member of the association, but as a way of acknowledging the number of individuals and organizations that are committed to ensuring effective compliance programs. Help us grow our membership by encouraging your peers to become members of HCCA.

In closing, I want to thank Steve Orquist and his 2004 Compliance Institute Planning Committee for their hard work in putting together this year’s institute. Their work planning the 2004 Compliance Institute began in April of 2003, and as they will acknowledge, it takes a full year of effort to organize a conference of this size. Thanks again for a job well done!

Compliance Today wants you!

Please email your article or topic ideas to Compliance Today editor, Margaret Dragon, at mrdragon@ziplink.net. Be sure to include your telephone number. Or call Margaret at 781/593-4924 to discuss your article ideas. Some topic ideas to consider: compliance and the Board, HIPAA compliance education and training, EMTALA compliance, conflicts of interest, and attorney/client privilege.
The Calendar OnON

### Resources

**HCCA**

**SITES & SCENES**

from HCCA’s Southwest Area Meeting, February 20th, 2004

![Image](image_url)

**April 2004**

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**2004 CONFERENCES:**

(See page 5 for upcoming audioconferences)

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For more information about events or resources, check out the HCCA Website, [http://www.hcca-info.org](http://www.hcca-info.org) or call 888/580-8373.

- Monitoring & Auditing Practices for Effective Compliance
- HCCA’s Compliance, Conscience, and Conduct™, a video-based compliance training program
- HCCA’s book, Compliance 101
- Individual & Small Group Physician Practice Compliance:
- What every physician should know
- Privacy Matters—HCCA’s video-based HIPAA Training Program
- HCCA’s CD Videos -
  - Alice Gosfield-Unplugged (with 2 HCCB CEUs)
  - HIPAA Forum Digital Reference CD (with 20 HCCB CEUs)
- Physician Group Practices Compliance Conference (with 3.6 HCCB CEUs)
HCCA’s Mission: HCCA exists to champion ethical practice and compliance standards in the health care community and to provide the necessary resources for compliance professionals and others who share these principles.

Board Leadership

Deliver services to members locally
- HCCA will provide high quality, local, inexpensive educational and networking opportunities for the membership.

Recruit and retain members
- HCCA will broaden the current health care membership base and minimize attrition.

Establish and enhance compliance as a profession
- HCCA will position the profession as a unique, valuable, and respected component of senior management.

Develop resources for members proactively
- HCCA will broaden the menu of learning resources for both experienced and new compliance staff.

Diversify and grow revenue
- HCCA will develop new sources of revenue to reduce reliance on conferences and membership dues.

Broaden the HCCA vision
- HCCA will explore the wisdom and feasibility of expanding its mission beyond health care.

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- HCCA will establish and maintain strong working relationships with all government and non-government enforcement entities.
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Get the latest “how to” information—tools you can implement—without even leaving your office! Register on the HCCA Website—www.hcca-info.org. Once payment is received you are registered and will receive an email a few days before the conference with any conference handouts and contact phone number and instructions.

➤➤ HIPAA Security
   Speakers: Frank Bresz, Michael McDermad and Nancy Scott
   March 10 and 12

➤➤ Health Care Privacy and Confidentiality Disputes, Administrative, Civil and Criminal Developments
   Speakers: Edward Shay and Ronald Levine
   March 23 and 24

➤➤ HIPAA Research Repositories
   Speakers: Linda Malek and Marti Arvin
   April 6

➤➤ JCAHO and Privacy
   Speakers: John Knapp and Joette Hanna
   April 8 and 9

Be on the lookout for:

➤➤ Cardiac Rehabilitation Centers

➤➤ Data Access and Analysis
   Hospital and Physician Focuses

➤➤ Coding Initiative FY 2005

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The pharmaceutical industry has always been a highly regulated industry with the Food and Drug Administration (FDA) being the key agency providing oversight. The FDA is responsible for establishing regulations based on the Food, Drug, and Cosmetic Act. Some of its activities include reviewing applications and approving drugs for market, enforcing manufacturing requirements, and regulating the information that a pharmaceutical company is allowed to provide to the public about its products. This has typically led to well established compliance functions for clinical and manufacturing practices within the Pharmaceutical industry.

As trends go in the life sciences and health care industries, the limited compliance focus is expanding and commercial activities (especially sales and marketing practices) are now coming under greater regulatory scrutiny. Such activities have been and will continue to be the target of government investigations and regulatory bodies have begun to target the pharmaceutical industry’s commercial and promotional activities. The time is ripe for establishing a compliance program for commercial and promotional activities.

The Pharmaceutical Research and Manufacture’s of America (PhRMA) recognized risks in this area and effective July, 2002 adopted a voluntary Code on interactions with health care professionals with respect to marketed products and related pre-launch activities. Then, on May 5, 2003 the Office of Inspector General published the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. The Guidance contains all the elements of a compliance program that it has historically included in its compliance guidance and also identifies specific risk areas.

The language of the federal anti-kickback law is very broad. It can be applied to a wide range of business practices, especially sales and marketing, within the pharmaceutical industry that may encourage the prescription or purchase of pharmaceutical and other medical products. Potential risk areas related to the sales and marketing business practices of the pharmaceutical industry identified in the OIG Guidance include:

identifies kickbacks as a specific risk area for pharmaceutical manufacturers. The federal anti-kickback law prohibits knowing and willful solicitation, receipt, offer, or payment of remuneration in cash or kind to induce or in return for:

1. referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid program or other federal government funded healthcare program, or
2. purchasing; leasing or ordering; or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item payable under the Medicare or Medicaid program, or other federal government funded healthcare program.

The language of the federal anti-kickback law is very broad. It can be applied to a wide range of business practices, especially sales and marketing, within the pharmaceutical industry that may encourage the prescription or purchase of pharmaceutical and other medical products. Potential risk areas related to the sales and marketing business practices of the pharmaceutical industry identified in the OIG Guidance include:
ducting ongoing monitoring to ensure that current risks are identified and corrected or managed while future risks are mitigated.

**Risk identification**

When identifying and prioritizing risk areas, some important things to consider include: current regulatory scrutiny and government investigations, internal assessment of perceived risks, the relative amount of promotional spending, and the pervasiveness of the activity.

The following steps outline a risk identification process:

1. Assess current regulatory environment. Assess for key areas of risk that pertain to your organization including all levels; locally, nationally, and globally.
2. Perform an internal risk assessment to identify any perceived risks by the organization’s management team. This can be accomplished through interviews, focus groups, management surveys, and other related activities.

**Note:** When conducting its risk assessment, an organization may consider using the following evaluation criteria:

- Whether the organization has established compliance standards with each substantive area
- Whether the organization has established mechanisms to audit for compliance with the areas under review
- Whether important information regarding a department’s compliance with the requirements in these areas is communicated up through the chain of command within the organization; and
- Whether the selected department’s documentation and/or the results of the review demonstrate any substantive problems within the scope of the review

3. Prioritize the risk universe established taking into consideration the current regulatory environment, the organization’s resources (fiscal and personnel), and the organization’s culture, vision, mission and strategic focus.

4. Define the timeframe for review or audit of risk. Give consideration to the organization’s resources along with the severity of the risk. High risk areas will require immediate attention, review and mitigation.

5. Validate risk at a basic level of the business process by comparing business practices to existing policies and procedures, industry standards and benchmarks, internal audit standards, and any other applicable standards.

6. Determine the measure or severity of risk identified and necessity for immediate remedial corrective action or whether a “timed” corrective action plan could be implemented. Assign accountability for corrective action.

With all this attention directed to the pharmaceutical industry’s commercial practices it is imperative that pharmaceutical and biotechnology organizations have effective compliance programs in place. These programs will not be unlike existing manufacturing compliance programs except that they will apply to the commercial/promotional activities of the organization. The program should include all seven elements of a compliance program as described in the OIG Guidance including having written standards (policies and procedures) and conducting ongoing monitoring to ensure that current risks are identified and corrected or managed while future risks are mitigated.

**Discounts, product support, educational grants, research funding, and other relationships with purchasers and their agents**

**Payments to PBMs, relationships with formulary committee members, formulary placement payments, and other formulary support activities**

**Relationships with physicians and others who can make or influence referrals or prescribe drugs including switching arrangements, consulting payments, business courtesies, and educational funding**

**Sales agents and the manufacturer’s commitment to training and monitoring of the sales agents**

- Whether the selected department’s documentation and/or the results of the review demonstrate any substantive problems within the scope of the review

Continued on page 8
Risk management
Identifying risks through a compliance monitoring program is crucial to risk management. A compliance monitoring program, as recommended by the OIG Guidance and by the Federal Sentencing Guidelines issued by the U.S. Sentencing Commission in 1991, should utilize audit and monitoring concepts designed to assess whether activities conducted by an organization’s commercial operations are in compliance with the organization’s established standards and to detect violations by the organization’s employees and other agents. Monitoring should take two forms—routine compliance reviews and investigations directed toward specific problems.

A. Routine monitoring
Routine compliance reviews are designed to identify and resolve problems before they become a significant threat to the organization. These reviews should focus on three primary goals: 1) effectively assessing compliance with the organization’s policies, procedures, and controls; 2) keeping abreast of the changing regulatory and operating environments to identify new risks; and 3) when indicated, developing compliance solutions that mitigate risk, provide guidance to employees, and are aligned with business objectives.

The organization should develop an annual monitoring plan that designates the compliance reviews that will occur for the year. Each review will be developed setting forth the scope, assumptions, and review criteria. The number or type of review may change from time to time based on revisions to current legislation, the focus of investigations by government agencies, or issues identified by an audit, but the review process, itself, remains constant.

The review process
- Define review scope and assumptions—Conduct interviews with business process owners, review existing policies and procedures, review industry standards, if applicable, and review education and training materials to determine the scope and assumptions for each review.
- Develop review criteria—Consider the universe/population, sources of data, and what is going to be done with the results when developing the review criteria. It is always a good idea to test your review criteria prior to conducting the actual review.
- Define review sample—The sample selected should reflect the purpose of the review or the outcome desired. For example, if the purpose is to determine how one department is handling a certain process and you simply want to “dip your toes in the water” and see how it feels, the sample can be a small probe. If the probe data raises concerns widen the sample to the size that gives you the significance desired based upon the universe of data.
- Conduct review—Apply defined review criteria to review the selected sample. Compliance reviews can be prospective, concurrent, or retrospective. Prospective reviews look at particular day-to-day operations to ensure prospective compliance with an organization’s policies, procedures, and controls. Retrospective reviews are regular, periodic compliance assessments by internal or external reviewers who have expertise in applicable rules, regulations, and industry standards.
- Document observations and findings—Summarize observations for each review area, determine the significance of the findings, and develop recommendations for significant findings. You can document by exception to the standard, all observations including compliant practices and exceptions, or high level summary of findings.
- Obtain management response—Share draft findings with business process owners and allow management to provide responses to findings, reactions to recommendations, and help develop a corrective action plan, if warranted.
- Finalize report and corrective action plan—Delegate individuals to be accountable for implementing corrective action as required within agreed upon timeframes. Re-review areas of corrective action to determine whether the issues identified are resolved.

Risk mitigation/corrective action
Monitoring of compliance risk areas should never end. It is a continuous process of identifying, managing, and mitigating risk. Once the process begins, the cycle of review will continue. Once risk areas have been identified, and compliance reviews have been conducted, the organization must respond to all known, suspected, or reported instances of potential non-compliance. Corrective actions plans should be implemented with clear accountabilities defined.
Note: Examples of corrective actions for mitigating risks of potential non-compliance may include:

- Requiring the development of an action plan by a department, business unit, or single employee to correct the cause of identified compliance problems
- Imposing specific restrictions on a process or a department
- Requiring additional educational sessions for specified employees
- Taking appropriate disciplinary action, including termination, under applicable company policies and in consultation with Human Resources

While the compliance officer is responsible for establishing and ensuring ongoing operations of the compliance program, the primary responsibility for compliance sits with each individual. For individuals to be responsible they need their respective business units to be equipped and the training and resources necessary to take ownership. Responsibility for conducting compliance reviews and implementing corrective action plans should be driven by the compliance department; however, it is not uncommon to get pushback from business owners who believe their focus should be on selling and marketing the organization's products not on compliance infrastructure.

Heightened government scrutiny in this area is quickly reaching all levels of Pharma organizations effectively positioning compliance as a value-add. Furthermore, by sufficiently communicating the benefit of an effective monitoring program and assigning well-defined responsibilities to specific job functions within the commercial organization for assisting with the monitoring and corrective action, and by building management incentives to participation the organization will be more likely to obtain buy-in from the commercial business owners.

Note: Benefits to the commercial organization include:

- Safeguarding the organization against personal and company exposure
- Providing clear process guidelines to help ensure compliance and optimize customer interaction
- Increasing awareness of process guidelines to assist with mitigating risk
- Empowering the commercial organization through self-compliance and regulation
- Improving efficiency and supporting future growth through process standardization
- Eliminating redundancy, duplication and confusion

B. Investigations directed toward specific risk

In the event a routine compliance review, hotline call, or other event indicates that there may be reason to suspect that a department, business unit, or an employee may not be acting in compliance with applicable laws, a specific review or directed investigation should be implemented. The directed investigation is a process by which specific issues that may appear to present compliance risk can be further investigated. This review should seek to determine:

- The presence and/or extent of the problem
- Root cause: how and why the problem arose

- Applicable policies and procedures, regulations apply
- Extent of the impact on the organization (operations, strategic plans, financial, public relations, criminal)
- Appropriate corrective action, i.e. remedial, educational, business process change; policy and procedure revisions or development
- The course of action and reporting/disclosure responsibilities

It is imperative that investigations regarding high risk issues not be conducted without the appropriate compliance resources in consultation with legal counsel. Investigations may raise complicated legal issues, and high risk investigations conducted without the advice of counsel could result in the waiver of important legal privileges and other prejudice to organization and the employees involved.

Conclusion

Compliance is not new and it is not going away. Furthermore, diligence regarding compliance with the laws is expected by government, Boards of Directors, shareholders, and the public in general. Commercial divisions of Pharma organizations could gain insights from the concepts used by their manufacturing compliance program. Additional insight can be gleaned from the OIG Guidance, Federal Sentencing Guidance, and PhRMA code, to name a few. These resources can assist the organization to build a solid, credible foundation for a commercial/Promotional Compliance Program.
On December 30, 2003 the United States Sentencing Commission published a notice of proposed amendments to its sentencing guidelines before submission to Congress, May 1, 2004. Proposed Amendment 2 seeks to provide greater guidance to organizations and courts regarding the criteria for an effective program to prevent and detect violations of the law (compliance programs). Tracking the recommendations of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines, the amendment proposes a new guideline to Chapter 8 (Sentencing of Organizations), Part B at §8B2.1 and deletes the previous criteria for effective compliance programs found in Application Note 3(k) in the Commentary to §8A1.2 of the current guidelines.

The notice seeks comments on several potential changes in the current guidelines that would benefit organizations that establish effective compliance programs such as increasing the reduction in an organization’s culpability score if a fine were to be imposed. The new guidelines may also set a standard for future compliance documents by federal agencies and generate a model of best compliance practice for organizations.

As proposed, §8B2.1(a) lists two objectives for organizations to achieve compliance. An organization must: (1) “exercise due diligence to prevent and detect violations of the law”; and (2) “otherwise promote an organizational culture that encourages a commitment to compliance with the law.” The term violations of the law is defined as violations of any law whether criminal or noncriminal (including a regulation) for which the organization is or would be liable.

Under §8B2.1(b) an effective compliance program must be reasonably designed, implemented, and enforced by the organization using the familiar seven-step compliance framework. The proposed requirements for each step are listed below:

- **Step 1.** §8B2.1(b)(1) requires an organization to “establish compliance standards and procedures to prevent and detect violations of law.” Compliance standards and procedures are defined as standards of conduct and internal control systems that are reasonably capable of reducing the likelihood of violations of the law. Thus no longer will a policy announcing a standard of conduct alone suffice to satisfy this step. Internal controls are mandated as well.

- **Step 2.** §8B2.1(a)(2) requires commitments to compliance by decision makers of an organization. There are three specific requirements: (a) Organizational leadership, including high level personnel and personnel with substantial authority, must be knowledgeable about the content and operation of the compliance program. Substantial authority personnel are individuals who within the scope of their authority exercise a substantial measure of discretion in acting on behalf of the organization. (b) The governing authority (i.e. Board of Directors or highest level governing body of the organization) “must be knowledgeable about the content and operation” of the compliance program. (c) Specific individual(s) within high-level personnel of the organization shall be assigned direct, overall responsibility to ensure the implementation and effectiveness of
the program. Such individuals shall be given adequate resources and authority to carry out such responsibility and report directly to the governing authority or one of its subgroups.11

■ Step 3. An organization “shall use reasonable efforts and due diligence not to include any individual as substantial authority personnel if the organization knew, or should have known, that he/she has a history of engaging in violation(s) of the law.”12 For this step, violations of the law refers to some official determination of a violation of a criminal or non-criminal law including a regulation.13

■ Step 4. Compliance training is required under §8B2.1(b)(4) and extends to all levels of the organization. The training must include communication via practical mechanisms of its compliance standards and procedures, the compliance program, and appropriate information concerning individual respective roles and responsibilities. In addition to employees and agents, the appropriate training extends to members of the governing authority and the organization’s leadership.14

■ Step 5. §8B2.1(b)(5) requires organizations to reasonably assess organizational conduct with respect to compliance standards and respond appropriately. This step requires reasonable action to develop a system for the organization’s employees and agents to report or seek guidance regarding potential or actual violations of law without fear of retaliation and including anonymous reporting mechanisms. The organization must

§8B2.1(c), the final element of due diligence, requires ongoing risk assessments by the organization to implement the seven steps above.

The application notes to the proposed guidelines state that an organization’s failure to incorporate within its compliance program any standard required by an applicable government regulation weighs against a finding of an effective compliance program under the guidelines. Furthermore, the guidelines expect hiring or promotion to positions of leadership or substantial authority to properly reflect the organization’s commitment to a culture of compliance with the law. In addition, risk assessments must be performed periodically and the compliance program must focus on the most serious and likeliest risks and modify the compliance program to reduce those risks.

These new guidelines are a significantly “beefed” up version of the current ones and will require all organizations that plan to meet these new criteria to outwardly embrace, commit to, and articulate the adoption of these goals. What is unknown is whether the incorporation of these new guidelines will generate any tangible or even intangible benefits for organizations or create more respect for activities performed using federal funds at extramural sites such as universities and, therefore, result in better stewardship of such funds, or rather will they serve as relatively ineffective but mandated costs of doing business in a highly regulated environment with government intervention still playing a prominent role. The answer is yet to come.

Pharma compliance...continued from page 9

Pharmaceutical Manufacturers, 68 FR 23731 (May 5, 2003)
3. The Anti-Kickback Statute, 42 USC Sec. 1320a-7b(b) (January 23, 2000)
4. While current Guidelines suggest monitoring as a possible way to implement reasonable steps to achieve compliance, recent proposed enhancements to the Sentencing Guidelines, if adopted, will go further to require monitoring activities to detect violations of the law and to require periodic evaluation of the effectiveness of these activities.

April 2004

Health Care Compliance Association • 888-580-8373 • www.hcca-info.org
Editors note: The following interview was conducted with Gene DeLaddy, Chief Compliance Officer/Chief Privacy Officer of Carolinas HealthCare System headquartered in Charlotte, North Carolina, by Greg Warner, Director for Compliance of Mayo Clinic, in February 2004. Carolinas HealthCare System includes acute care, rehabilitation, mental health, and long term care facilities and an integrated primary and specialty physician practice network. Greg Warner may be reached at 507/284-9029. Gene DeLaddy may be reached at 704/355-7720.

GW: Mr. DeLaddy, thank you for taking the time to share with your HCCA colleagues a little about yourself and the compliance program at Carolinas HealthCare System. Perhaps we would start by reviewing your background and how it prepared you for your role as a Chief Compliance Officer.

GD: My first health care assignment was as a financial analyst with the Greenville Hospital System in South Carolina. After several other financial assignments, including Director of Internal Auditing, I served as Treasurer of the multi-hospital system. In 1984, I joined Alexandria Hospital in Alexandria, Virginia as CFO, and after four years I moved to Charlotte, North Carolina to be CFO of Mercy Health Systems. In 1996, after a merger of the Carolinas HealthCare System and the Mercy Health Systems, I was selected Group Vice President for the Corporate Services division. The major functions under my responsibility at that time were Architecture, Facilities Support, Materials Management, and Property Management.

In June 2000, Carolinas HealthCare System, an early supporter of a formal Compliance Program since its introduction in 1997, designated me Chief Compliance Officer, which supervised the functions of compliance and internal auditing. The combination of my experience in corporate finance and corporate support services at a senior level was good preparation for my new compliance role. Over the years I had enjoyed identifying opportunities to help health care become more cost effective and I understood the need for constant attention to the ever-changing Medicare and Medicaid regulations. I had also experienced the opportunity to attract competent employees, organize their energies toward a team effort, and then help them and the organization achieve their fullest potential. I strongly believe in our System’s corporate values, and compliance gives me the opportunity to build professionally on my previous experiences.

In May 2001, I was appointed Chief Privacy Officer for the System, which allowed for the collaboration of these three key compliance areas under the direction of one senior administrator.

GW: I understand Carolinas HealthCare System is a multi-hospital system. Tell us a little about the System.

GD: Carolinas HealthCare System is comprised of 22 health care delivery facilities that are either owned, managed, or leased in North Carolina and South Carolina. We have approximately 24,000 employees. It is the largest health care system in the southeast and the third largest public multi-hospital system in the country. Our system includes 360 physician and mid-level providers called the Carolinas Physicians Network (CPN), which encompasses approximately 100 health care delivery facilities.
care delivery sites in 11 counties throughout North and South Carolina. Additionally, our Graduate Medical Education program at Carolinas Medical Center includes rotating internships in 10 specialty areas that consist of 135 faculty physicians and 200 residency physicians.

GW: How would you describe the essential ingredients of your Compliance Program?
GD: The spirit of our compliance program starts with our Board of Commissioners and their commitment to integrity and quality. They selected Michael Tarwater as President and CEO of our organization because of his experience and the fact that he is a tremendous example of these values. With this commitment from the top, it is natural that the senior vice presidents who work for Mr. Tarwater are also committed to a culture of compliance, and their commitment is passed along throughout the organization through their line management and also through a special group of over 200 employees designated to be a part of our Compliance Matrix.

It is the ability of our large organization to work together toward the same corporate goals that has allowed our Compliance Program to foster a culture of compliance for our employees. Our people want to do a good job, a quality job, and they want to do it in a way that they can be proud of what they do. This comes through the individual and collective support of the four cornerstones of our corporate culture: caring, commitment, integrity, teamwork.

GW: How does the Compliance Program support these values, and who oversees the compliance activities?
GD: The elements that we would look for in this culture are described in detail in our employee handbook on compliance, called “A System of Integrity”. The first page of this book carries a message of support from Michael Tarwater, outlining the desires of the Board and senior staff to have an effective compliance program in place in order to promote a culture of compliance at all levels of our organization. This book is shared with every new employee at the time of their orientation.

On a quarterly basis, the compliance team (Compliance, Internal Auditing, and Privacy) meets with our Corporate Compliance Steering Committee, which is chaired by Mr. Tarwater and comprised of many of his senior management team. This committee provides a forum for the review of compliance education and monitoring activities performed by our Matrix and compliance staff during the quarter. I also report to the Board’s Finance & Compliance Committee each quarter to receive their input and oversight on our compliance program.

GW: You mentioned a Compliance Matrix. What is it and how does it help in communicating the compliance message?
GD: The Compliance Matrix has four key components that work together towards providing an effective compliance program:
1. Each of our 22 facilities has designated a Facility Compliance Director (FCD) who works for the Administrator of that facility in a senior capacity but has, as one of their designated duties, a dotted line relationship to our Compliance Program. Their role is to develop action plans to address compliance issues and coordinate communications between their facility and the Compliance department.
2. There are 20 Functional Compliance Coordinators (FCCs) who, because of their knowledge and experience, have been designated as corporate leaders for functional areas that have been highlighted by the OIG as needing special attention because of the complexity of the regulations.
3. There are approximately 165 people serving as local monitors in the special functional areas at each facility. These leaders, called Functional Compliance Advisors (FCAs), serve on a committee chaired by their FCD. The FCAs communicate directly with their corporate counterparts (the FCCs) to share information of a more technical nature about any compliance questions in their specialty area and to support the local compliance action plans of their FCD.
4. The coordination of this number of people could not happen without the competent leadership of Sherri DeShazo, RN, Director of Corporate Compliance, (and FCD of our largest hospital Carolinas Medical Center) and Sara Herron, RN, RHIT, Director of Facility Compliance, who are instrumental to our success. Together they provide educational information to all of the Matrix participants, participate in auditing and monitoring of certain key areas, and provide written and verbal reports on the outcomes to the facility Administrator. They also
we have found a collaborative approach to be most effective.

An environment centered on education builds relationships, which in turn lead to an appreciation and better understanding of the message we are trying to convey (e.g., improved documentation, compliance with State and Federal requirements). The providers understand that we have their best interests in mind, and as a result they feel comfortable about asking questions and seeking guidance when the billing regulations are not clear.

**GW:** How has your Compliance Program been recognized as adding value to your organization?

**GD:** Our physician practices, as well as our facilities, from time to time receive inquiries from either Medicare or Medicaid requesting follow up of information. Through our ongoing compliance efforts, we have been able to keep the number of inquiries to a relatively low volume due to the ongoing quality of our work. In those few instances where we have had inquiries, we have been able to provide support for our conduct and billing procedures that espouses our position that it was clearly an error as opposed to an intentional or willful disregard of the guidelines.

More often than not, we find instances where our providers have not billed for services that their documentation would support, and as a result of aligning billing with the documentation, our team is recognized for the work they have done.

**GW:** Are your challenges any different in the managed or leased facilities than in the owned facilities?

**GD:** As a part of our compliance program, we focus on services rendered by the physician as well as those rendered by the mid-level provider. The providers’ reviews are conducted by a small group of Compliance Specialists who are Certified Professional Coders, reporting to Pam Benet, RHIA, Assistant Vice President for Physician Compliance. We have found that by assigning our Compliance Specialists to work directly with physicians/physician practices, we are able to develop a one-on-one relationship with the providers. This technique has proven to be very effective in creating an environment that supports our initiative to educate the providers. Although we have the authority to take disciplinary measures, we have found a collaborative approach to be most effective.

An environment centered on education builds relationships, which in turn lead to an appreciation and better understanding of the message we are trying to convey (e.g., improved documentation, compliance with State and Federal requirements). The providers understand that we have their best interests in mind, and as a result they feel comfortable about asking questions and seeking guidance when the billing regulations are not clear.

**GW:** How does your Privacy program support your overall compliance objectives?

**GD:** We have used a similar approach for implementing our HIPAA Privacy program. Our Privacy department is a key component of our compliance structure with responsibility for ensuring that all HIPAA requirements are met using a reasonable, cost effective approach. Todd Harrington, Assistant Vice President of Corporate Privacy, serves as the Facility Privacy Director for Carolinas Medical Center and provides support for the Facility Privacy Directors (FPDs) at our other facilities.

Our Facility Privacy Directors have, in addition to their normal duties, responsibility for local privacy compliance, audits, and issues at the facility level.

Corporate resources in terms of policies, notices, educational material, and initiatives are made available to each facility. The Facility Privacy Directors meet on a quarterly basis to discuss current topics of concern and to share knowledge with each other regarding research or experiences with HIPAA Privacy.

The majority of the tools used for the HIPAA Privacy program have been developed internally by Todd and his staff, thus saving thousands of dollars for the System. One difference between compliance and privacy is that each of the non-owned facilities establishes their own privacy program and shares their results with the owned facilities.

**GW:** Your Matrix for facilities is extensive. What techniques have you found most effective for engaging physicians? Or to put it another way, how do you get their buy-in?

**GD:** As a part of our compliance program, we focus on services rendered by the physician as well as those rendered by the mid-level provider. The providers’ reviews are conducted by a small group of Compliance Specialists who are Certified Professional Coders, reporting to Pam Benet, RHIA, Assistant Vice President for Physician Compliance. We have found that by assigning our Compliance Specialists to work directly with physicians/physician practices, we are able to develop a one-on-one relationship with the providers. This technique has proven to be very effective in creating an environment that supports our initiative to educate the providers. Although we have the authority to take disciplinary measures, we have found a collaborative approach to be most effective.

An environment centered on education builds relationships, which in turn lead to an appreciation and better understanding of the message we are trying to convey (e.g., improved documentation, compliance with State and Federal requirements). The providers understand that we have their best interests in mind, and as a result they feel comfortable about asking questions and seeking guidance when the billing regulations are not clear.

**GW:** How has your Compliance Program been recognized as adding value to your organization?

**GD:** Our physician practices, as well as our facilities, from time to time receive inquiries from either Medicare or Medicaid requesting follow up of information. Through our ongoing compliance efforts, we have been able to keep the number of inquiries to a relatively low volume due to the ongoing quality of our work. In those few instances where we have had inquiries, we have been able to provide support for our conduct and billing procedures that espouses our position that it was clearly an error as opposed to an intentional or willful disregard of the guidelines.

More often than not, we find instances where our providers have not billed for services that their documentation would support, and as a result of aligning billing with the documentation, our team is recognized for the work they have done.

**GW:** Are your challenges any different in the managed or leased facilities than in the owned facilities?
GD: Our system prides itself in giving each of our facilities the autonomy to meet the specific needs of their location and patient demand. There are many competent leaders and active compliance supporters at our regional (non-owned) facilities. Harrison Trammell, President of the Regional Facilities division, has encouraged the sharing of compliance and privacy activities to the mutual benefit of the corporate and local programs. We learn from each other and the collaboration of effort makes for a stronger System.

One of the significant pluses of our System is the common bond of understanding and philosophy that is shared by our senior management staff and understood by the individual administrators at our various facilities. The opportunities at the managed or leased facilities normally come about when we recognize that their unique set of circumstances requires a unique response to the compliance challenges. At the same time, we provide a corporate model that allows them to draw upon centralized expertise to guide or supplement their individual programs.

We all come together on a quarterly basis as one common team, sharing the ideas and experiences of each facility with peers so as to have not only the most comprehensive program, but also the best program for our system.

GW: Besides compliance and privacy, I notice you are also a Certified Internal Auditor (CIA) with responsibility for the Internal Auditing program. Tell me more about the role of the Internal Auditing program and how its work supports the overall compliance efforts of the system?

GD: Once again, I must give our Board of Commissioners credit for being right on top of this opportunity for improving the internal controls of our organization. Two years before the introduction of the Sarbanes-Oxley Act, our Board had encouraged the expansion of our Internal Auditing program to not only a more comprehensive review of our owned facilities, but also for direct support to the managed and leased facilities as well. This program, which is centrally managed by my Director of Internal Auditing, Mike Morrow, CISA, provides value-added services through the dual benefit of internal control reviews and operational assessments that not only reduce expenses but also identify lost revenue opportunities.

The Internal Auditing department works in a collaborative fashion with the management at each of our facilities to develop an audit plan that addresses the high risk areas of their operation. As the internal audits are completed, a formal written report is issued which provides the assessment of the area audited along with recommendations that, when approved, will improve internal controls.

Additionally, our Internal Auditing program provides a valuable service in its annual assessment of our Corporate Compliance Program through a comprehensive audit at each facility within our System. A formal report and scoring mechanism is used to rate the level of compliance support at each facility and to identify specific areas for focused improvement for the coming year. This information is shared with our Corporate Compliance Steering Committee.

GW: Throughout this interview, you have used terms such as culture, teamwork, top management support, collaborative effort, and competent staff. How would you summarize where your compliance program is today?

GD: I believe it starts with our program, and “our” includes our Board members, our CEO, our senior staff and their mid-level management, members of our Compliance and Privacy Matrix, and all of the individual employees in our System who want to do a good job every day. Overall, our program has improved its effectiveness each year since its inception, and I believe that our work in 2004 will bring us closer to our goal of a culture of compliance at its highest level. Our mantle of “A System of Integrity” is not just the name on our handbook, but it is the verbalization of who we are. We are happy to share what we’ve learned with our colleagues.
We recently completed a survey on corporate compliance programs in large corporations across various industries. The survey includes 83 companies in industries that included aerospace, manufacturing, food services, medical device, banking, health insurance, oil and gas manufacturing, pharmaceutical, and others. Our targets were large corporations that have complex organizational structures. We intentionally targeted companies outside of health care to get a better understanding of how large corporations have handled issues such as compliance officer independence and compliance in large multi-tiered structures. In total, companies from five countries and three continents participated in the survey including 38 Fortune 1000 companies.

A common function across industries

The most surprising observation from the survey was the maturity of corporate compliance programs in companies operating in historically less regulated industries. Most of the survey respondents, including manufacturing and food service companies appear to have implemented the standard seven elements of a corporate compliance program. Certain industries such as financial service and aerospace companies appear to have the most mature and defined corporate compliance programs. We rank ordered the respondents in the survey based on their responses to 17 indicators. Financial service companies represented the highest rated industry with six companies ranking in the top ten. Interestingly, a manufacturing company ranked number three in the scoring.

Most common practices

The most common practices we identified across industries include:

- Annually developing compliance goals and objectives
- Reporting of compliance activities to the Board or a Board committee
- Participation of outside directors in the oversight of compliance activities
- Using intranets to provide compliance information to employees
- Measuring compliance training effectiveness
- Annual compliance risk assessments

Our survey suggests that large corporations could strengthen their compliance activities in the following areas:

Compliance officer independence

Most companies do not have a dedicated compliance officer with complete independent reporting to the Board. In most of the respondents, the General Counsel or an attorney in the General Counsel’s office serves as the corporate compliance officer. Even in the few companies that have a fully dedicated corporate compliance officer, reporting to the Board is not independent. In most of these companies, the General Counsel or another executive reviews and edits communications from the Corporate Compliance Officer to the Board.

Training of outside directors

While most companies involve outside directors in oversight of the compliance function, few train those directors on corporate compliance and business ethics for companies to provide training to outside directors it should include:

- Requiring directors to participate in the same corporate compliance training as employees
- Developing special compliance training for outside directors
- Developing Board level corporate compliance oversight responsibility training for all Board members

Executive communications

Executives need to provide more frequent communications on compliance and business ethics. In one of the few subjective questions in the survey, respondents indicated that their leaders could do a better job of communicating to employees their company’s commitment to compliance and business
ethics. Working with some companies on this issue, we have found that compliance often needs to improve its communication strategy in a couple areas. First, compliance officers can play a role in improving executive communications. Working with executives, compliance officers can provide text on business ethics, brief updates on compliance achievements, and anecdotal stories of ethical behavior in the company. Second, often compliance communications are targeted to the masses or to senior executives. Targeted communications to mid-level managers are commonly overlooked. By targeting communications to managers, compliance officers can raise managerial awareness and use of policies, compliance tools, and other resources.

Compliance program effectiveness measures
The survey participants generally reported rudimentary compliance measures based on achieving certain objectives. Few companies reported having quantitative measures of compliance risk reduction. Aerospace companies appeared to have the most sophisticated and quantitative measures.

Survey observations
The following are specific observations from the survey:

Structure
A company’s business model, size, and the legal-regulatory environment of its industry are primary influencing considerations on the structure of a corporate compliance program. Most respondents report their companies have a centralized corporate compliance structure. Decentralized corporate compliance programs are more common in highly regulated industries such as financial services and insurance. Even so, only 52% of financial services companies and only 31% of insurance companies reported having decentralized compliance programs.

Board involvement
Nearly all the responding companies (93%) report compliance activities to the Board, the Board Audit Committee, or a subcommittee such as a compliance subcommittee. The most common practice is the reporting of compliance activities to the Audit Committee (49% of respondents). Only 11% of the respondents have a Board-level compliance subcommittee overseeing compliance activities. These companies are primarily in the financial services, insurance, or health care industries. Even within those sectors, only 15% of the respondents have a Board-level compliance subcommittee. In contrast, 40% of oil, gas, and chemical manufacturing companies report compliance activities directly to the full Board.

Survey participants responded that their Board, or Board committees responsible for compliance oversight, are active in reviewing, approving, and suggesting compliance activities. The most common compliance activities for Board committees are reviewing audit reports, compliance risk assessments, and audit plans. When reviewed by industry segment, there appear to be no significant trends other than Boards of certain companies that engage in a broader scope of compliance oversight activities.

Of the responding companies, 97% include outside directors on the Board or on the Board compliance committee responsible for compliance program oversight. However, only 30% of responding companies train outside directors on compliance.

Independence
Independent reporting to the Board on issues related to business ethics and legal compliance is a complex matter. Ideally, an individual such as a corporate compliance officer who has no other operational or functional role in the company may be best suited to make a truly independent report to the Board. In order to make a complete and accurate report to the Board, the corporate compliance officer must have access to risk assessments, audit reports, and investigation reports. In addition, to preserve independence, the corporate compliance officer’s reports should not be subject to editing or revision by management.

The corporate compliance officer should not provide the Board with the sole voice on compliance and ethics. Instead, the corporate compliance officer’s communications to the Board should validate and enhance the communications to the Board from management, internal audit, and the General Counsel, (GC). Only 12% of respondents report having an independent compliance reporting process defined as a fully dedicated corporate compliance officer who submits reports to the Board without managerial review.

As mentioned earlier, few companies have independent corporate compliance officers. The corporate compliance officer has another role in the organization...
in 67% of the responding companies. In 66% of those companies, the corporate compliance officer is also the GC or an attorney in the GC’s office. Even when companies have a corporate compliance officer with no other role in the organization, only 22% of respondents submit reports to the Board without management’s review while 52% of the respondents have a management review of the reports prior to their submission to the Board.

Goal-setting
Compliance should not be a static process, but rather a dynamic and evolving process that responds to a company’s business environment and business model. Compliance activity goals and objectives should be reexamined and reestablished periodically to meet changing compliance risks. Of the responding companies, 85% establish compliance program goals and objectives on an annual basis.

The corporate compliance officer plays a role in setting compliance goals and objectives in all but 5% of respondents, who leave the goal-setting process completely up to the company’s business units. Corporate compliance officers either establish goals and objectives or provide general goal-setting guidance to business units in 72% of respondents. The Board establishes goals and objectives at the other 22% of respondent companies, which we assume would include the corporate compliance officer’s input and assistance.

For the participating companies with business unit compliance officers, the business unit executives have a primary role in establishing the business unit compliance officer goals and objectives in 69% of the responding companies. The business unit executives establish business unit compliance officer goals and objectives either independently or with the corporate compliance officer.

Resource-planning
In large, complex organizations, the risk is greater for duplication of resource use and purchasing. For example, compliance officers in different business units of a large company might independently purchase the same Web-based learning system because no one in the organization is coordinating compliance purchasing. Similarly, it is beneficial for purchasing of compliance consulting or vendor services to be consolidated in order to maximize a company’s purchasing power. In general, it appears that to some extent, companies centralize their compliance purchasing and development. Of the survey respondents, 89% indicated their company purchases or develops compliance tools; 86% of those report that the corporate compliance officer has a role in leading or coordinating purchasing and development.

The survey suggests that purchasing and development of compliance tools and services, even in decentralized structures, is more centralized in order to leverage purchasing power and efficiencies.

Visibility
Whistle-blowers have had significant media attention following the events with Enron, Worldcom, and other high-publicity corporate scandals. An excellent way to prevent a whistle-blower case is to prevent illegal or unethical behavior using a compliance program that is proactive and trusted by employees. Employees will use compliance resources to the extent that compliance resources are visible, available, and understood. Employees must understand that the company has a corporate compliance program and that it provides a mechanism to report concerns in the company without retribution.

Auditing and monitoring
Of the respondents, 97% conduct compliance audits and investigations and 91% conduct an annual risk assessment of compliance issues. Internal audit is the most common function to perform a compliance risk assessment, followed by compliance. Internal audit is also the most common function to perform compliance audits. Most internal auditors conduct compliance audits with direction from the GC’s office. A small number of companies have compliance audits conducted by an internal audit function reporting directly to the GC.

Due to the sensitive nature of some compliance-related issues, it is important on occasion to conduct compliance audits under the protection of attorney-client privilege. However, the attorney client privilege can be overused or potentially abused if all compliance audits are conducted under privilege. Most responding companies in the survey (80%) report that compliance audits are not always conducted under...
Measures

Measures of corporate compliance effectiveness provide important information to management and the Board. Compliance effectiveness measures are difficult to create and quantify. Of the responding organizations that measure compliance risk, most use measures such as meeting specific goals and objectives, results of regulatory audits, and fines imposed by regulatory bodies. Only 9% of respondents indicate they have developed quantifiable measures of reduction in legal and regulatory exposure.

Comparing industry segments, the aerospace industry scored significantly higher in measuring compliance effectiveness and the use of quantifiable risk measures.

Compliance and ethics training is an important and potentially costly endeavor in large companies. Surprisingly, 28% of responding companies do not evaluate the effectiveness of compliance and ethics training. The most common measurement practice is to require training participants to complete a quiz or test.

Corporate compliance appears to be a common practice in large companies regardless of industry. Compliance officers in large organizations have special challenges in overcoming complex business structures, multiple layers of management, public scrutiny of business ethics, and a diversity of business interests. Fortunately, as our survey suggests, compliance officers in large organizations across industries and national borders can learn from one another.

The Healthcare Compliance Certification Board (HCCB) compliance certification examination is available in all 50 States. Join your peers and become Certified in Healthcare Compliance (CHC).

CHC certification benefits:
- Enhances the credibility of the compliance practitioner
- Enhances the credibility of the compliance programs staffed by these certified professionals
- Assures that each certified compliance practitioner has the broad knowledge base necessary to perform the compliance function
- Establishes professional standards and status for compliance professionals
- Facilitates compliance work for compliance practitioners in dealing with other professionals in the industry, such as physicians and attorneys
- Demonstrates the hard work and dedication necessary to perform the compliance task

CHC Certification, developed and managed by HCCB, became available June 26, 2000, since that time hundreds of your colleagues have become Certified in Healthcare Compliance. Linda Wolverton, CHC, Director, Compliance, Triad Hospitals, Inc. says that she sought CHC Certification because “...many knowledgeable people work in compliance, and I wanted my peers to recognize me as ‘one of their own’.” With certification she is “recognized as having taken the profession seriously, having met the national professional standard.”

For more information on how you can become CHC Certified, please call 888/580-8373, email hccb@hcca-info.org, or visit the HCCA Website: http://www.hcca-info.org/Template.cfm?section=HCCB_Certification

Congratulations on achieving CHC status! The Healthcare Compliance Certification Board announces that the following individuals have recently successfully completed the Certified in Healthcare Compliance (CHC) examination, thus earning CHC designation:

Kari B. Adakz, CHC
Atiq S. Akson, CHC
Prudence I. Arnoquist, CHC
Christine Bachrach, CHC
John R. Beetle, CHC
La Donna Belangie, CHC
Tammy S. Bell, CHC
Kathleen J. Boush, CHC
Rita Ann Broad, CHC
Dana L. Brown, CHC
Mia D. Burn, CHC
Shannon A. Church, CHC
Letoia J. Crozier, CHC
Cindy F. Daigle, CHC
Don L. Daniel, CHC
Charlene A. Dickerson, CHC
Lynn C. Dophe, CHC
Pamela F. Farnier, CHC
Dana L. Ferland, CHC
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Lynda S. Hilliard, CHC
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Catherine A. King, CHC
Linda L. Koste, CHC
Beth C. Kramer, CHC
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Kimberly F. Van Campen, CHC
Leila Wilson, CHC
Kimberly A. Winnak, CHC
Susan L. Wrubel, CHC
Allison is a compliance professional with a strong financial background. Prior to Allison joining the Executive Committee, we relied heavily on an association management company to manage our finances. As a result of Allison’s work, we have made significant improvements to all aspects of our accounting systems and procedures.

In the past, we also relied heavily on an association management company for all aspects of our operations. We were particularly dependant on them for accounting until Allison came along. We now have our own staff. Working with our finance manager, Stephanie Lentch, Allison has made great strides. From a compliance perspective, finance is one of the greatest risk areas for an association. It is important to get it right.

Our financial statements are more accurate, readable, and timely. Allison has worked with us to improve our annual audit process. Our response to our audit firm’s management letters has been swift and effective. Issues identified by our auditors have dropped significantly.

Sarbanes Oxley recommends that a controls audit be performed. Allison worked with our auditors to perform a controls audit. The controls audit reviews the systems and procedures we use to manage the flow and tracking of cash. We have improved our systems and procedures.

As a result of the transition away from an association management company to self management, many things have improved. In addition to improved financial accounting, we have improved our financial position. In 2003, we had a better year than the previous six years combined. We have increased our reserve. We are a young association and although our reserve is not up to national average, we are doing well.

Allison has helped to improve many aspects of HCCA. We have saved a lot of money by getting it done right the first time. We are making better decisions because we have better data. We are making decisions on a timely basis because we get information quickly. We are very fortunate that we have so many effective volun-

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MICHELLE BOBBITT

Each time you add a compliance document to the HCCA Website you will have an additional chance to win a Dell pocket PC* **, courtesy of Sheeder & Welch. Add 30 documents and you will have 30 chances to win each month for a period of 12 months—November 2003 to October 2004. One Pocket PC will be given away each month for 12 months. Any non-copyrighted compliance document will count, such as policies, procedures, forms, memos, presentations, educational tools, government documents, articles, white papers, or miscellaneous documents. Just visit eCommunities on the HCCA Website:

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*No repeat winners.  
**HCCA staff members are not eligible.
Characteristics of effective Codes of Conduct

An effective Code, one more likely to achieve the desired ends, has the following characteristics:

Readability

The Code should have a readability level of 8th-10th grade. Many Codes have a 12th grade or higher reading level—often because they are written by lawyers and are very legalistic in their tone and language. Use plain, direct language. The syntax should be uncomplicated.

Additional readability tips:
- Use an active voice rather than a passive voice. Turn on the grammar check in Word to help you. (Tools: Options: Spelling & Grammar)
- Avoid repeated long references. Instead of using "Directors, officers, employees, and contractors" repeatedly, use "you" or "staff" or "everyone." This will make it a more personal and friendly document and lower your readability score.
- Keep sentences to 14 words or less and paragraphs to no more than five lines.

Purpose of the Code of Conduct

Why have a Code of Conduct? A good Code of Conduct can be a powerful tool for an organization. It is a way for a company to tell employees about the company’s requirements and expectations. The Code can also be the employees’ primary resource concerning:
- Conduct that is or is not acceptable
- How to decide on what to do when there is not a rule that applies
- What to do if they have a question
- Who to tell if they suspect misconduct

The Code can also encourage and empower employees. Employees are more loyal to employers they believe are ethical. Such employees are also less likely to engage in misconduct that can get the company into trouble or conduct that hurts the company, such as employee theft. Finally, employees who have been given guidance and tools that help them make compliant and ethical business decisions feel more empowered to do so—it is more likely they will do what is right.

About the organization’s values. Employees are told how to resolve issues for which there is no rule by using the organization’s values as their guide.

You are responsible for drafting your organization’s first Code of Conduct (Code) or you want to replace an existing Code. Where do you start? First, determine whether the organization has a rules-based compliance program, a values-based compliance program or a rules and values-based compliance program. What is the difference?

Rules-based compliance program

Employees receive a set of rules to follow—ideally for every situation they may face. Employees do not receive guidance or information about the organization’s values, mission, goals, or ethics. They are told to go to management if they encounter a situation that falls outside the rules.

Values-based compliance program

Employees receive few, if any, rules about how to conduct themselves on the job. The organization describes its values, mission, and ethical framework and tells employees to act accordingly.

Rules and values-based compliance program

Employees receive rules for frequently encountered and high-risk issues. Employees also receive information about the organization’s values. Employees are told how to resolve issues for which there is no rule by using the organization’s values as their guide.
Use one- and two-syllable words.
Use the right word rather than the long word.
Use as few words as possible.
Avoid assumptions—define acronyms—and avoid jargon.
Check the "show readability statistics" button on the Spelling & Grammar options so you know how you are doing.

Format
Have a user friendly and attractive organization and layout, with plenty of white space. Employees are turned off by Codes that look and read like a legal document. The Code will not have the desired impact if the employees do not read the Code because of its format and readability.

If you have a graphics designer to help with the format—great. If you don’t, use the word art and graphic features available in Word. Even if you only change the spacing and font type and size, it is better than a long narrative in Times Roman. Just make it interesting to look at.

Additional format tips:
- Use the talent you have in the organization—your marketing department. They are experts at taking complicated information and communicating it in an easy to understand and appealing manner.
- Establish a brand for the entire compliance program, including the Code of Conduct. The brand can help "sell" the Code to your employees.
- Try different formats within the document to move the reader’s eye.

Tone
Use a consultative and helpful tone—not a series of threatening "thou shalt" and "thou shalt not." Rather, convey that the company wants to be successful and wants to do so through compliant and ethical business conduct. Make the employee feel guided, not threatened.

Additional tone tips:
- Use pronouns and other "friendlier" terms when referring to employees.
- Use "us," "we," and "our," instead of "the company" - this promotes a sense of being in it together rather than an us vs. them mentality.
- Talk about how everyone can be successful and feel good about working for the company, not just how to avoid problems and legal violations.

Statement of values
In a rules- and values-based compliance program, the Code should contain a statement of the values employees can use to interpret how the rules should apply and what to do in the absence of a rule. Explicitly address management’s position that although it is important for the company to be vigorously competitive and successful, it must do so using compliant and ethical business practices. Consequently, the "sale at any cost" approach is not acceptable. This can be a difficult message for employees to believe, so they need to see it backed up by management’s conduct.

Additional statement of values tips:
- Do not include it if it is not an honest reflection of the company’s culture and management. A statement of values that is broadly perceived as untruthful is worse than no statement at all.
- Align the statement of values with any other values and mission statements the organization has adopted.
- Provide guidance for how to handle

"A good Code of Conduct can be a powerful tool for an organization. It is a way for a company to tell employees about the company’s requirements and expectations."
Conduct guidelines...continued from page 23

situations that are not addressed by a rule. For example, "service to the customer is the first concern and should be the foundation for all other decisions and actions." Alternatively, "Providing high quality safe products is the most important service we provide—everything you do and every decision you make should be based on quality and safety."

- Include ways that employees can figure out the right thing to do, e.g., the newspaper test—would the employee want to read about their conduct in the newspaper?

**Directions for asking questions and reporting concerns**

Employees need to know that they are expected to notify the company if they think there is misconduct. They also need to know how to ask questions and report any concerns they have.

- Whom do they contact?
- Can they go to someone other than their boss?
- Can they report a concern anonymously?
- What will happen when they report a concern—what is the process?
- Will anyone else know they reported a concern?
- What if it is an employment issue?

You need to answer all of these questions so employees know what to expect. You also want employees to believe the company takes their reports of possible misconduct seriously and that it will stop any misconduct. Placing this information after the statement of values and before the description of policies tells employees that the company wants to know about problems and fix them.

**Additional reporting process tips:**

- Employees are nervous about reporting problems—make them feel comfortable and secure in doing so.
- Be very clear about what an employee can expect when he or she reports a concern. Answer all of the questions listed above, as well as any others your employees may have.
- Tell employees what they can expect to be told or not be told about investigation results. For example, tell them they will not be told about employment action that resulted from a report because of the other employee’s right of confidentiality.
- Tell employees that there can be instances in which there is additional information they are not aware of that can result in a decision that something is not misconduct—and that you may not be able to share that other information with them.
- Provide multiple alternatives for reporting a concern so if they are uncomfortable with one option, they have others.
- Explain how anonymity is achieved and maintained.
- Let employees know that there are times when an anonymous caller’s identity may be known. For example, if an employee who has been working with Human Resources also makes an anonymous call to the hotline, the company may be able to identify the anonymous caller. State how the company will deal with that type of situation.
- Tell employees that if they report something anonymously, additional information is sometimes required to complete an investigation and if the anonymous reporter does not provide the requested information, the case may have to be closed.

- Let them know that there are some types of issues, such as many employee relations issues, that cannot be handled anonymously.

**Note:** If you have separate communication collateral about the hotline, such as a brochure, incorporate some of these tips in it instead of the Code. If there is no other communication collateral about the hotline, then include the information in the Code.

**Non-retaliation promise**

Because employees are afraid of retaliation if they report a problem, the Code must assure them that the company has and strictly enforces a non-retaliation policy. Employees are very concerned and sensitive about what can happen to them if they report a problem—especially about something management is doing. They are even more concerned if their boss is involved.

The promise should include a commitment to discipline anyone who retaliates against another employee. The non-retaliation promise is not very meaningful if there are no real consequences to the retaliator.

The Code should also instruct employees what to do if they think they are a retaliation victim. Tell employees to immediately contact Human Resources and/or call the hotline. Remind them that this type of issue can not be addressed on an anonymous basis.
Additional non-retaliation tips:

■ Have a stand-alone non-retaliation policy that is separate from non-retaliation in a sexual harassment and discrimination policy.
■ Include in the policy a provision for disciplinary action for anyone who retaliates against another employee.
■ This is one of the few cases in which clearly stated and definitive "thou shalt" and "thou shalt not" is appropriate.

Easy to read and understand description of the important policies

Do not make the Code the sole source of information about the company’s policies. A Code that is the sole source of the company’s policies will result in an ineffective Code. Complete policies should be available elsewhere—such as an employee handbook and/or policy manual.

Include summaries of the most important policies in the Code. Organize and write the policy summaries so they are intuitive and easy for the reader to follow and understand.

Instead of saying, "Do not violate insider trading laws," explain what insider trading is and provide examples of how it can occur. The average employee may not know how insider trading can occur. They may not know that providing tips to someone else who buys or sells the stock is an insider trading violation, or, that the law applies to information they have about another company.

Instead of saying "It is against company policy for family members to report to each other," state "In order to avoid the bad feelings and other problems that can occur when family members report for each other, we do not allow one family member to have a reporting relationship to another family member."

This approach may result in a slightly longer Code, but if you provide explanation and examples, employees are more likely to read, use, and understand it.

Do not summarize all of the company’s policies—only those that are higher-risk issues and/or applicable to most employees. Either omit or include only very brief discussion about any policies that are low risk or applicable to only a limited number of employees.

Which policies do you include? Below is a list of policies an organization may have. Your organization may have a different list of policies. To decide which ones to include in the Code:

1 List your policies
2 Decide which policies are either (a) most important to your organization’s compliant and ethical business practices; and/or (b) apply to most employees

Remind employees in the Code about the other policies they are required to comply with and where they can find them.

Business Practices

■ Accurate billing practices
■ Business courtesies (receiving and giving gifts, gratuities, and entertainment)
■ Charitable contributions
■ Environmental protection
■ Fraud, abuse, and theft
■ Government contracting
■ Government interviews of company employees
■ Information practices, including Health Information Privacy (confidentiality)
■ Product quality and safety

“Because employees are afraid of retaliation if they report a problem, the Code must assure them that the company has and strictly enforces a non-retaliation policy.”

■ Protecting shareholder rights
■ Regulatory compliance
■ Sales agents, consultants, or other professional services
■ Truth in advertising, marketing, and sales
■ Using agents, representatives, contractors and consultants

Company property, records, and procurement

■ Accurate books and records
■ Procurement practices
■ Protecting company information, ideas, and intellectual property
■ Records retention

Continued on page 26
If length is an issue, refer to the location of the other policies and focus attention on the highest risk areas for your business. Organize the policies so the flow is logical and intuitive to the reader. Provide examples of appropriate and inappropriate conduct that the employees can recognize. If possible, explain why the policy is good for them.
Other recommendations

Versioning and archiving
Know what version of the Code was in effect when. This information may be important if your organization is investigated or subject to any enforcement action. Fines and penalties can be reduced under the organizational sentencing guidelines if an effective compliance program was in place at the time of the misconduct. To prove an effective compliance program, you need to know what it was when the misconduct happened.

Clearly identify the version of the Code (as well as all policies and other elements of the compliance program) on the document itself. You will also need to be able to produce the Code, so archive all versions of the Code for easy retrieval at a later date.

Although there should be some type of reference within the Code (and other compliance documents) that identifies the version, you can track more detailed information, such as when it became effective, in a separate log. If you are not maintaining a separate log, then include the effective date in the document.

References to other policies
The Code may be the only statement of a policy or it may be summarizing a policy that exists independent of the Code. If the Code summarizes another policy, then reference the full policy and where it can be located.

Distributing and webizing
You need to make sure that employees actually have access to the Code—either through distribution of a paper copy and/or posting it on the company intranet. If an organization has an intranet, consider “webizing” the Code and posting it on the intranet, including links to other related documents that are available on the intranet, e.g., the employee manual. This improves the accessibility of the Code. If most employees have access to the intranet and the Code is available on the intranet, you can enhance its profile and availability.

Employee awareness
Regularly and repeatedly remind employees about the Code. Do not remind employees about the code just once a year. In newsletters, meetings or emails and any other employee communication avenues you have, remind employees that there is a Code and about certain issues addressed in it.

Employees receive so much information that reminders about the Code are necessary long after you are tired of sending them out. Plus, you need to catch the new employees who did not receive all of the previous messages.

Acknowledgments or certifications
Decide whether to require employees to acknowledge or certify they received, read, and understood the Code. If you are going to require acknowledgements or certifications, consider alternatives to the typical paper chase. For example, consider a web-based acknowledgement, making certification part of the annual review processes, etc. Whatever methodology you adopt, make sure you can manage it.

Posting the Code on the internet
Decide whether to post the Code on the company’s public internet site. An increasing number of companies are doing so. Probably because they believe it reflects a significant commitment by the organization. Before posting the Code, have a Code that is ready to be scrutinized (and criticized) by others.

Alternatively, some companies just have a discussion on their website about their commitment to compliance and ethics.

Sample Codes of Conduct
Check out other companies’ Codes of Conduct. Although it is helpful to review codes from your own industry, Codes used by other industries can also be enlightening. The HCCA has recently posted a listing with links to the codes of conduct for the Forbes 100 that could be located on the internet, which is available at http://www.hcca-info.org/Content/NavigationMenu/Compliance_Resources/External_Links/External_Links.htm
To access the Forbes 100 go to the Compliance Info tab on the HCCA Website and click on External Links. Take a look at these codes and you might get some good ideas of what you should do and what you should avoid.

If you want to look at the Codes for other companies, if they are posted on the internet, it is often on the Corporate Governance page of the company’s website, which is often under Investor Relations. ■

1 See, Managing Ethics and Legal Compliance: What Works and What Hurts, A Summary of a 1999 study by Arthur Andersen. You can request a copy of this report from Vickie McCormick, Halleland Lewis Nilan Sipkins & Johnson at vmccormick@halleland.com.
Tommy Thompson said “Mark McClellan will be an outstanding leader for the Centers for Medicare & Medicaid Services as the agency works to implement the new Medicare law and increase access to quality health care for American families.”

In a prepared statement Senator Chuck Grassley (R-Iowa), Chairman of the Committee on Finance, noted that “Dr. McClellan is well-regarded on Capitol Hill, and his background and expertise make him a strong nominee.”

For more from the White House: http://www.whitehouse.gov/news/releases/2004/02/20040220.html

CMS releases National Provider Identifier Final Rule
The Centers for Medicare & Medicaid Services (CMS) announced on January 22 the adoption of the National Provider Identifier (NPI) as the standard unique health identifier for health care providers to use in filing and processing health care claims and other transactions. A final rule establishing the NPI as the standard unique health identifier was published in the January 23rd Federal Register. For more: http://www.cms.hhs.gov/media/press/releases/2004/02/200402220.html

CA Hospital Agrees to Pay $4.1 Million, Settle Medicare Fraud Claims
On February 2, US Attorney for Central California Debra W. Yang announced that Coast Plaza Doctors Hospital and the estate of the former CEO Gerald J. Garner defrauded the federal Medicare program. For more: http://www.usdoj.gov/usao/cac/pr2004/011.html

Tenet receives subpoenas from OIG
Tenet Healthcare Corporation announced January 23rd that it has received copies of subpoenas issued by the Office of the Inspector General in the U.S. Department of Health and Human Services to two physicians who have financial arrangements with three Tenet hospitals in El Paso, Texas. The subpoenas request documents relating to financial arrangements between these physicians and Tenet or its subsidiaries. According to its press release, Tenet anticipates receiving a request for documents in connection with this inquiry, and intends to cooperate with federal authorities in this matter. For more: http://www.tenethealth.com/TenetHealth/PressCenter/PressReleases/Tenet+Informed+of+New+Inquiry.htm

Congressman Tauzin and Greenwood want more information on hospital billing
As part of an investigation into the billing problems many uninsured patients face during hospital visits, House Energy and Commerce Committee Chairman Billy Tauzin (R-LA) and Oversight and Investigations Subcommittee Chairman James Greenwood (R-PA) sent a letter requesting information from the Department of Health and Human Services on federal regulations affecting hospital billing practices. For more: http://energycommerce.house.gov/108/letters/01222004_1196.htm Link to Tauzin and Greenwood letter: http://energycommerce.house.gov/108/letters/01222004_1195.htm

FDA Commissioner nominated to lead CMS
On February 20, President Bush announced his intention to nominate current U.S. Food and Drug Administration Commissioner Mark McClellan to be the Administrator of the Centers for Medicare and Medicaid Services at the Department of Health and Human Services. McClellan previously served as a member of the White House Council of Economic Advisers. In a statement issued on February 20, Health and Human Services Secretary

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Compliance among top 10 hot executive jobs
Chief Compliance Officer ranks 8th and Chief Ethics Officer ranks 7th in the Christian & Timbers’ Hot Jobs for 2004. The ranking according to a December 3, 2003 press release from Christian & Timbers’ of the 10 Hot Executive Jobs in 2004 are:
1. Board director at public company
2. Human resource director: technology or healthcare industry
3. Executive vice president of sales
4. Executive at medical devices company
5. Campaign managers
6. Chief nursing officer
7. Chief ethics officer
8. Chief compliance officer
9. VP data mining
10. EVP at national security/DOD consulting company


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